



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

Updated 5/11/2023

IMPORTANT: Effective May 12, 2023, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians. The most recent PREP Act Amendment can be accessed [here](#).

Additional guidance on the administration of vaccines by pharmacy technicians can be accessed here: www.pharmacy.ohio.gov/TechAdmin

Under the Federal PREP Act Declaration, state-licensed pharmacists are permitted to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to are permitted to administer, COVID-19 and seasonal influenza vaccinations to persons ages 3 or older, subject to certain requirements.

Please be advised that this update under the [PREP Act](#) creates two very similar 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 below. 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 or seasonal influenza 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 or seasonal influenza 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.

The most recent PREP Act Amendment can be accessed [here](#).

COVID-19 Vaccination Requirements

	Ohio Requirements	Federal Requirements
Age of Administration	<p>Ohio law and rules permit the administration of any FDA-approved or FDA-licensed COVID-19 and seasonal influenza vaccines (including those under an EUA) to any of the following:</p> <ul style="list-style-type: none"> ▪ Individuals 7 years or older (no prescription required). 	<p>The federal authorization permits the administration of any FDA-approved or FDA-licensed COVID-19 and seasonal influenza vaccines (including those under an EUA) 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>

		NOTE: The federal process is the only one that permits the administration of COVID-19 or seasonal influenza vaccines to individuals below the age of 7.
Physician Approved Protocol	Requires physician approved protocol (see OAC 4729:1-3-02).	No physician-approved protocol is required, as pharmacists are authorized to order COVID-19 vaccines under the federal guidance.
Training Requirements <i>NOTE: This section only applies to training coursework. BLS and CPR are addressed in the next section.</i>	The pharmacist or pharmacy intern must meet the requirements established in OAC 4729:1-3-02 . REMINDER: Ohio’s current training requirements only require a minimum of 5 hours in length.	The licensed pharmacist or pharmacy intern must have completed the immunization training that the licensing state requires.
Basic Life Support Training	Requires a pharmacist or pharmacy intern to receive and maintain certification to perform basic life-support procedures by	The licensed pharmacist and licensed or registered pharmacy intern must have a current

	<p>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>certificate in basic cardiopulmonary resuscitation.</p> <p>According to HHS, this requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education.</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>
<p>Continuing Education</p>	<p>There are no Ohio-specific continuing education</p>	<p>The licensed pharmacist must complete a minimum of two hours of ACPE-approved,</p>

	requirements for licensees providing immunizations.	immunization-related continuing pharmacy education during each state licensing period. NOTE: Not a requirement for a pharmacy intern.
Record keeping <i>See Q13 of this document for record keeping update.</i>	The Board’s record keeping requirements for COVID-19 immunization administration were updated on 1/11/2021 to streamline record keeping requirements across all licensees. See Q13 of this document for more information.	The licensed pharmacist or pharmacy intern must comply with record keeping and reporting requirements of the jurisdiction in which they administer vaccines. The Board’s record keeping requirements for COVID-19 immunization administration were updated on 1/11/2021 to streamline record keeping requirements across all licensees. See Q13 of this document for more information.
Reporting <i>See Q11 of this document for</i>	For each immunization administered to an individual by a pharmacist or pharmacy intern, other than an immunization for influenza administered to an	The licensed pharmacist or pharmacy intern must comply with Ohio’s reporting requirements.

<p>reporting requirement update.</p>	<p>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>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 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</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 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</p>

	well-child visits, including informational handouts. Click here for more information.	informational handouts. Click here for more information.
Compliance with CDC Requirements	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).	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).
Vaccine Register Query	Not required but encouraged.	The supervising qualified pharmacist must review the vaccine registry or other vaccination records prior to ordering the vaccination to be administered by the pharmacy intern or technician. NOTE: This requirement was added under a PREP Act Amendment issued on October 20, 2020.

		<p>Otherwise, the administering pharmacist must review the vaccine registry or other vaccination records prior to administering a vaccine.</p>
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Q2) Does Ohio law permit the administration of the COVID-19 vaccine?

Yes. Rule [4729:1-3-02](#) 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 or seasonal influenza vaccine to a patient who does not meet Ohio’s age criteria?

Yes. A pharmacist or pharmacy intern may only administer a COVID-19 or seasonal influenza 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 the appropriate state training requirements to provide immunizations.
- 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)

[According to HHS](#), this requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the

American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education.

Q6) How do I know if my immunization training meets the training standards required by HHS?

As a result of a December 3, 2020 update to the PREP Act, HHS requires a licensed pharmacist or pharmacy intern to complete immunization training that the licensing state requires. The training requirements are set forth in OAC [4729:1-3-02](#).

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 (see Q13 of this document).

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 or seasonal influenza 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.

REMINDER: 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).

UPDATE (12/11/2020): Please be advised that OAC 4729:1-3-02 of the Administrative Code requires a pharmacist or pharmacy intern to notify a patient's family physician (or primary

care provider) or local health department of immunization administration using any of the following methods:

- (1) Electronic mail;
- (2) Interoperable electronic medical records system;
- (3) Facsimile;
- (4) Electronic prescribing system;
- (5) Electronic pharmacy record system;
- (6) Documented verbal communication; or
- (7) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

To streamline reporting requirements, the Board has adopted the following resolution (Adopted 12/11/2020):

Pursuant to paragraph (L)(7) of rule 4729:1-3-02 of the Administrative Code, the State of Ohio Board of Pharmacy hereby recognizes the reporting of required vaccine administration to the Ohio Impact Statewide Immunization Information System (ImpactSIIS) as a method for submitting the required notification to a patient's primary care provider or local health department.

The resolution now permits reporting to [ImpactSIIS](#) as an additional method for meeting the notification requirements of section 4729.41 of the Revised Code and rule 4729:1-3-02 of the Administrative Code.

Q12) Am I required to obtain informed consent prior to the administration of a COVID-19 vaccine?

Ohio's record keeping and vaccine administration laws and rules require informed consent of the patient. However, as all available COVID-19 vaccines have been approved under an FDA

Emergency Use Authorization (EUA), the Board has adopted the following resolution as it pertains to consent:

Resolution on Informed Consent for COVID-19 Vaccine Administration (Adopted 12/1/2020)

In order to ensure uniform vaccination requirements, the State of Ohio Board of Pharmacy has adopted the following resolution regarding the informed consent requirements set forth in OAC 4729:1-3-02 and 4729:5-5-04 of the Administrative Code. This resolution is being issued in accordance with a Board resolution adopted on May 5, 2020.

*In lieu of the informed consent requirement, pharmacy personnel may adhere to the “Information for Recipients” guidance issued by the FDA for drug approved via Emergency Use Authorization (EUA) (see page 24 of the following document: <https://www.fda.gov/media/97321/download>). **Please note that this resolution does not replace or supersede any patient education requirements set forth by any other federal or state agency.***

Q13) What are Ohio’s record keeping requirements for pharmacy personnel administering COVID-19 vaccinations? UPDATE (1/11/2021)

In response to the COVID-19 pandemic, the State of Ohio Board of Pharmacy has adopted the following resolution:

To ensure streamlined vaccine administration, the State of Ohio Board of Pharmacy temporarily authorizes records of COVID-19 vaccine administration by pharmacy personnel (pharmacists, interns, technicians) to comprise the following:

Records of COVID-19 vaccine administration by pharmacy personnel shall contain the name, strength, dosage form, and quantity of the vaccine administered, the name and date of birth of the person to whom or for whose use the vaccine was administered, the date of administration, and the identification of the pharmacy personnel administering

the drug. This resolution does not supersede any record keeping requirements from the Ohio Department of Health or any federal agency.

This resolution is being issued in accordance with a Board resolution adopted on May 5, 2020. This resolution shall remain in effect until rescinded by the Board.

With the adoption of this resolution, pharmacy personnel should note the following:

1. Vaccine administration records across all TDDDs are now uniform. These are the same record keeping requirements for the administration of vaccines in clinics and other non-pharmacy sites.
2. This only applies to the administration of COVID-19 vaccine.
3. The resolution only requires the identification - not the positive identification - of the individual administering the drug. This means that pharmacy personnel administering the COVID-19 vaccine will still need to document who administered the vaccine, but that such documentation does not have to meet the standard of positive identification.
4. Nothing in this resolution prohibits pharmacy personnel from complying with the original vaccine record keeping requirements set forth in OAC [4729:5-5-04](#) (L).

Q14) Can nurses and EMS certificate holders help administer a pharmacy's COVID-19 vaccine drug stock? UPDATE (1/19/2021)

Yes. Nurses and EMS certificate holders may be used to administer a pharmacy's COVID-19 vaccine stock. The pharmacy must have a physician authorized protocol that contains the following information pursuant to OAC [4729:5-3-12](#) (B):

- (1) Include a description of the intended recipients to whom the drugs are to be administered; drug name and strength; instructions of how to administer the drug, dosage, and frequency; signature of a prescriber or some other form of positive identification of the prescriber as defined in agency 4729 of the Administrative Code; and date of signature;
- (2) Be administered by an individual authorized by law to administer the drugs;

- (3) Be made readily retrievable (i.e. be able to be produced within 72 hours upon request);
- (4) Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care; and
- (5) Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of authorization or reauthorization following any modification or amendment.

Additionally, nurses and EMS personnel must also comply with the record keeping requirements specified in Q13 of this guidance.

EMS personnel must also comply with the requirements set forth by the [Ohio EMS Board](#). The EMS Board also has additional vaccine training resources for EMS personnel on its [website](#).

IMPORTANT: The pharmacy may update their existing pharmacist/intern protocol to include nurse and EMS certificate holders or may maintain a separate protocol.

Q15) Am I required to comply with Ohio’s compounding standards when engaged in the dilution of the Pfizer or Moderna vaccine? UPDATE (1/19/2021)

Unless otherwise stated by the FDA or CDC, pharmacies must adhere to the manufacturer’s requirements for preparation and administration of the Pfizer or Moderna vaccine. Therefore, any conflict between Ohio's compounding standards and instructions from the federal government/manufacturer on vaccine preparation should defer to the federal government/manufacturer.

Q16) How many pharmacy interns providing COVID-19 immunizations may a pharmacist supervise at any time? UPDATE (2/16/2021)

Under the Ohio process, OAC 4729:2-1-01 authorizes a pharmacist to supervise up to six pharmacy interns providing immunizations. To increase capacity, the Board adopted the following resolution:

To maximize the safe administration of COVID-19 vaccines, the State of Ohio Board of Pharmacy temporarily expands the pharmacy intern supervision requirements in OAC 4729:2-1-01 (O)(4) as follows:

Pursuant to OAC 4729:2-1-01, the Board authorizes a pharmacist to supervise up to six pharmacy interns providing immunizations. The Board hereby expands the number of pharmacy interns providing COVID-19 vaccines a pharmacist can supervise as follows:

- *A pharmacist may supervise between 7-12 pharmacy interns at once if a nurse licensed or registered under Chapter 4723. of the Revised Code or an Ohio EMS certificate holder practicing in accordance with the [vaccine administration guidance](#) from the Ohio EMS Board is present and assisting with the administration of COVID-19 vaccines.*
- *A pharmacist may supervise between 13-18 pharmacy interns at once if two or more nurses licensed or registered under Chapter 4723. of the Revised Code or two or more Ohio EMS certificate holders practicing in accordance with the [vaccine administration guidance](#) from the Ohio EMS Board are present and assisting with the administration of COVID-19 vaccines.*

This resolution is being issued in accordance with a Board resolution adopted on May 5, 2020. This resolution shall remain in effect until rescinded by the Board.

IMPORTANT REMINDERS:

- Any pharmacy utilizing non-pharmacy staff should verify that non-pharmacy staff (e.g., nurses and EMS) are administering pursuant to a prescriber-authorized protocol.
- The federal process approved under the PREP Act **does not** have any limitations on the number of interns that may be supervised by a qualified pharmacist at any one time.
- Supervising pharmacists must be able to provide immunizations under the respective processes (state or federal) to supervise interns providing COVID-19 vaccines.