NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order for FDA Authorized COVID-19 Vaccine Administration
February 25, 2021

Purpose: To meet the goal of administering FDA-authorized COVID-19 vaccines, and to protect and save lives in the COVID-19 pandemic by vaccinating persons who meet the criteria authorized by the Food and Drug Administration and recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy: This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Executive Order 193, or as a covered person under the federal PREP Act, functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA through an Emergency Use Authorization (EUA) and per conditions of this order.

COVID-19 Vaccination		
Condition or Situation	**Pfizer**	**Moderna**
	Patients (recipients of vaccine), 16 years of age and older, present requesting and consent to **Pfizer-BioNTech COVID-19 Vaccine** and have legal and decisional capacity to consent to the vaccine.	Patients (recipients of vaccine), 18 years of age and older, present requesting and consent to **Moderna COVID-19 Vaccine** and have legal and decisional capacity to consent to the vaccine.
Assessment Criteria		
Assessment Criteria	**Pfizer**	**Moderna**
	Patients shall be vaccinated with Pfizer-BioNTech COVID-19 Vaccine based on: 1. the conditions of this order 2. no history of complete 2-dose COVID-19 vaccination, regardless of brand.	Patients shall be vaccinated with Moderna COVID-19 Vaccine based on: 1. the conditions of this order 2. no history of complete 2-dose COVID-19 vaccination, regardless of brand.
Plan of Care		
Actions	**Pfizer**	**Moderna**
	1. Patient Education and Data Collection a. Prior to patients receiving the COVID-19 vaccine, the vaccinator or designee (if delegation permitted by licensure and/or law) shall provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include:	**1. Patient Education and Data Collection** b. Prior to patients receiving the COVID-19 vaccine, the vaccinator or designee (if delegation permitted by licensure and/or law) shall provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include: i. Where, how, and when to obtain the **second** COVID-19 vaccination.

	i. Where, how, and when to obtain the **second** COVID-19 vaccination. ii. CDC Pre-Vaccination Checklist for COVID-19 Vaccine iii. Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older iv. Provide the V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe. Note: Providers need to assure the most current version of this document by visiting: https://www.cvdvaccine-us.com/	ii. CDC Pre-Vaccination Checklist for COVID-19 Vaccine iii. Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older iv. Provide the V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe. Note: Providers need to assure the most current version of this document by visiting: https://www.modernatx.com/covid19vaccine-eua/providers/
	Content Below Applies to Both Pfizer and Moderna COVID-19 Vaccines	
	2. COVID-19 Vaccination Administration Procedures a. Review Interim Clinical Considerations for Use of COVID-19 vaccines - https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html b. Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA COVID-19 vaccine. c. A medical provider, defined as a physician, physician assistant, nurse practitioner, must be accessible to provide medical supervision of the vaccination site/service, to assess and evaluate individuals who present with precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility. d. Review *Precautions*, *Contraindications*, and *Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine. e. Instruct patients with a history of allergic reactions, including severe allergic reactions, NOT related to vaccines or injectable therapies, components of mRNA	

COVID-19 vaccines (including Polyethylene Glycol), or polysorbates that these are NOT contraindications or precautions to vaccination with currently authorized COVID-19 vaccines. Inform these patients that there are unknown risks of developing a severe allergic reaction and they will be observed for any signs of allergic reaction for 30 minutes after vaccination.

f. Review the patient-completed *CDC Pre-Vaccination Checklist for COVID-19 Vaccines*.

g. Following the current *CDC Pre-Vaccination Checklist for COVID-19 Vaccines Information for Healthcare Providers*, instruct patients who present under the following conditions:

1. If a patient indicates they are feeling sick on the Pre-Vaccination Checklist, ask them if they have a moderate to severe illness. If patient says yes, consult the supervising medical provider.
2. Instruct patients with bleeding disorders or who take blood thinners
   a. they may have increased bleeding after intramuscular injection, and
   b. to call their primary care provider or seek other medical care if the injection site starts bleeding after leaving the vaccination clinic and cannot be stopped by applying pressure.
3. Instruct patients who have received passive antibody therapy as a treatment for COVID-19 that COVID-19 vaccination will be deferred for at least 90 days since their last treatment as a precautionary measure to avoid interference of the antibody treatment with vaccine-induced immune responses.
4. Instruct patients who have had another vaccine in the last 14 days that the vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration with any other vaccine. Patients will need to schedule the vaccine appointment to allow for the 14-day interval between vaccines.
5. Instruct patients with known current symptomatic SARS-CoV-2 infection their vaccine will be deferred until the patient has recovered from the acute illness and criteria have been met for them to discontinue isolation.
6. Instruct patients who are immunocompromised regarding unknown vaccine safety and effectiveness, that the vaccine might be less effective than in someone who is immunocompetent, potential for reduced immune responses. and the need to continue to follow all current guidance to protect themselves against COVID-19.
7. Instruct patients who are pregnant or lactating (breastfeeding) that these conditions are not contraindications to Pfizer and Moderna COVID-19 vaccine and may choose to get vaccinated. Educate the patient that there are no data currently available on the safety of COVID-19 vaccines in pregnant women, but studies and results are expected soon. Data demonstrate that while the absolute risk is low, pregnant women with

COVID-19 have an increased risk of severe illness. Also, educate patients that there are no data available for lactating women on mRNA vaccines' effects on lactating women.

h. Consent must be obtained from the patient or the patient's legally authorized representative prior to vaccine administration per agency policy and in accordance with G.S. 90-21.13. Consent may be obtained verbally.

3. Personal Protective Equipment: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per CDC guidelines for COVID-19 vaccinations to protect against the transmission of COVID-19.
4. Vaccine Preparation and Administration:
   a. **Preparation**: Mix, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine. Refer to: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
   b. **Pfizer BioNTech COVID-19 Vaccine Administration**: Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection in the deltoid muscle of the arm to patients 16 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used. This vaccine is administered in a 2-dose series. Second doses should be scheduled at 21 days after first dose.
   c. **Moderna COVID-19 Vaccine Administration**: Administer 0.5 mL Moderna COVID-19 Vaccine by intramuscular (IM) injection in the deltoid muscle of the arm to patients 18 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used. This vaccine is administered in a 2-dose series. Second doses should be scheduled at 28 days after first dose.
   d. **Second dose of COVID-19 vaccine**:
      i. **Vaccine product:** Patients shall receive the second COVID-19 vaccine dose of the same brand as first administered. Also, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. See "Administration" and "Interchangeability with other COVID-19 vaccine products" headers: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
      ii. **Timing of second dose:** Second doses should be scheduled as close to recommended interval as possible, but no sooner than 4 days earlier than recommended interval. Doses administered within a grace period of 4 days earlier than the second dose's recommended date are still considered valid. Doses inadvertently administered earlier than the grace period do not need to be repeated. There is no maximum interval between the first and second doses for either vaccine. Therefore, if the second dose is administered >3 weeks after the first Pfizer-BioNTech

vaccine dose or >1 month after the first Moderna vaccine dose, there is no need to restart the series.

e. **Needle Gauge**: Changing needles between drawing up vaccine from a vial and injecting it into a patient is not necessary unless the needle has been damaged, contaminated, or if the needle used to draw up the vaccine is not the correct size for the patient based on their reported weight. Patients may self-report their weight for needle selection purposes. See needle sizing chart below:

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site*
Female or male fewer than 130 lbs.	22–25	5/8 ** –1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs.	22–25	1-11/2"	Deltoid muscle of arm
Male 153–260 lbs.	22–25	1-11/2"	Deltoid muscle of arm
Female 200+ lbs.	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	11/2"	Deltoid muscle of arm

* Alternatively, the anterolateral thigh also can be used.

** Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

f. **Bleeding Risk**: Patients with blood disorders or who are on blood thinners: administer the vaccine using a 23 gauge or smaller caliber needle, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

g. **Post-vaccination Observation**: Nurses, EMS, or other individuals who are trained and supervised by clinical staff shall observe patients post-vaccination for immediate allergic reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/) for the following time periods:

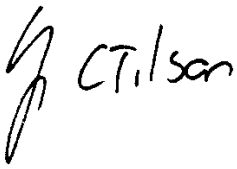
   i. 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause.

   ii. 15 minutes: All other persons

   Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

	h. **Coadministration with other vaccines**: COVID-19 vaccines shall not be administered at the same time as other vaccines. Separate COVID-19 vaccines from other vaccines by 14 days before or after the administration of COVID-19 vaccine. i. **CVMS**: Document vaccine record in CVMS **within 24 hours** after vaccine administration per system guidelines found at https://immunize.nc.gov/providers/covid-19training.htm. If vaccine is documented in the EHR within 24 hours, providers have **no more than 72 hours** from administration to also enter data in CVMS. j. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy. k. Provide vaccine recipients and/or their legal representative COVID-19 Vaccination Record Card indicating the vaccine dose number, product name/manufacturer, lot number, date of vaccination, name/location of vaccinator and clinic site. l. Counsel when and how patient needs to schedule return appointment for second dose of COVID-19 vaccine, if applicable.
Follow-up	1. Vaccinators administering COVID-19 vaccine must report the following information associated with the administration of the vaccine in accordance with each manufacturer's fact sheets for healthcare providers administering vaccine: Pfizer: https://www.cvdvaccine-us.com/ Moderna: https://www.modernatx.com/covid19vaccine-eua/providers/dosing-administration • Vaccine administration errors, whether associated with an adverse event or not • Serious adverse events (irrespective of attribution to vaccination) • Cases of Multisystem inflammatory syndrome in children and adults • Cases of COVID-19 that result in hospitalization or death Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA or "Moderna COVID- 19 Vaccine EUA" as appropriate in the report's description section. Vaccinators are required to follow the instructions in the letter issued by the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for emergency use of COVID-19 for both Pfizer-BioNTech COVID-19 Vaccine and Moderna Vaccine. Pfizer letter: https://www.fda.gov/media/144412/download Moderna letter can be found here: https://www.fda.gov/media/144636/download
Precautions for Use of this Order	1. History of an immediate allergic reaction to any other vaccine or therapies [excluding subcutaneous immunotherapy of allergies, i.e., "allergy shots"] not related to a component of mRNA COVID-19 vaccines or polysorbate). Persons with a precaution

	to vaccination must be counseled about the unknown risks of experiencing a severe allergic reaction and balance these risks against the benefits of vaccination. 2. Patient self-reported moderate to severe acute illness.
Contraindications for Use of this Order	Do not give this vaccine if patient has history of • Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components • Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])* • Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG*) *These persons should not receive mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna) 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).
Criteria or Circumstances for Notifying Medical Provider	1. Allergic reaction: Call 911, implement medical emergency protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service. 2. Patient reports a precaution for the vaccine. 3. Patient is unaware of the COVID vaccine that they previously received. 4. Notify the Medical Provider from the organization providing clinical supervision of the vaccination site/service at any time there are questions or problems with carrying out this standing order.



Approved by: _____ Date Signed: _2-25-21_____

Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

This order is effective immediately upon signing and may be revised or revoked by the State Health Director according to his/her discretion. This order will expire upon rescission off the State of Emergency Executive Order Number 116. Legal Authority: Executive Order 193.