NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
for Pfizer-BioNTech mRNA COVID-19 Vaccine Administration in Patients Ages 5-11 Years
Revised November 19th, 2021

Purpose: To meet the goal of administering FDA-Emergency Use Authorization (Pfizer-BioNTech) herein-after Pfizer vaccines and to protect and save lives in the COVID-19 pandemic by vaccinating persons aged 5-11 years old who meet the criteria set-forth by the Food and Drug Administration.

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 236, or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer FDA approved COVID-19 Vaccines and/or COVID -19 vaccines authorized by the FDA through an Emergency Use Authorization (EUA) per conditions of this order.

COVID-19 Vaccination	
Condition or Situation	Patients 5-11 years old presenting for a first or second dose of Pfizer COVID-19 vaccination authorized by the FDA through an Emergency Use Authorization (EUA). Per Session Law 2021-110, the parent or legal guardian of the patient (recipient of vaccine) must provide **written consent** prior to the patient being vaccinated with Pfizer COVID-19 vaccine. **Primary 2-Dose Series under the following situations:** • Patients, 5-11 years old who present for Pfizer vaccine for the first or second dose of their 2-dose primary series. NOTE: Patients should receive the age-appropriate formulation of Pfizer based on the age they are the day of vaccination.
Assessment Criteria	
Assessment Criteria	Patients shall be vaccinated with Pfizer COVID-19 Vaccine based on: 1. the conditions of this order 2. If patient is presenting for first dose of Pfizer: ensure there is no history of previous COVID-19 vaccination, regardless of brand. 3. **If patient is presenting for second dose of Pfizer:** ensure that at least 21 days have passed since the first dose was administered.
Plan of Care	
	Patient Education and Data Collection 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 and parent/ legal guardian, which at a minimum shall include: 1. Vaccinators may review suggested comfort holds or embraces with the patient and their parent/ legal guardian to reduce stress and facilitate vaccine administration, if applicable. 2. Where, how, and when to obtain follow-up COVID-19 vaccinations, as appropriate and as outlined above. 3. CDC Pre-Vaccination Checklist for COVID-19 Vaccine 4. Fact Sheet for Recipients and Caregivers About the Pfizer COVID-19 Vaccine for Use in Individuals 5-11 Years of Age

5. V-safe information sheet to vaccine recipients and their parent/legal guardian and encourage vaccine recipients to participate in V-safe.

Pfizer COVID-19 Vaccination Administration Procedures

1. Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.
2. Review the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) for Pfizer for 5-11 Years of Age.
3. 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.
4. A medical provider, defined as a physician, physician assistant, nurse practitioner, or a pharmacist authorized to order COVID-19 vaccines by the PREP Act must be accessible to provide medical supervision of the vaccination site/service, to assess and evaluate individuals who present with contraindications or precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.
5. Review *Special Circumstances*, *Precautions*, *Contraindications*, and *Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine.
6. Following the current *CDC Pre-Vaccination Checklist for COVID-19 Vaccines*, instruct patients accordingly or consult with overseeing provider.
7. Written consent must be obtained from the patient's parent or legal guardian prior to vaccine administration per agency policy and in accordance with NC General Statute. 90-21.13 and NC General Statute 90-21.5 and Session Law 2021-110.
8. 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.
9. **Vaccine Administration**:
    a. **Ensure the appropriate Pfizer formulation is selected.** Pfizer COVID-19 vaccine for ages 5-11 (10 µg) has an **ORANGE** cap and label and is marked "Age 5y to <12y". Using the formulation for ages 12 and older (30 µg) may result in vaccine administration errors and should not be used in this age group**.**

✓ **Orange plastic cap and label with orange border.**

b. **Preparation**: Mix, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine. Refer to Pfizer Vaccine Preparation Summary for 5-11 Years Formulation.

c. **Vaccine Product and Dosing:**
   i. **First Dose: Administer 0.2 mL** (10 µg) Pfizer COVID-19 Vaccine. This vaccine is administered in a 2-dose series. If a child aged 5-11 inadvertently receives a 30 µg first dose (from the PURPLE cap formulation), they do not need to repeat the first dose. Second doses should be scheduled at least 21 days after first dose.
   ii. **Second dose: Administer 0.2 mL** (10 µg) Pfizer COVID-19 vaccine. If a child aged 5-11 inadvertently receives a 30 µg second dose (from the PURPLE cap formulation), they should be considered as having completed the primary series.

d. **Route of Administration:** Administer Pfizer vaccine by intramuscular (IM) injection in the deltoid muscle of the arm to patients 5-11 years of age. The deltoid muscle is the preferred IM injection site for this age group. If contraindications exist to using the deltoid, the anterolateral thigh also can be used.

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 age. See needle sizing chart below:

Age of Patient	Needle Gauge	Needle Length	Injection Site
5-10 years old	16-25 mm	*5/8-1 inch	Deltoid muscle
	25-32 mm	1-1.25 inches	Anterolateral thigh
11 years old	16-25 mm	*5/8-1 inch	Deltoid muscle
	25-38 mm	1-1.25 inches	Anterolateral thigh

* A 5/8 inch needle may be used in patients weighing less than 130lbs in the deltoid only if subcutaneous tissues are not bunched and injection is made at 90-degree angle.

f. **Multiple vaccinations:** If multiple vaccines are administered at a single visit, administer each injection in a different injection site following guidance in the CDC Interim Clinical Considerations. Injection sites should be separated by at least 1 inch.
   i. In patients who are 11 years old, the deltoid muscle can be used.
   ii. In patients who are 5-10 years old, if more than 2 vaccines are injected in the same limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site due to greater muscle mass.

g. **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.

12. **Timing:**

a. The second dose of Pfizer vaccine should be administered as close to the recommended interval as possible, but not earlier than recommended (21 days). However, individuals who receive the second dose up to 4 days before or at any time after the recommended date can be considered fully vaccinated.

13. **Documentation:**

a. **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.

b. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.

c. Provide vaccine recipients and their parent/ legal guardian with 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.

	d. Counsel when and how patient needs to schedule return appointment for second dose of COVID-19 vaccine, if applicable.
	Pfizer COVID-19 Vaccination Observation and Follow-Up **1. 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 for the following time periods: **a. 30 minutes:** i. Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine ii. Persons with a history of anaphylaxis due to any cause iii. People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to a viral vector vaccine-Janssen/Johnson and Johnson who receive a mRNA vaccine-COMIRNATY/Pfizer or Moderna) should be observed for 30 minutes following vaccination. iv. Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy b. **15 minutes**: All other persons 2. **Anaphylaxis Management**: 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. 3. **Syncope:** Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.
Special Circumstances	**1. People who were vaccinated outside the United States with a currently FDA-approved or FDA-authorized COVID-19 vaccine:** a. If they received all of the recommended doses of a single dose or 2-dose primary COVID-19 vaccine series, they are considered fully vaccinated. People who are moderately or severely immunocompromised and were vaccinated with a 2-dose mRNA COVID-19 vaccine primary series should receive an additional primary dose as detailed in Considerations for COVID-19 vaccination in moderately or severely immunocompromised people. People vaccinated with an FDA-approved or FDA-authorized COVID-19 vaccine outside the United States should also follow guidance for booster doses as detailed in Considerations for use of a COVID-19 booster dose.

b. If they received the first dose of a 2-dose mRNA COVID-19 vaccine series, they **do not need to restart** the vaccine series in the United States. They should receive the second dose as close to the recommended time as possible and are considered fully vaccinated upon completion of the 2-dose primary series. This also applies to people who were vaccinated in countries where only a single mRNA dose is administered; they are not considered fully vaccinated in the United States until after completion of the 2-dose series.

2. **People who completed all of the recommended doses of an WHO-EUL COVID-19 vaccine not approved or authorized by FDA, or people who completed a heterologous (mix and match) series composed of any combination of FDA-approved, FDA-authorized, or WHO-EUL COVID-19 vaccines**:
   a. Are considered fully vaccinated.
   b. Under the CDC's Emergency Use Instructions (EUI), moderately or severely immunocompromised people aged ≥12 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as detailed in Considerations for COVID-19 vaccination in moderately or severely immunocompromised people.
   c. Under the EUI, people aged ≥18 years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 6 months after completing their primary series, if they fall into one of the groups at increased risk for serious complications of COVID-19 or exposure to SARs-CoV-2 as detailed in Considerations for use of a COVID-19 vaccine booster dose.
3. **People who received only the first dose of a multidose WHO-EUL COVID-19 primary series that is not FDA-approved or FDA-authorized, or who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO**:
   a. Should be offered primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine (i.e., 2-dose mRNA series or single Janssen dose), with a minimum interval of at least 28 days since receipt of the last dose of a non-FDA-approved/authorized vaccine.
   b. After completion of primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine, these individuals are considered fully vaccinated.

***These persons require medical consultation**

4. **Participants in clinical trials within or outside the United States who received all of the recommended "active" (not placebo) primary series doses of a WHO-EUL COVID-19 vaccine that is not FDA-approved or FDA-authorized**

	or a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy (i.e., Novavax COVID-19 vaccine, Moderna COVID-19 vaccine in children aged 6-17 years): a. Are considered fully vaccinated. b. Unless they have received or plan to receive an additional dose through a clinical trial, under EUI, moderately or severely immunocompromised clinical trial participants aged ≥12 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as detailed in the Considerations for COVID-19 vaccination in moderately or severely immunocompromised people. c. Unless they have received or plan to receive a booster dose through a clinical trial, under EUI, clinical trial participants aged ≥18 years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 6 months after completing their primary series, if they fall into one of the groups at increased risk for serious complications of COVID-19 or exposure to SARs-CoV-2 as detailed in Considerations for use of a COVID-19 booster dose. d. If clinical trial participants have questions about whether they should receive an additional and/or booster dose outside of the clinical trial, they should consult with their healthcare provider. ***Clinical trial participants who did not receive all of the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series.
Follow-up	Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA: • Vaccine administration errors Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix A. Administration errors should be reported to VAERS • Serious adverse events • Cases of Multisystem Inflammatory Syndrome • Cases of COVID-19 that result in hospitalization or death Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.govexternal icon or by calling 1-800-822-7967.
Precautions for Use of this Order	1. Persons with a history of an immediate allergic reaction to any other vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or

	subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]). This includes people with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, even if it is unknown which component elicited the immediate allergic reaction. 2. Persons with a contraindication to one type of a COVID-19 vaccine (e.g., viral vector – Janssen/Johnson and Johnson) have a precaution to another (e.g., mRNA – COMIRNATY/Pfizer or Moderna) because of potential cross-reactive hypersensitivity. Consultation with an allergist-immunologist should be considered prior to vaccination and patients with this precaution should be vaccinated in a health care setting where allergic reactions can be immediately managed and under the supervision of a health care provider experienced in the management of severe allergic reactions. 3. Patient or parent/legal guardian on their behalf reports moderate to severe acute illness. 4. Patient or parent/legal guardian on their behalf who report 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. 5. Persons with a history of myocarditis or pericarditis. 6. Persons with a history of MIS-C.
Contraindications for Use of this Order	Do not administer the COVID-19 Vaccine to individuals with a history of: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine • Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine. See Appendix C: Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Approved or Authorized in the United States.
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 or parent/legal guardian on their behalf reports a precaution for the vaccine. 3. COVID-19 vaccine history cannot be determined or is not available. 4. Patients vaccinated with COVID-19 vaccines not authorized or approved in the US. 5. Patients vaccinated with active COVID-19 vaccine as part of a clinical trial. 6. Patient reports they are a HCT or CAR-T cell recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred. 7. 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. Note: Healthcare providers or health departments in the United States can request a consultation from CISA COVIDvax for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines.

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Revised November 19th, 2021

Approved by: _____ Date Signed: _11-19-2021_____

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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 236..