



**STATE OF
OHIO**
BOARD OF PHARMACY

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

Updated 9/23/2020

IMPORTANT: Specific guidance on the administration of childhood vaccines during COVID-19 can be accessed here: www.pharmacy.ohio.gov/CV2020

On September 9, 2020, the U.S. Department of Health and Human Services (HHS), through the Assistant Secretary for Health, [issued guidance](#) under the Public Readiness and Emergency Preparedness Act (PREP Act) to expand access to safe and effective COVID-19 vaccines when they are made available.

This guidance authorizes state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, COVID-19 vaccinations to persons ages 3 or older, subject to certain requirements.

Please be advised that this update under the PREP Act creates two processes for the administration of FDA-authorized or FDA-licensed COVID-19 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 temporary 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 COVID-19 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 COVID-19 vaccines in Ohio?

A pharmacist or pharmacy intern, under the direct supervision of a pharmacist, may administer any FDA-approved or FDA-licensed COVID-19 vaccines 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 COVID-19 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 COVID-19 vaccinations can be accessed [here](#).

COVID-19 Vaccination Requirements

	Ohio Requirements	Federal Requirements
Age of Administration	<p>Ohio rules (effective 12/1/2020) and a Board resolution permits the administration of any FDA-approved or FDA-licensed COVID-19 vaccine to any of the following:</p> <ul style="list-style-type: none"> ▪ Individuals 13 years or older (no prescription required). ▪ Individuals between ages 7 through 12 (prescription required). <p>NOTE: Pharmacists are not permitted to administer COVID-19 vaccinations to individuals under the age of 7 unless the pharmacist or intern complies with the federal requirements.</p>	<p>The federal authorization permits the administration of any FDA-approved or FDA-licensed COVID-19 vaccines to persons ages 3 or older.</p> <p>COVID-19 vaccines must be ordered and administered according to the Advisory Committee on Immunization Practices' (ACIP) COVID-19 vaccine recommendation.</p> <p>NOTE: The federal process is the only one that permits the administration of COVID-19 vaccines 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 COVID-19

		vaccines under the federal guidance.
Approved COVID-19 Immunizations	Any FDA-approved or FDA-licensed COVID-19 vaccines.	Any FDA-approved or FDA-licensed COVID-19 vaccines.
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>	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.
Basic Life Support Training	<p>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 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>The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.</p> <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 COVID-19 vaccines under the federal guidance.</p>
Continuing Education	There are no Ohio-specific continuing education requirements for licensees providing immunizations.	<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>

<p>Record keeping</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>	<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>
<p>Reporting</p>	<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, 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>The licensed pharmacist or pharmacy intern must comply with Ohio’s reporting requirements.</p>
<p>Well-Child Visit Reminder</p>	<p>Not a requirement. However, if the patient is 18 years of age or younger, the Board strongly encourages licensees to inform the patient and the adult caregiver accompanying the</p>	<p>The licensed pharmacist must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit</p>

	<p>patient 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>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>
Compliance with CDC Requirements	<p>The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).</p>	<p>The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).</p>

Q2) Do Ohio rules and Board policy permit the administration of the COVID-19 vaccine?

Yes. The Board recently issued the following resolution:

To ensure Ohio pharmacists and interns are prepared to provide COVID-19 vaccines, the State of Ohio Board of Pharmacy hereby authorizes pharmacists and pharmacy interns to administer any FDA-approved or FDA-licensed COVID-19 vaccines in accordance with section 4729.41 of the Revised Code and rules adopted thereunder.

This resolution is being issued in accordance with a Board resolution adopted on March 2, 2020 and shall expire on December 1, 2020 when rule [4729:1-3-02](#) of the Administrative Code becomes effective.

IMPORTANT: Please be advised that effective December 1, 2020, rule [4729:1-3-02](#) goes into effect. This rule includes a specific authorization for the administration of COVID-19 vaccines by pharmacists and pharmacy interns.

Q3) Am I required to comply with all federal requirements to administer a COVID-19 vaccine to a patient who does not meet Ohio's age criteria?

Yes. A pharmacist or pharmacy intern may only administer a COVID-19 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, 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 licensed pharmacist must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient 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](#).
- The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

Q4) Am I required to document a well-child visit reminder?

Yes. If required, 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.

Q5) Am I required to maintain a current certificate in basic cardiopulmonary resuscitation from a specific organization to meet the federal requirements?

The guidance 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)

Q6) 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.

Q7) 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.

Q8) 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.

Q9) 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 provide COVID-19 vaccines to children three and older. If you do not meet all the HHS requirements, you may only provide immunizations according to Ohio's process.

Q10) Do the federal requirements need the patient to have a patient-specific prescription or use of a physician-authorized protocol?

No. The HHS guidance specifically authorizes the ordering of COVID-19 vaccines by pharmacists.

For the federal process only: Pharmacists must document the order for COVID-19 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.

Q11) 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.

Additionally, a licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable reporting requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).