NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
MODERNA COVID-19 VACCINE (2023-2024 FORMULA), FOR INDIVIDUALS 6 MONTHS THROUGH 11 YEARS OF AGE
January 22, 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 Moderna COVID-19 vaccine 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.

Note: On September 11, 2023, the FDA rescinded the EUA for all mRNA bivalent COVID-19 vaccine products. Consistent with the totality of the evidence and input from the FDA's expert advisors, the FDA authorized Moderna COVID-19 Vaccine (2023-2024 Formula) in single dose vials with dark blue caps and labels with a green box (each 0.25 mL dose containing a total of 25 mcg of mRNA) for use in individuals 6 months through 11 years of age. The vaccine has been updated to include a monovalent (single component that corresponds to the Omicron variant XBB.1.5.)

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COVID-19 Vaccination

Condition/Situation:

Patients present requesting vaccination will receive, with appropriate written consent from an authorized caregiver:

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

- **Unvaccinated individuals**: Administer two doses 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula). The second dose shall be administered 4-8 weeks after the first.
- **Individuals who have received 1 dose of Moderna COVID-19 Vaccine, including Moderna COVID-19 Vaccine, Bivalent**: Administer a single dose 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula), 4-8 weeks after the dose of Moderna COVID-19 Vaccine.
- **Individuals who have received ≥2 doses of Moderna COVID-19 Vaccine, including Moderna COVID-19 Vaccine, Bivalent**: Administer a single dose 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula), at least 8 weeks after the last dose of Moderna COVID-19 Vaccine.

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

Number of Previous Doses of Moderna COVID-19 Vaccine(s)[a]	Moderna COVID-19 Vaccine (2023-2024 Formula) Dosing Regimen, Dose and Schedule[b]
0[c]	2 doses,[d] 0.25 mL each Dose 1: week 0 Dose 2: 4-8 weeks
1	Single Dose, 0.25 mL Four to eight weeks after receipt of a previous dose of Moderna COVID-19 vaccine[a]
≥2	Single dose, 0.25 mL At least 8 weeks after receipt of the last previous dose of Moderna COVID-19 vaccine[a]

[a] Previous dose(s) of Moderna COVID-19 vaccine(s) refers to Moderna COVID-19 Vaccine (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). These vaccines are no longer authorized for use in the United States.
[b] For individuals with certain kinds of immunocompromise previously vaccinated with a Moderna COVID-19 vaccine, see below for dosing information.
[c] Not previously vaccinated with any COVID-19 vaccine.
[d] Individuals turning from 4 years to 5 years of age during the vaccination series should receive both doses with Moderna COVID-19 Vaccine (2023- 2024 Formula).

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Individuals 5 Years Through 11 Years of Age, Regardless of COVID-19 Vaccination Status

- Administer a single dose 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula). If previously vaccinated with any COVID-19 vaccine administer at least 8 weeks after receipt of the last previous dose of COVID-19 vaccine.

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

Moderna COVID-19 Vaccine (2023-2024 Formula) Dosing Regimen, Dose and Schedule[a]	[a] For individuals with certain kinds of immunocompromise, see below for further dosing information. [b] COVID-19 vaccine refers to the monovalent COVID-19 vaccines that encode the spike protein of the original SARS-CoV-2 and the bivalent COVID-19 vaccines encoding the spike protein of original SARS-CoV-2 and of the Omicron variant lineages BA.4 and BA.5 that are no longer authorized for use in the United States.
Single dose, 0.25 mL If previously vaccinated, at least 8 weeks after receipt of the last previous dose of COVID-19 vaccine[a,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 Moderna COVID-19 Vaccination Status

- **Unvaccinated individuals**: Administer three doses 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula). The interval between the first and second dose shall be administered 4 weeks, and the third dose should be given at least 4 weeks after the second dose.
- **Individuals who have received 1 dose of Moderna COVID-19 Vaccine, including Moderna COVID-19 Vaccine, Bivalent**: Administer two doses 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula), the first dose should be administered 4 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 Moderna COVID-19 Vaccine, including Moderna COVID-19 Vaccine, Bivalent**: Administer a single dose 0.25 mL of Moderna

COVID-19 Vaccine (2023-2024 Formula), at least 4 weeks after the last dose of Moderna COVID-19 Vaccine.

- **Individuals who have received ≥3 doses of Moderna COVID-19 Vaccine, including Moderna COVID-19 Vaccine, Bivalent**: Administer a single dose 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula), at least 8 weeks after the last dose of Moderna COVID-19 Vaccine.

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

Number of Previous Doses of Moderna COVID-19 Vaccine(s)[a]	Moderna COVID-19 Vaccine (2023-2024 Formula) Dosing Regimen, Dose and Schedule[b]
0[c]	3 doses,[d] 0.25 mL each Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: at least 4 weeks
1	2 doses,[d] 0.25 mL each Dose 1: 4 weeks after last dose Dose 1 and Dose 2: at least 4 weeks
2	Single dose, 0.25 mL At least 4 weeks after receipt of the last previous dose of Moderna COVID-19 vaccine[a]
≥3	Single dose, 0.25 mL At least 8 weeks after receipt of the last previous dose of Moderna COVID-19 vaccine[a]

[a] Previous dose(s) of Moderna COVID-19 vaccine(s) refers to Moderna COVID-19 Vaccine (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). These vaccines are no longer authorized for use in the United States.
[b] For individuals with certain kinds of immunocompromise previously vaccinated with a Moderna COVID-19 vaccine, see below for dosing information.
[c] Not previously vaccinated with any COVID-19 vaccine.
[d] Individuals turning from 4 years to 5 years of age during the vaccination series should receive both doses with Moderna COVID-19 Vaccine (2023- 2024 Formula).

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

- **Unvaccinated individuals**: Administer three doses 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula). The interval between the first and second dose shall be administered 4 weeks, and the third dose should be given at least 4 weeks after the second dose.
- **Individuals who have received 1 dose of Moderna COVID-19 Vaccine, including Moderna COVID-19 Vaccine, Bivalent**: Administer two doses 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula), the first dose should be administered 4 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 Moderna COVID-19 Vaccine, including Moderna COVID-19 Vaccine, Bivalent**: Administer a single dose 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula), at least 4 weeks after the last dose of Moderna COVID-19 Vaccine.
- **Individuals who have received ≥3 doses of any mRNA COVID-19 Vaccine:** Administer a single dose 0.25 mL of Moderna COVID-19 Vaccine (2023-2024 Formula), at least 8 weeks after the last dose of Moderna COVID-19 Vaccine.

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

Number of Previous Doses of Moderna COVID-19 Vaccine(s)[a]	Moderna COVID-19 Vaccine (2023-2024 Formula) Dosing Regimen, Dose and Schedule[b]
0[c]	3 doses,[d] 0.25 mL each Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: at least 4 weeks
1	2 doses,[d] 0.25 mL each Dose 1: 4 weeks after last dose Dose 1 and Dose 2: at least 4 weeks
2	Single dose, 0.25 mL At least 4 weeks after receipt of the last previous dose of Moderna COVID-19 vaccine[a]
≥3	Single dose, 0.25 mL At least 8 weeks after receipt of the last previous dose of Moderna COVID-19 vaccine[a]

[a] Previous dose(s) of Moderna COVID-19 vaccine(s) refers to Moderna COVID-19 Vaccine (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). These vaccines are no longer authorized for use in the United States.
[b] For individuals with certain kinds of immunocompromise previously vaccinated with a Moderna COVID-19 vaccine, see below for dosing information.
[c] Not previously vaccinated with any COVID-19 vaccine.
[d] Individuals turning from 4 years to 5 years of age during the vaccination series should receive both doses with Moderna COVID-19 Vaccine (2023- 2024 Formula).

Condition	In addition to criteria above, the following conditions regarding consent must be met: • Patients (recipients of vaccine) 6 months through 11 years of age presenting for vaccination whose parent or legal guardian has provided **written** consent to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status**.**
Assessment Criteria	
Assessment Criteria	Patients shall be vaccinated with Moderna COVID-19 Vaccine (2023-2024 Formula), 6 mos.-11 years based on: 1. The conditions/situations of this order (see above).

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Plan of Care	
Actions	**Patient Education and Data Collection** Prior to patients receiving the COVID-19 booster 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 for Moderna COVID-19 Pediatric vaccine 6 months through 11-years
	Moderna COVID-19 Vaccine, 6 months through 4-years **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 sheet for healthcare providers: Fact Sheet for Healthcare Providers Administering Moderna Vaccine for 6 Months Through 11 Years 3. Moderna COVID-19 Vaccine (2023-2024 Formula), is supplied in a single dose of 0.25 mL with a dark blue cap and a green label 4. The vaccinator shall be familiar with procedures for preparation, storage & handling of the Moderna formulation they are using. 5. 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. 6. 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. 7. Review *Special Circumstances*, *Precautions*, *Contraindications*, *and Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine (2023-2024 Formula). 8. Following the current *CDC Screening Checklist for Contraindications*, instruct patients accordingly or consult with overseeing provider. 9. 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. 10. 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.

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Vaccine Product & Preparation:

- Moderna COVID-19 Vaccine (2023-2024 Formula) is a suspension for intramuscular injection
- **Vaccine Preparation**: Follow manufacturer's guidance for storing/handling vaccine. This product **does not** require diluent.
- **Dosing:**
  a. Administer a single 0.25 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 Moderna 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, they should receive the vaccine product and dosage for the older age group for all subsequent doses according to CDC's Interim Clinical Considerations on Transitioning from a younger to older age group.
- **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. 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
- **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.

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	Moderna 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 (2023-2024 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 (2023-2024 formula) mRNA COVID-19 vaccine that is FDA approved or FDA authorized or listed for emergency use by the World Health Organization. COVID-19 vaccines that are 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 (2023-2024 formula) mRNA vaccine depending on vaccination history as noted within this standing order.
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.

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	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-immunologist should be considered. See Considerations for people with a history of allergies or allergic reactions.

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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: _1-22-2024_____
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.