



**STATE OF
OHIO**
BOARD OF PHARMACY

Administration of Childhood Vaccines during the COVID-19 Pandemic

Updated 9/23/2020

IMPORTANT: Specific guidance on the administration of COVID-19 vaccines can be accessed here: www.pharmacy.ohio.gov/COVIDvaccine

Recently, the U.S. Department of Health and Human Services (HHS) [issued a third amendment - PDF](#)* to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to “increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.”

The amendment authorizes state-licensed pharmacists to order and administer vaccines to individuals ages three through 18 years, subject to several requirements. Additionally, it permits pharmacy interns, acting under a pharmacist’s supervision, to administer vaccines in accordance with the provisions of the amendment.

Please be advised that the amendment under the PREP Act creates two processes for the administration of vaccines by Ohio pharmacists and pharmacy interns, one authorized by section 4729.41 of the Revised Code (which has been in effect since 2015) and a process established by HHS in response to the COVID-19 pandemic. To assist pharmacists and pharmacy interns in understanding the options available to them, the Board has developed the following guidance document.

For questions about vaccine administration, please review the frequently asked questions starting on the next page of this 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) What are the two processes for pharmacists and pharmacy interns administering vaccines in Ohio?

A pharmacist or pharmacy intern, under the direct supervision of a pharmacist, may administer vaccinations in accordance with Ohio laws and rules **or** the process established by the U.S. Department of Health and Human Services (see table below).

IMPORTANT: Pharmacists and pharmacy interns must comply with either the federal or state process for vaccine administration. Failure to fully comply with either process could result in administrative discipline against the licensee and possibly the pharmacy and the pharmacy's responsible person.

- More information on Ohio's requirements for pharmacist and pharmacy intern vaccinations can be accessed [here](#).
- More information on HHS requirements for pharmacist and pharmacy intern administration of childhood vaccinations can be accessed [here](#).

Childhood Vaccination Requirements

	Ohio Requirements	Federal Requirements
Age of Administration	<p>Ohio law permits the administration of any vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) and any immunization specified in rules adopted by the Board of Pharmacy to:</p> <ul style="list-style-type: none"> ▪ Individuals 13 years or older (no prescription required). ▪ Individuals between ages 7 through 12 (prescription required, except for the flu vaccine). <p>NOTE: Pharmacists and interns are not permitted to administer vaccinations to individuals under the age of 7 unless the pharmacist or intern complies with the federal requirements.</p>	<p>The federal amendment permits administration of any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule (ACIP-recommended vaccines).</p> <p>NOTE: The federal process is the only one that permits the administration of vaccines by pharmacists and interns to individuals below the age of 7.</p>

Physician Approved Protocol	Requires physician approved protocol (see OAC 4729-5-37).	No physician-approved protocol is required, as pharmacists are authorized to order vaccines under the federal amendment.
Approved Immunizations	<p>Any of the following (within the specified age ranges):</p> <ol style="list-style-type: none"> 1) Any immunization recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC). 2) Any immunization specified in rules adopted by the Board of Pharmacy (see OAC 4729-5-38). 3) Influenza vaccine. <p>Click here for more information on pharmacist and intern administration of COVID-19 vaccines.</p>	<p>Any vaccine (within the specified age range) that meets both of the following:</p> <ol style="list-style-type: none"> 1) The vaccine must be FDA-authorized or FDA-licensed. 2) The vaccination must be ordered and administered according to ACIP's standard immunization schedule. <p>Click here for more information on pharmacist and intern administration of COVID-19 vaccines.</p>
Training Requirements	<p>The pharmacist or pharmacy intern must meet the requirements established in OAC 4729-5-36.</p> <p>REMINDER: Ohio's current training requirements only require a minimum of 5 hours in length and are not required to be ACPE approved.</p>	<p>The licensed pharmacist or pharmacy intern must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.</p>
Basic Life Support Training	Requires a pharmacist or pharmacy intern to receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course that	The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.

	<p>is certified by any of the following:</p> <ol style="list-style-type: none"> 1) The American Red Cross; 2) The American Heart Association; or 3) The American Safety and Health Institute (ASHI) 	<p>IMPORTANT: Extensions granted to BLS certification by the Board due to COVID-19 cannot be applied to the federal requirements. Therefore, a pharmacist or pharmacy intern must have a valid, current BLS certification to administer immunizations under the federal process.</p>
Continuing Education	<p>There are no Ohio-specific continuing education requirements for licensees providing immunizations.</p>	<p>The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period.</p> <p>NOTE: Not a requirement for a pharmacy intern.</p>
Record keeping	<p>The Board's record keeping requirements for immunization administration are listed in paragraph (O) of OAC 4729-5-27.</p> <p>IMPORTANT: Please be advised that effective 12/1/2020, vaccine record keeping requirements will be moved to paragraph (I) rule 4729:5-5-04 of the Administrative Code.</p>	<p>The licensed pharmacist or pharmacy intern must comply with record keeping and reporting requirements of the jurisdiction in which they administer vaccines.</p> <p>The Board's record keeping requirements for immunization administration are listed in paragraph (O) of OAC 4729-5-27.</p> <p>IMPORTANT: Please be advised that effective 12/1/2020, vaccine record keeping requirements will be moved to paragraph (I) rule 4729:5-5-04 of the Administrative Code.</p>
Reporting	<p>For each immunization administered to an individual by a pharmacist or pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older,</p>	<p>The licensed pharmacist or pharmacy intern must comply with Ohio's reporting requirements.</p>

	<p>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 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.</p>	
<p>Well-Child Visit Reminder</p>	<p>Not a requirement. However, the Board strongly encourages licensees to inform childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.</p> <p>The American Academy of Pediatrics offers information on well-child visits, including informational handouts. Click here for more information.</p>	<p>The licensed pharmacist or pharmacy intern must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.</p> <p>The American Academy of Pediatrics offers information on well-child visits, including informational handouts. Click here for more information.</p>

Q2) Am I required to comply with all federal requirements to administer a vaccine to a patient who does not meet Ohio’s age criteria?

Yes. A pharmacist or pharmacy intern may only administer a vaccine to a patient who does not meet the age criteria for an immunization under Ohio law by following **ALL** the federal requirements listed above.

As a reminder, this includes, but is not limited to, the following:

- The pharmacist or intern has completed a 20-hour ACPE course that meets the federal training requirements listed Q1 of this document.
- The pharmacist will complete or has completed at least 2-hours of ACPE-approved, immunization-related continuing pharmacy education during the current state

licensing period. Therefore, the CE must be completed between September 15, 2019 and September 15, 2021. **NOTE: Completion of this continuing education requirement will count towards Ohio's [biennial CE requirements for pharmacists](#).**

- The pharmacist or intern has a valid, current certificate in basic cardiopulmonary resuscitation.
- The pharmacist or intern must inform childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate. As a reminder, the American Academy of Pediatrics offers information on well-child visits, including informational handouts. [Click here for more information](#).

Q3) Am I required to document a well-child visit reminder?

Yes. Well-child visit reminders should be documented to demonstrate compliance with the federal requirements. Such documentation must be maintained for three years and must be able to be produced within 3-business days upon the request of the Board or employee of the Board.

Q4) Am I required to maintain a current certificate in basic cardiopulmonary resuscitation from a specific organization to meet the federal requirements?

The amendment from HHS does not specify an organization. However, pharmacists and pharmacy interns are encouraged to obtain certification from the three organizations approved by the Board:

- 1) The American Red Cross;
- 2) The American Heart Association; or
- 3) The American Safety and Health Institute (ASHI)

Q5) How do I know if my immunization training meets the training standards required by HHS?

As a reminder, the federal process requires the following training:

The licensed pharmacist or intern must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

Licensees should review coursework or contact their course provider to determine if their training course meets the requirements established by HHS.

Q6) Does the authorization by HHS have an expiration date?

The authorization by HHS is in response to the COVID-19 pandemic. The Board will provide notification to licensees when/if the federal authorization is rescinded.

Q7) Do I need to document which process was followed (Ohio or HHS)?

A licensee must be able to prove they meet the requirements of either process and should maintain documentation demonstrating compliance with that process.

REMINDER: A pharmacist and pharmacy intern must comply with the record keeping requirements for immunization administration listed in paragraph (O) of OAC [4729-5-27](#) regardless of whether the pharmacist performed the vaccination under the Ohio or the HHS process. Please be advised that effective 12/1/2020, vaccine record keeping requirements will be moved to paragraph (I) rule [4729:5-5-04](#) of the Administrative Code.

Q8) I meet all the Ohio requirements, but not all of the HHS requirements. Does that mean I can only immunize children ages 7 and up?

Yes. You must meet **ALL** HHS requirements to immunize children three and older. If you do not meet all the HHS requirements, you may only provide immunizations according to Ohio's process.

Q9) Do the federal requirements need the patient to have a patient-specific prescription or use of a physician-authorized protocol?

No. The HHS amendment specifically authorizes ordering and administration of vaccines by pharmacists, as follows:

*The Secretary now amends section V of the Declaration to identify as qualified persons covered under the PREP Act, and thus authorizes, certain State-licensed pharmacists to **order and administer [emphasis added]**, and pharmacy interns (who are licensed or registered by their State board of pharmacy and acting under the supervision of a State-licensed pharmacist) to administer, any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule (ACIP-recommended vaccines).*

For the federal process only: Pharmacists must document the order for vaccine administration and those administered by a pharmacy intern they are supervising on a prescription form or other record, which may be assigned a number for record keeping purposes. Such records must be maintained for three years from the date of the order.

Q10) If I follow the federal process, am I required to comply with the Ohio vaccine reporting requirements?

Yes. The process established by HHS requires a licensed pharmacist or pharmacy intern to comply with Ohio's vaccine reporting requirements. As a reminder, Ohio's reporting requirements are as follows:

For each immunization administered to an individual by a pharmacist or pharmacy intern, 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 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.

IMPORTANT: The State of Ohio Board of Pharmacy **strongly recommends** submitting childhood immunization data to the Ohio Impact Statewide Immunization Information System (ImpactSIIS). Click [here](#) for more information.