NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
Moderna COVID-19 Vaccine Administration for 6 months through 5 years
July 25, 2022

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 2022-72, Sec. 9G.7.(a)-(e) 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.

<table>
<tr><th colspan="2">COVID-19 Vaccination</th></tr>
<tr><td>Condition/Situation: Patients who are NOT immunocompromised (most patients)</td><td>Patients who are NOT immune compromised and present requesting vaccination will receive, with appropriate written consent from an authorized caregiver:

➢ <u>Moderna COVID-19 vaccine 6 months through 5years Primary 2-Dose Series for non-immunocompromised:</u>
• 6 months through 5 years of age presenting for a 2-dose primary series vaccination.

<u>Dose Intervals for Moderna 6 months through 5 years Primary Series in Non-immunocompromised:</u>
Dose 1 to Dose 2 | 4-8 weeks
*See "Patient Education and Data Collection" and Considerations for intervals for mRNA COVID-19 vaccine primary series for information on counseling patients on the interval between dose 1 and dose 2. See Table 2 vaccination schedule in CDC Interim Clinical Considerations.
<u>Booster Dose for Moderna 6 months through 5 years Non-immunocompromised:</u>
• Boosters are NOT authorized or recommended at this time for any person 6 months through 5 years who received a Moderna primary series.</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Condition/Situation: Moderately to Severely Immunocompromised Patients</td><td>Patients who self-attest, or whose authorized caregiver attests, to the patient being moderately to severely immunocompromised and present requesting vaccination with appropriate written consent will receive:

➢ <u>Moderna COVID-19 Vaccine 6 months through 5 years Primary 3-Dose Series for Immunocompromised:</u>
• 6 months through 5 years of age presenting for a 3-dose primary series vaccination.
<u>Dose Intervals for Moderna 6 months through 5 years Primary Series in Moderate to Severely immunocompromised:</u></td></tr>
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	Dose 1 to Dose 2 | 4 weeks **Dose 2 to Dose 3** | At least 4 weeks See Table 3. COVID-19 vaccination schedule for people who are moderately or severely immunocompromised **Booster Dose for Immunocompromised:** • Boosters are NOT authorized or recommended at this time for any person 6 months through 5 years who received a Moderna primary series.
Condition	In addition to criteria above, the following conditions regarding consent must be met: • Patients (recipients of vaccine) 6 months through 5 years of age presenting for a 1st, 2nd or 3rd primary series dose and whose parent or legal guardian has provided **written** consent to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status**.** (See table below for clarification).
Assessment Criteria	
Assessment Criteria	Patients shall be vaccinated with Moderna COVID-19 Vaccine based on: 1. The conditions/situations of this order (see above). 2. If patient is presenting for first dose of Moderna: ensure there is no history of previous COVID-19 vaccination, regardless of brand. 3. If patient is presenting for second or third dose of primary series of Moderna, ensure that the minimum interval between doses has been met (see appropriate Tables above or CDC Clinical Considerations Vaccination Schedule for further guidance). 4. Patients 6 months to 5 years old who received Moderna primary series are NOT currently recommended to receive a booster.
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 Pre-Vaccination Checklist for COVID-19 Vaccine 2. Provide education on optimal vaccine intervals so that the patient can choose when they would like to return for their second shot. 3. Fact Sheet for Recipients and Caregivers for Moderna COVID-19 vaccine 6 months through 5-years 4. 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 for primary and booster doses. Refer to Interim Clinical Considerations for latest vaccine information. 5. V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe.

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Moderna COVID-19 vaccine 6 months through 5-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 Sheets for Healthcare Providers Administering Moderna COVID-19 vaccine 6 months through 5years. Moderna COVID-19 Vaccine supplied in multiple-dose vials with a dark blue cap and a label with a magenta border intended for use in individuals 6 months through 5 years of age should not be used in individuals 6 years of age and older because of the potential for vaccine administration errors, including dosing errors.
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. For additional information see COVID-19 Vaccines for Special Populations.
6. Following the current *CDC Pre-Vaccination Checklist for COVID-19 Vaccines*, instruct patients accordingly or consult with overseeing provider.
    a. The pre-vaccination checklist shall be followed with the following exception: COVID-19 vaccination should ***not*** be deferred in patients who received monoclonal antibody treatment or convalescent plasma. Patients ***should*** delay taking EVUSHELD for two weeks after COVID-19 vaccination.
7. Individuals under 18 presenting for COVID vaccine 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.
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.

Vaccine Product & Preparation:

1. **Vaccine Preparation**: Follow manufacturer's guidance for storing/handling mixed vaccine. Refer to: Moderna COVID-19 Vaccine Preparation and Administration

Summary. In general, the same mRNA vaccine product should be used for all doses in the primary series. See CDC guidance for exceptional situations.

2. **Dosing:** Administer **25 mcg** Moderna COVID-19 vaccine for:

Dosing for Moderna COVID-19 vaccine 6 months through 5-years	
Primary series: Dose 1, 2 or 3rd	25 mcg, Moderna **BLUE cap** with **magenta border**: 0.25 mL IM injection

*****Patients shall receive the same brand of COVID-19 vaccine for their entire primary series. If a dose of a different mRNA product is inadvertently administered, that dose is valid and does not need to be repeated.

*When a patient inadvertently receives an incorrect or inappropriate dose of COVID-19 vaccine, review Interim Clinical Considerations, Appendix C for COVID-19 vaccine errors and deviations, and take action as directed.

3. **Timing:**
   a. All recommended doses of Moderna COVID-19 vaccine shall be administered as close to the recommended interval as possible. More information on timing is available in the CDC Interim Clinical Considerations guidance. 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. (See interval tables above)
   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 during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine product and dosage for the older age group for all subsequent doses. For specific guidance see CDC Interim Clinical Considerations on Transitioning from a younger to older age group.
   c. Timing (interval) of booster doses is determined by brand of COVID-19 Vaccine administered for Primary Series
   (Also, see CDC Clinical Considerations for further guidance.
4. See Interim Clinical Considerations, Appendix C for information on COVID-19 vaccine errors and administration deviations.
5. **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	25 mm	1 inch	Anterolateral thigh
Toddlers, 1-2 years	25-32 mm	1-1.25 inch	Anterolateral thigh
	16-25 mm	*5/8 inch-1 inch	Deltoid muscle
Children, 3-5 years	16-25 mm	*5/8 inch-1 inch	Deltoid muscle
	25-32 mm	1-1.25 inch	Anterolateral thigh

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**).

6. **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 Coadministration of COVID-19 vaccines with other vaccines.
7. **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.
8. **Documentation:**
    a. Patient self-attestation to severe or moderate immunocompromise should be done within the notes section in CVMS or comparable section of an EHR or other documenting systems.
    b. **CVMS/NCIR**: Document vaccine record in CVMS or NCIR **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 or NCIR. Determining whether to document in CVMS versus NCIR should occur according to site protocol; it is not necessary to document in both systems.
    c. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.
    d. Provide recipient's authorized caregiver 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.
    e. Counsel when and how patient needs to schedule return appointment for follow up of COVID-19 vaccine, if applicable.

Moderna COVID-19 vaccine 6 months through 5-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: 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, 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:** The recommendations for people vaccinated outside of the United States depend on the vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received. Refer to Interim Clinical Considerations, Appendix A (People who received COVID-19 vaccine outside the United States) and take action/ consult with medical provider as directed. • **Participants in clinical trials within or outside the United States** who received all the recommended primary series doses of a WHO-EUL COVID-19 vaccine (i.e., not placebo) that is not FDA-approved or FDA-authorized are considered fully vaccinated. In addition, individuals who received 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 are considered fully vaccinated. *These persons require medical consultation. • Clinical trial participants 5 years and older who received a Pfizer primary series, (including moderately or severely immunocompromised people) **should** receive a

	single booster dose of Pfizer-BioNTech COVID-19, unless they have received or plan to receive a booster dose through a clinical trial. • 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 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. For more information, refer to Interim Clinical Considerations, Appendix B (People who received COVID-19 vaccine as part of a clinical Trial)
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 C. Vaccine administration errors and deviations. 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 self-reported moderate to severe acute illness. 4. 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.

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	5. Persons with a history of myocarditis or pericarditis. 6. Persons with a history of MIS-C or MIS-A.
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 A: 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 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 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: _7-25-22_____
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 2022-72, Sec. 9G.7.(a)-(e) 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.