



DIRECTOR JOURNAL ENTRY

In re COVID 19 Volunteer Vaccine Providers.

WHEREAS, the Governor declared a State of Emergency on March 9th, 2020, due to novel Coronavirus (2019-nCoV, known as COVID-19), a disease of major public concern; and

WHEREAS, the United States Food and Drug Administration (FDA) has granted Emergency Use Authorizations (EUAs) to the COVID vaccines developed by Pfizer and Moderna; and

WHEREAS, a large-scale campaign will be needed to vaccinate all Ohioans who wish to be vaccinated once the vaccines become sufficiently available; and

WHEREAS, general and city health departments have plans to use points of dispensing and clinic locations to support a large-scale vaccination campaign; and

WHEREAS, Medical Reserve Units have been established throughout Ohio to support a large-scale vaccination campaign; and

WHEREAS, there may be an insufficient number of health professionals available to conduct a large-scale vaccination campaign; and

WHEREAS, Section 3701.048 of the Revised Code, allows the Director of Health to, in consultation with the appropriate professional regulatory boards of Ohio, develop protocols that authorize individuals to administer, deliver, or distribute drugs, other than schedule II and III controlled substances, during a period of time the Governor declares to be an emergency that affects the public's health;

NOW THEREFORE, I, Stephanie McCloud, Director, Ohio Department of Health (ODH), in accordance with my authority set forth in Section 3701.048, **HEREBY ORDER AND AUTHORIZE**, the following professionals, within the scope of their respective licensure and according to the competencies set forth by their respective licensing board, unless otherwise stated herein, to administer, deliver, or distribute the

drugs, other than schedule II and III controlled substances, set forth in this order during this COVID State of Emergency, notwithstanding any statute or rule that otherwise prohibits or restricts the administration, delivery, or distribution of drugs by these professionals:

- (1) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;
- (2) A physician assistant licensed under Chapter 4730. of the Revised Code;
- (3) A dentist or dental hygienist licensed under Chapter 4715. of the Revised Code;
- (4) A registered nurse licensed under Chapter 4723. of the Revised Code, including an advanced practice registered nurse, as defined in section 4723.01 of the Revised Code;
- (5) A licensed practical nurse licensed under Chapter 4723. of the Revised Code;
- (6) An optometrist licensed under Chapter 4725. of the Revised Code;
- (7) A pharmacist or pharmacy intern licensed under Chapter 4729. of the Revised Code;
- (8) A respiratory care professional licensed under Chapter 4761. of the Revised Code;
- (9) An emergency medical technician-intermediate (now known as an “Advanced EMT”) or emergency medical technician-paramedic (now known as a “Paramedic”) who holds a certificate to practice issued under Chapter 4765. of the Revised Code;
- (10) A veterinarian licensed under Chapter 4741. of the Revised Code.

For this Order to apply, these individuals will need to be Registered Volunteers pursuant to Section 5502.281 of the Revised Code and actively deployed by a recognized Medical Reserve Corps (MRC) unit in support of points of dispensing.

Pharmacy interns, medical, and nursing students who are sufficiently advanced in their education at their respective professional schools with the necessary

competencies, according to the manner set out by the appropriate licensing board, may also administer COVID vaccine if properly supervised and actively deployed by a recognized Medical Reserve Corps unit.

Training

Proper vaccine administration is critical to ensure that vaccination is safe and effective. All personnel administering vaccines must receive comprehensive, competency-based training on vaccine administration policies and procedures as well as training on the recognition and management of anaphylaxis **BEFORE** administering vaccines. Vaccinating personnel must comply with any competencies set forth by their respective licensing boards. If the board has not set a competency, vaccinating personnel may meet this training requirement through the e-training listed below.

The free vaccine administration e-Learn is available that offers continuing education for health care personnel. The training can be found at the following links:

- <https://www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp> and
- <https://www.foodallergy.org/recognizing-responding-anaphylaxis>

Procedure

1. Assess adults and adolescents in need of vaccination against the SARS-CoV-2 virus based on the following criteria:
 - a. Must be 16 years and older for the Pfizer-BioNTech COVID-19 Vaccine (Pfizer) or 18 years of age and older for Moderna COVID-19 Vaccine (Moderna). Children and adolescents younger than age 16 are NOT authorized to receive Pfizer and children and adolescents younger than age 18 are NOT authorized to receive Moderna at this time.
 - b. If the recipient has received a previous dose of Pfizer or Moderna, the second dose of the same brand should be administered.
 - c. The vaccines are administered in a 2-dose series separated by at least 21 days for Pfizer and 28 days for Moderna. Individuals should be scheduled as close to the recommended interval as possible. For

Pfizer, if the second dose was given as early as 17 days after the first dose, the dose is considered valid. For Moderna if the second dose was given as early as 24 days, the dose is considered valid. The second dose of the vaccines may be administered up to 6 weeks (42 days) after the first dose. There is currently limited data on the efficacy if administered beyond that interval. If the second dose for either vaccine is administered beyond these intervals there is no need to restart the series. Also, doses inadvertently administered earlier than the grace period should not be repeated.

- d. The Pfizer and Moderna should not be administered with any other vaccines. Best practice is to separate the Pfizer and Moderna from other vaccines by 14 days before or after administration of either vaccine.
2. Screen all adults and adolescents for contraindication and precautions for the mRNA COVID-19 (Pfizer or Moderna) vaccines.
 - a. Contraindications.
 - i. Under 16 years of age for Pfizer and under 18 years of age for Moderna.
 - ii. Do not give the mRNA COVID-19 vaccines to an individual who has experienced a serious reaction* (e.g., anaphylaxis) to a prior dose of mRNA COVID-19 vaccine or to any of the mRNA COVID-19 vaccine components. For more information on Pfizer vaccine components, refer to the Fact Sheet for Healthcare Providers at <https://www.fda.gov/media/144413/download>. For more information on the Moderna vaccine components, refer to the Fact Sheet for Healthcare Providers at <https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf>
 - iii. Do not give the mRNA COVID-19 vaccines to an individual who has had an immediate allergic reaction of any severity to a previous dose of any mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*.

- iv. Do not give the mRNA COVID-19 vaccine to an individual who has had an immediate allergic reaction of any severity to polysorbate (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG**).

*An immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticarial, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following exposure to a previous dose of an mRNA COVID-19 vaccine or any of its components. For more information regarding contraindications and precautions when administering the mRNA COVID-19 vaccines, see Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinicalconsiderations.html#Contraindications>

** These individuals should not receive mRNA COVID-19 vaccines at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).

b. Precautions

- i. Moderate or severe acute illness with or without a fever.
- ii. Severe allergic reaction** (e.g., anaphylaxis) to a previous dose of any vaccine (not including Pfizer-or Moderna as this would be a contraindication).

1. Action:

- a. Assess the risk of vaccination
- b. Observe patient for 30 minutes following vaccination.

- iii. Severe allergic reaction** (e.g. Anaphylaxis) to a medication that is injectable.

1. Action:

- a. Assess the risk of vaccination.
- b. Observe patient for 30 minutes following vaccination.
- iv. Delay vaccination in individuals in community or outpatient settings who have a known SARS-CoV-3 exposure until quarantine period has ended, unless individual resides in congregate healthcare setting or resident of other congregate settings (e.g., correctional facilities, homeless shelter)
- v. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation
- vi. Delay vaccination if the individual has had passive antibody therapy for COVID-19 until 90 days have passed from completion of said therapy

** Providers may consider deferring vaccination with the mRNA COVID-19 vaccines at this time until the individual has been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available). Considerations that can be used to help the provider conduct a risk assessment for mRNA COVID-19 vaccinations include the risk of exposure to SARS-CoV-2 or risk of severe disease or death due to COVID-19. For further guidance, visit <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications>.

- 3. Special Populations for which special counseling is recommended.
 - a. Pregnant females are recommended for vaccine depending on the following:
 - i. Level of COVID-19 community transmission (risk of acquisition).
 - ii. Personal risk of contracting COVID-19 to the person and potential risks to the fetus.

- iii. The efficacy of the vaccine.
- iv. The known side effects of the vaccine.
- v. The lack of data about the vaccine during pregnancy.
- b. Lactating (Breastfeeding) is not a contraindication to vaccination; however, there are no data on the safety of mRNA COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion.
- c. Immunocompromised persons
 - i. Immunocompromised persons are those with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies.
 - ii. Data are not currently available to establish safety and efficacy of vaccine in these groups
 - iii. These individuals may still receive COVID-19 vaccine unless otherwise contraindicated
 - iv. Individuals should be counseled about:
 - 1. Unknown vaccine safety and efficacy profiles in immunocompromised persons.
 - 2. Potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19.
- 4. Routine testing for pregnancy or COVID-19 antibody testing is not recommended prior to vaccination
- 5. Prior to vaccination, provide the person/legal representative the following:
 - a. Emergency Use Authorization (EUA) Fact Sheet.
 - i. Provide all -persons(or in the case of minors or incapacitated adults their legal representative) with a copy of the Emergency Authorization Fact Sheet. Provide non-English language if one

is available and desired; at The Pfizer EUA Fact Sheet for Healthcare Providers can be found at <https://www.fda.gov/media/144413/download> and for recipients and caregivers at <https://www.fda.gov/media/144414/download> . The Moderna EUA Fact Sheet for Healthcare Providers can be found at <https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf> and for recipients and caregivers at <https://www.fda.gov/media/144638/download> .

- b. Vaccine Information Statement (VIS).
 - i. Provide all persons (or in the case of minors or incapacitated adults their legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language if one is available and desired; these can be found at www.immunize.org <https://www.cdc.gov/vaccines/covid-19/eua/index.html>
6. Prepare for Vaccination
- a. Choose the correct needle length and gauge for an intramuscular injection
 - b. For persons 16 through 18 years of age: 1-inch needle is recommended
 - c. 19 years of age or older (see table):

Gender and Weight of patient	Needle Gauge	Needle Length	Injection Site
Female or Male less than 130 pounds	22-25	5/8" – 1"	Intramuscular Deltoid
Female or Male 130-152 pounds	22-25	1"	Intramuscular Deltoid
Female 153- 200 pounds	22-25	1"-1 ½"	Intramuscular Deltoid
Male 153-260 pounds	22-25	1"-1 ½"	Intramuscular Deltoid

Female 200 + pounds	22-25	1 ½”	Intramuscular Deltoid
Male 260 + pounds	22-25	1 ½”	Intramuscular Deltoid

- d. Prepare the PfizerBioNTech COVID-19 vaccine
- i. The vaccine must be thawed and mixed with diluent before administration. The vaccine can be thawed in the refrigerator for two to three hours between 36°F and 46°F or at room temperature for thirty minutes to two hours up to 77°F. Vials at room temperature must be mixed within 2 hours or returned to the refrigerator. Do not refreeze thawed vaccine.
 - ii. Perform hand hygiene before vaccine preparation. Remove vaccine from refrigerator and allow to come to room temperature. With the vaccine at room temperature, GENTLY invert vial 10 times.
 - iii. Using a sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials. Using a 21-gauge (or narrower) needle, withdraw 1.8 mL of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Inject 1.8 mL 0.9% sodium chloride into the vaccine vial. Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vial.
 - iv. GENTLY invert the vaccine and diluent vial 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter.
 - v. Note the date and time the vaccine was mixed on the vial.
 - vi. Keep the mixed vaccine at room temperature (36°F to 77°F) and administer within 6 hours. Discard any unused vaccine after 6 hours.
 - vii. Due to production, a sixth dose may be available in the vaccine vial; however, any remaining vaccine that does not equal a full 0.3 mL dose should not be pooled with other remaining vaccine to obtain a full 0.3 mL dose.

- e. Prepare the Moderna COVID-19 vaccine:
 - i. The vaccine must be thawed before administration. Do not mix the vaccine with a diluent. The vaccine can be thawed in the refrigerator for two hours and thirty minutes between 36°F and 46°F or at room temperature for one hour between 59°F and 77°F. Vials that have not been punctured may be kept between 46°F and 77°F for up to 12 hours. Do not refreeze thawed vaccine.
 - ii. Perform hand hygiene before vaccine preparation. With the vial upright, GENTLY swirl the vaccine.
 - iii. Examine the vaccine. It should be white to off white in color and may contain white particles. Do not use if liquid contains other particulate matter or is discolored.
 - iv. Using a sterile alcohol prep pad, wipe off the stopper of the vaccine vial before withdrawing a dose. Gently swirl the vaccine before withdrawing subsequent doses.
 - v. Note the date and time the vial was first punctured. Keep the vaccine between 36°F and 77°F for up to six hours. Discard any unused vaccine after six hours.

7. Administer the mRNA Vaccine (Pfizer or Moderna)

Type of Vaccine	Age group	Dose	Route	Instruction	Dose Schedule
Moderna	Adults 18 years of age and older	0.5mL	Intramuscular	Administer vaccine in deltoid muscle	Give dose # 2 at least 21 days from dose # 1 for Pfizer and dose #2 at least 28 days from dose #1 for Moderna.
Pfizer	Adolescents 16years of age and older	0.3mL			

- a. Patients who do not receive the 2nd vaccination dose at 21 days or 28 days should still receive the 2nd dose as soon as possible thereafter.
- b. The second dose should be administered as close to the recommended interval as possible.

- c. However, if it is not feasible to adhere to the recommended interval, the second dose of Pfizer and Moderna may be scheduled for administration 4 days before the 21 or 28 day intervals depending on product being administered and up to 6 weeks (42 days) after the first dose.
 - d. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window.
 - e. If the second dose is administered beyond these intervals, there is no need to restart the series.
8. Document the Vaccination.
 - a. Medical Record: Record the date and the vaccine that was administered, the manufacturer and lot number, the vaccination site and route, the vaccine dosage, and the name and title of the person administering the vaccine. Document the VIS given, and VIS publication date.
 - b. Immunization Record Card: Record the date of vaccination, product name/manufacturer, lot number and the name/location of the administering clinic or healthcare professional.
 - c. Documentation of the vaccination in Ohio's immunization information system - ImpactSIIS within 24 hours following vaccination.
9. Observe the Vaccine Recipient.
 - a. 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause.
 - b. 15 minutes: All other persons.
10. Emergency Protocols
 - a. If a patient experiences itching and swelling confined to the injection site where the vaccination was given, apply a cold compress to the injection site. Observe patient closely for the development of generalized symptoms until symptoms subside.

- b. If symptoms are generalized (generalized itching, redness, urticaria (hives); or include angioedema (swelling of the lips, face, or throat); shortness of breath; shock; or abdominal cramping; call 911 and notify the supervising healthcare professional. Notifications should be done by a second person while the primary healthcare professional assesses the airway, breathing, circulation and level of consciousness of the patient. Vital signs (heart rate, respirations and blood pressure, pulse ox) should be taken every 5 minutes.
 - i. First-line treatment of an anaphylactic reaction is to administer Epinephrine (1 mg/ml aqueous solution [1:1000 dilution]) intramuscularly.
 - ii. The adult dose is 0.3mg to 0.5mg with maximum dose of 0.5mg; or as auto-injector (0.3 mg)
 - iii. For hives or itching, you may also administer diphenhydramine (orally or intramuscular with a standard dose of 25-50mg.) or hydroxyzine (standard oral dose is 25mg -100mg or 0.5-1.0 mg/kg.
 - iv. Monitor the person closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.
 - v. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5-15 minutes for up to 3 doses depending on the person's response.
 - vi. Record the person's reaction to the vaccine (e.g., hives, anaphylaxis), all vital signs, and medications administered to the person, including time dosage, response, and the name of the medical personnel who administered the medication and other relevant clinical information.
 - vii. Adverse events must be reported to the Vaccine Adverse Event Reporting System (VAERS) at <https://vaers.hhs.gov/reportevent.html> or call 1-800-822-7967.
 - viii. Report the adverse event to the person's primary care provider.

Pursuant to R.C. 3701.352, this order is to prevent a threat to the public's health; no person shall fail to follow this order.



2.12.2021

Stephanie McCloud
Director of Health

Date