NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
for Administering Pfizer-BioNTech Covid-19 Vaccine (2024-2025 Formula) Children 6 months through 11 Years
August 30, 2024

Purpose: To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and to administer Pfizer-BioNTech (herein-after Pfizer vaccines) to persons who meet criteria set-forth by the Food and Drug Administration in accordance with FDA Emergency Use Authorization.

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 Session Law 2022-74, Sec. 9G.7.(a)-(e) and Session Law 2023-65, Sec. 9G.7 (to extend authorization through December 31, 2024) 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 per conditions of this order.

COVID-19 Vaccination	
Condition/ Situation:	All children **6-months through age 11 years** are eligible for Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula). Patients present requesting vaccination will receive, with appropriate written consent from an authorized caregiver: **Individuals <u>6 Months Through 4 Years</u> of Age by Pfizer-BioNTech COVID-19 Vaccination Status:** • **<u>Unvaccinated children</u>**: Administer 3 doses 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula). The first two doses are administered 3-8 weeks apart. The third dose is administered at least 8 weeks after the second dose. • **<u>Children who have received 1 dose of any Pfizer-BioNTech COVID-19 Vaccine</u>:** Administer 2 doses 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula). The first dose shall be given 3-8 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 vaccine; the second dose shall be given at least 8 weeks after dose 1. • **<u>Children who have received 2 doses of Pfizer-BioNTech COVID-19 Vaccine</u>:** Administer a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) at least 8 weeks after the last Pfizer-BioNTech COVID 19 vaccine. • **<u>Children who have received 3 or more doses of Pfizer-BioNTech COVID-19 Vaccine, NOT including at least 1 dose 2024-2025 Pfizer-BioNTech:</u>** Administer a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) at least 8 weeks after the last Pfizer-BioNTech COVID-19 vaccine.

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Individuals 6 Months Through 4 Years of Age by Pfizer-BioNTech COVID-19 Vaccination Status

Number of Previous Doses of Pfizer-BioNTech COVID-19 vaccine(s)[a]	Pfizer-BioNTech COVID-19 Vaccine, (2024-2025 Formula) Vial Cap and Label Border Color	Pfizer-BioNTech COVID-19 Vaccine (2042-2025 Formula) Dosing Regimen, Dose and Schedule[b]
0[c]	Yellow cap; yellow label	3 doses[d], 0.3 mL each Dose 1: Week 0 Dose 2: 3-8 weeks Dose 3: At least 8 weeks after Dose 2
1	Yellow cap; yellow label	2 doses[d], 0.3 mL each Dose 1: 3-8 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 vaccine[a] Dose 2: At least 8 weeks after Dose 1
2	Yellow cap; yellow label	Single dose, 0.3 mL ≥8 weeks after receipt of the last previous dose of Pfizer-BioNTech COVID-19 vaccine[a]
3 or more, NOT including at least 1 dose 2024-2025 Pfizer-BioNTech	Yellow cap; yellow label	Single dose, 0.3 mL ≥8 weeks after receipt of the last previous dose of Pfizer-BioNTech COVID-19 vaccine[a]

a. Previous doses of Pfizer-BioNTech COVID-19 vaccine(s) refers to doses of any prior Pfizer-BioNTech COVID-19 Vaccine that is no longer authorized for use in the United States.
b. For individuals with certain kinds of immunocompromise previously vaccinated with Pfizer-BioNTech COVID-19 vaccines, see below for dosing information.
c. Not previously vaccinated with any COVID-19 vaccine.
d. For individuals turning from 4 to 5 years of age during the vaccination series, who have received 1 or 2 doses of Pfizer-BioNTech COVID-19 Vaccine, administer a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) supplied in vials with blue caps and labels with blue borders, on or after the date the individual turns 5 years of age.

Individuals <u>5 Years Through 11 years</u> of Age, Regardless of COVID-19 Vaccination Status

- Administer a single dose 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula).

For individuals 5 years through 11 years of age previously vaccinated with any COVID-19 vaccine, administer the dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) at least 8 weeks after receipt of the last previous dose of COVID-19 vaccine.

Individuals 5 Years Through 11 years of Age Irrespective of COVID-19 Vaccination Status

Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Vial Cap and Label Border Color	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Dosing Regimen, Dose and Schedule[a]	a. For individuals with certain kinds of immunocompromise, see below for dosing information. b. Previous dose refers to a dose of any prior COVID-19 vaccine that is no longer authorized for use in the United States.
Blue cap; blue label	Single dose, 0.3 mL (If previously vaccinated, administer the dose at least 8 weeks after receipt of the last previous dose of COVID-19 vaccine[b])	

Immunocompromised individuals 6 months through 11 years of age:

- Individuals who are moderately to severely immunocompromised 6 months through 11 years of age should follow the schedule below. Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Please see the CDC clinical consideration here for more detail.

Moderately to Severely Immunocompromised Individuals 6 Months Through 4 Years of Age by Pfizer-BioNTech COVID-19

- **Unvaccinated individuals**: Administer three doses 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula). The interval between the first and second dose shall be 3 weeks, and the third dose should be given at least 8 weeks after the second dose.
- **Individuals who have received 1 dose of any Pfizer-BioNTech COVID-19 Vaccine**: Administer two doses 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), the first dose should be administered 3 weeks after the last dose, and the second dose shall be administered at least 8 weeks after the first.
- **Individuals who have received 2 doses of any Pfizer-BioNTech COVID-19**: Administer a single dose 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), at least 8 weeks after the last dose of Pfizer-BioNTech COVID-19 Vaccine.
- **Individuals who have received 3 or more doses any Pfizer-BioNTech Vaccine, NOT including at least 1 dose 2024-2025 Pfizer-BioNTech**: Administer a single dose 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), at least 8 weeks after the last dose of Pfizer-BioNTech COVID-19 Vaccine.

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Moderately to Severely Immunocompromised Individuals 6 Months Through 4 Years of Age by Pfizer-BioNTech COVID-19 Vaccination Status

Number of Previous Doses of Pfizer-BioNTech COVID-19 vaccine(s)[a]	Pfizer-BioNTech COVID-19 Vaccine, (2024-2025 Formula) Vial Cap and Label Border Color	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Dosing Regimen, Dose and Schedule[b]
0[c]	Yellow cap; yellow label	3 doses[d], 0.3 mL each Dose 1: Week 0 Dose 2: 3 weeks Dose 3: At least 8 weeks after Dose 2
1	Yellow cap; yellow label	2 doses[d], 0.3 mL each Dose 1: 3 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 vaccine[a] Dose 2: At least 8 weeks after Dose 1
2	Yellow cap; yellow label	Single dose, 0.3 mL At least 8 weeks after receipt of the last previous dose of Pfizer-BioNTech COVID-19 vaccine[a]
3 or more, NOT including at least 1 dose 2024-2025 Pfizer-BioNTech	Yellow cap; yellow label	Single dose, 0.3 mL ≥8 weeks after receipt of the last previous dose of Pfizer-BioNTech COVID-19 vaccine[a]

a. Previous doses of Pfizer-BioNTech COVID-19 vaccine(s) refers to doses of any prior Pfizer-BioNTech COVID-19 Vaccine that is no longer authorized for use in the United States.
b. For individuals with certain kinds of immunocompromise previously vaccinated with Pfizer-BioNTech COVID-19 vaccines, see below for dosing information.
c. Not previously vaccinated with any COVID-19 vaccine.
d. For individuals turning from 4 to 5 years of age during the vaccination series who have received 1 or 2 doses of Pfizer-BioNTech COVID-19 Vaccine, administer a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) supplied in vials with blue caps and labels with blue borders, on or after the date the individual turns 5 years of age.,.

Administration of additional doses as follows:

Children in this age group **may** receive 1 additional dose of 2024–2025 Pfizer-BioNTech COVID-19 vaccine at least 2 months after the last 2024–2025 Pfizer-BioNTech COVID-19 vaccine dose.

Further additional doses of 2024-2025 Pfizer-BioNTech COVID-19 vaccine may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. Such instances are beyond the scope of this standing order. Notify the medical provider for an assessment of the individual's clinical circumstances to determine the need for additional doses. Any further additional doses should be administered at least 2 months after the last 2024–2025 Pfizer-BioNTech COVID-19 vaccine dose.

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Moderately to Severely Immunocompromised Individuals 5 Years Through 11 Years of Age by Pfizer-BioNTech COVID-19 Vaccination Status

- **Unvaccinated individuals**: Administer three doses 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula). The interval between the first and second dose shall be 3 weeks, and the third dose should be given at least 4 weeks after the second dose.
- **Individuals who have received 1 dose of any Pfizer-BioNTech COVID-19 Vaccine,**: Administer two doses 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), the first dose should be administered 3 weeks after the last dose, and the second dose shall be administered at least 4 weeks after the first.
- **Individuals who have received 2 doses of any Pfizer-BioNTech COVID-19 Vaccine**: Administer a single dose 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), at least 4 weeks after the last dose of Pfizer-BioNTech COVID-19 Vaccine.
- **Individuals who have received 3 or more doses of any mRNA vaccine, NOT including at least 1 dose any 2024-2025 mRNA vaccine**: Administer a single dose 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), at least 8 weeks after the last dose of Pfizer-BioNTech COVID-19 Vaccine

Moderately to Severely Immunocompromised Individuals 5 Years Through 11 Years of Age by Pfizer-BioNTech COVID-19 Vaccination Status

Number of Previous Doses of Pfizer-BioNTech COVID-19 vaccine(s)[a]	Pfizer-BioNTech COVID-19 Vaccine, (2024-2025 Formula) Vial Cap and Label Border Color	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Dosing Regimen, Dose and Schedule[b]
0[c]	Blue cap; blue label	3 doses[d], 0.3 mL each Dose 1: Week 0 Dose 2: 3 weeks Dose 3: At least 4 weeks after Dose 2
1	Blue cap; blue label	2 doses[d], 0.3 mL each Dose 1: 3 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 vaccine[a] Dose 2: At least 4 weeks after Dose 1
2	Blue cap; blue label	Single dose, 0.3 mL At least 4 weeks after receipt of the last previous dose of Pfizer-BioNTech COVID-19 vaccine[a]

a. Previous doses of Pfizer-BioNTech COVID-19 vaccine(s) refers to doses of any prior Pfizer-BioNTech COVID-19 Vaccine that is no longer authorized for use in the United States..
b. For individuals with certain kinds of immunocompromise previously vaccinated with Pfizer-BioNTech COVID-19 vaccines, see below for dosing information.
c. Not previously vaccinated with any COVID-19 vaccine.
d. For individuals turning from 4 to 5 years of age during the vaccination series who have received 1 or 2 doses of Pfizer-BioNTech COVID-19 Vaccine, administer a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) supplied in vials with blue caps and labels with blue borders, on or after the date the individual turns 5 years of age

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	<table><tr><td>3 or more any mRNA</td><td>Blue cap; blue label</td><td>Single dose, 0.3 mL At least 8 weeks after receipt of the last dose</td><td></td></tr></table> Administration of additional doses as follows: Children in this age group **may** receive 1 additional dose of 2024–2025 mRNA COVID-19 vaccine (either Moderna or Pfizer-BioNTech, regardless of the manufacturer for the initial series) at least 2 months after the last 2024–2025 mRNA vaccine dose. Further additional mRNA dose(s) may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. Such instances are beyond the scope of this standing order. Notify the medical provider for an assessment of the individual's clinical circumstances to determine the need for additional doses. Any further additional doses should be administered at least 2 months after the last 2024–2025 mRNA vaccine dose/
Assessment Criteria	
Assessment Criteria	Patients **6 months through 11 years** of age shall be vaccinated with Pfizer BioNTech COVID-19 Vaccine (2024-2025 Formula) based on: 1. The conditions/situations of this order (see above). 2. The patient is presenting for first dose or subsequent dose/s of Pfizer and there is no history of previous COVID-19 vaccination using another vaccine brand. 3. The patient is presenting for a dose of Pfizer and the minimum interval between doses has been met (for further guidance see CDC Clinical Considerations COVID-19 vaccination schedule)
Plan of Care	
Actions	**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, which at a minimum shall include: 1. Review CDC Screening Checklist for Contraindications. 2. Fact Sheet for Recipients and Caregivers About Pfizer-BioNTech COVID-19 Vaccine for 6 Months through 11 Years of Age. Patient's authorized caregiver should consult primary care or other health care provider if they have questions regarding which COVID-19 vaccine they should receive. Refer to Interim Clinical Considerations for latest vaccine information.

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Pfizer COVID-19 Vaccine 6 months through 11 years:
Administration Procedures

- Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.
- Review the Fact Sheet for Healthcare Providers
- Pfizer COVID-19 vaccine for pediatric patients 6 months through 4 years of age is supplied in a **YELLOW CAP** formulation. No other formulation should be used in this population.
- Pfizer COVID-19 vaccine for pediatric patients 5 years through 11 years of age is supplied in a **BLUE CAP** formulation. No other formulation should be used in this population.
- The vaccinator shall be familiar with procedures for preparation, storage & handling of the Pfizer formulation they are using.
    a. Review the Fact Sheet for Healthcare Providers Administering Pfizer Vaccine for 6 Months Through 11 Years
- 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.
- 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.
- Review *Special Circumstances*, *Precautions*, *Contraindications*, and *Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine. More information is available at the Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States..
- Following the current *CDC Screening Checklist for Contraindications*, instruct patients accordingly or consult with overseeing provider.
- Individuals under 18 presenting for COVID vaccines under an Emergency Use Authorization must have written consent from the patient's authorized parent or caregiver prior to administration per agency policy and in accordance with NC General Statute. 90-21.13.
- 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.

Vaccine Product & Preparation:

- **Vaccine product:** Ensure the appropriate Pfizer formulation, based on age is selected.

Vial Cap and Vial Label Border Color	Age of Recipient	Vial Type	Dilution Required
Yellow	6 months through 4 years of age	Multiple dose	Yes
Blue	5 through 11 years of age	Single dose	No

- **Pfizer-BioNTech COVID-19 Vaccine vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.**
- **Preparation**:
  • If vials are frozen, they must be thawed prior to use [for thawing instructions, see How Supplied/Storage and Handling in section 16 of the Fact Sheet for Healthcare Providers Administering Pfizer Vaccine for 6 Months Through 11 Years.
  • Prior to use, mix by inverting thawed vial gently 10 times. **NEVER** shake the vials or vaccine.
  • Check the contents of the vaccine during preparation and right before use. The liquid should be clear to slightly opalescent with no visible particles. Do not use if liquid is discolored or if other particles are observed.

For multiple dose vials with yellow caps and labels with yellow borders:

- **Dilute** prior to use
  a. Add 1.1 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.
  b. Before removing the needle from the vial, equalize vial pressure by withdrawing air into the empty diluent syringe.
  c. Gently invert the vaccine vial 10 times to mix. Do not shake.
  d. Record the date and time of dilution on the vial label.
  e. Store at 2ºC to 25ºC (35ºF to 77ºF) and discard after 12 hours.
- After dilution, multiple-dose vials contain 3 doses of 0.3 mL each.
- If the amount of vaccine in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vaccine Vial Cap and Label Color	Amount of Sterile 0.9% Sodium Chloride Injection to Use as Diluent
Yellow caps and labels with yellow borders	1.1 mL

For single dose vials with blue caps and labels with blue borders:

a. **Do Not Dilute**.
b. Prior to withdrawing the dose, mix by inverting the vial gently 10 times. Do not shake.
c. Withdraw a single 0.3 mL dose.
d. Discard vial and any excess volume.

- **Dosing:**
  a. Administer a single 0.3 mL dose intramuscularly.
  b. Patients 6 months to 4 years old or moderately to severely immunocompromised shall receive all doses of COVID-19 vaccine from the same manufacturer unless one of the following exceptional situations are present: Same vaccine not available; Previous dose unknown, Person would otherwise not complete the vaccination series; Person starts but is unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication. In such instances, a different age-appropriate COVID-19 vaccine may be administered. If a dose of a different mRNA product is inadvertently administered, that dose is valid and does not need to be repeated. For further information see guidance on vaccine administration errors and deviations (CDC Interim Clinical Considerations for COVID-19 Vaccine Administration Appendix B).
  c. When a patient inadvertently receives an incorrect/inappropriate dose of COVID-19 vaccine, review Appendix B. Vaccine administration errors and deviations, and take action as directed.
- **Timing:**
  a. All recommended doses of Pfizer shall be administered as close to the recommended interval as possible. Doses that are given up to 4 days (the "grace period") before the recommended interval are valid and should not be repeated. The 4-day grace period shall not be used to prospectively schedule or administer a COVID-19 vaccine dose earlier than recommended.
  b. People should receive the recommended age-appropriate vaccine dosage based on their age on the day of vaccination. If a person moves from a younger age group to an older age group, the vaccinator should check the CDC Interim Clinical Considerations on Transitioning from a younger to older age group. Note: The FDA EUA provides that individuals turning from 4 to 5 years of age during the vaccination series who have received 1 or 2 doses of Pfizer-BioNTech COVID-19 Vaccine, administer a single

dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) supplied in vials with blue caps and labels with blue borders, on or after the date the individual turns 5 years of age

- **Administration:**
  a. **Route of Administration:** Use the chart below to determine appropriate needle gauge and site of intramuscular injection.

Age of Patient	Needle Gauge	Needle Length	Injection Site
Infants, 6-12 months	22-25-gauge	1 inch	Vastus lateralis muscle of the anterolateral thigh
Toddlers, 1-2 years	22-25-gauge	1-1.25 inch	Vastus lateralis muscle of the anterolateral thigh
	22-25-gauge	*5/8 inch-1 inch	Deltoid muscle
Children, 3-10 years	22-25-gauge	*5/8 inch-1 inch	Deltoid muscle
	22-25-gauge	1-1.25 inch	Vastus lateralis muscle of the anterolateral thigh
Children, 11 years	22-25-gauge	*5/8 inch-1 inch	Deltoid muscle

  b. **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. A patient's authorized caregiver may self-report the child's weight for needle selection purposes. *If a 5/8-inch needle is used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

- **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 on Simultaneous administration of COVID-19 vaccines with other vaccines .
- **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.
- **Documentation:**
  a. Patient or caregiver attestation to severe or moderate immunocompromise should be documented within the patient's electronic health record or other documenting system.
  b. **NCIR**: Document vaccine record in NCIR at the time of administration or by close of business day, after vaccine administration

	c. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic health record per agency policy. d. Provide a signed immunization record, at no charge, to the parent, guardian, or patient each time an immunization is given as specified in G.S. 130A-154 and when needed for schools, childcare facilities, colleges/universities, or wherever immunization records are required. e. Counsel when and how patient needs to schedule return appointment for subsequent doses of COVID-19 vaccine, if applicable.
	Pfizer COVID-19 Vaccine 6 months through 11 years: 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:** Individuals with the following medical histories: • Non-severe, immediate (onset within 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type • Diagnosed non-severe allergy to a component of the COVID-19 vaccine 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, particularly in adolescents. Procedures should be in place to avoid injury from fainting.
Special Circumstances	**People who received COVID-19 vaccination outside the United States:** Everyone ages 6 months and older vaccinated outside the U.S. should receive at least 1 dose of an updated (2024-2025 formula) mRNA COVID-19 vaccine regardless of past COVID-19 vaccination history (e.g., vaccine type(s), vaccine manufacturer(s), number of doses) unless they received an updated (2024-2025 formula) mRNA COVID-19 vaccine that is FDA-approved or FDA-authorized (i.e., Moderna or Pfizer-BioNTech), or prequalified or listed for emergency use by the World Health Organization (WHO). COVID-19 vaccines that are pre-qualified or listed for emergency use by WHO, but are not approved or authorized by FDA, have not been evaluated for efficacy or safety by CDC or ACIP. Children ages 6 months – 4 years and those who are moderately or severely immunocompromised may be recommended to receive more than 1 dose of an updated (2024-2025 formula) mRNA vaccine depending on vaccination history as noted within this standing order. See

	Appendix A in the Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for more information.
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: 1. Vaccine administration errors 2. Serious adverse events 3. Cases of myocarditis, cases of pericarditis, and cases of Multisystem Inflammatory Syndrome (MIS) 4. 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.gov or by calling 1-800-822-7967.
Precautions for Use of this Order	1. Persons with a history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine. * 2. Persons with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine. ** 3. Patient self-reported moderate to severe acute illness, with or without fever. 4. Persons with a history of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine. 5. Persons with a history of MIS-C or MIS-A. * 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. **Persons with an allergy-related precaution to one COVID-19 vaccine type may receive the alternative COVID-19 vaccine type in the usual vaccination setting. Vaccination with the same COVID-19 vaccine type may be considered on an individual basis; the same vaccine type should be administered in an appropriate setting and under the supervision of a health care provider experienced in the management of severe allergic reactions. An observation period of 30 minutes post-vaccination should be followed. Referral to an allergist-immunologist should be considered.
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 COVID-19 vaccine* See Table 3. Contraindications and precautions to COVID-19 vaccination:: Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Approved or Authorized in the United States *People with a contraindication to one COVID-19 vaccine type may receive the alternative COVID-19 vaccine type in the usual vaccine setting. Consultation with an allergist-

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	immunologist should be considered. See Considerations for people with a history of allergies or allergic reactions
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. 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. Patient reports they are an HCT, CAR-T cell, or B-cell-depleting therapy recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred. 6. 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 COVID 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.

Approved by: ____ CTilson _____ Date Signed: __8-30-2024_____

Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

This standing order is effective immediately and authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Session Law 2022-74, Sec. 9G.7.(a)-(e). and Session Law 2023-65, Sec. 9G.7 (to extend authorization through December 31, 2024) 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 per conditions of this order.