NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
For Moderna mRNA COVID-19 Vaccine Administration for 6 years through 11 years of age
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></td><td>For an up-to-date vaccination schedule for primary, additional (for moderately or severely immunocompromised persons), and booster doses of authorized COVID-19 Vaccines for 6 months and older is available here.</td></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 6 through 11 years Primary 2-Dose Series for Non-immunocompromised:</u>
6 through 11 years of age who are not immune compromised, presenting for a 2-dose primary series vaccination and with written consent from an authorized caregiver.

<u>Intervals for Doses in Moderna 6 through 11 years Primary Series for Non-immunocompromised:</u>
<table><tr><td>Dose 1 to Dose 2</td><td>4 – 8 weeks</td></tr></table>*See "Patient Education and Data Collection" , Considerations for intervals for mRNA COVID-19 vaccine primary series for information on counseling patients on the interval between dose 1 and dose 2.

<u>Booster Dose</u>
Boosters are NOT authorized or recommended at this time for any persons 6 months through 17 years who have completed the Moderna COVID-19 primary series.</td></tr>
<tr><td>Condition/Situation: Moderately to Severely Immunocompromised Patients</td><td>Patients 6 through 11 years of age who self-attest, or whose authorized caregiver attests, to being moderately to severely immunocompromised and present requesting vaccination will receive, with appropriate written consent:<table><tr><th colspan="2">Intervals for Doses in the Moderna 6 through 11 years) Primary Series: Moderately to Severely Immunocompromised People</th></tr><tr><td>Dose 1 to Dose 2 of Moderna</td><td>4 weeks</td></tr><tr><td>Dose 2 to Dose 3 Moderna</td><td>At least 4 weeks*</td></tr></table></td></tr>
</table>

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	*See "Patient Education and Data Collection" and considerations for intervals for mRNA COVID-19 vaccine primary series for information on counselling patients on the interval between doses. **Booster Dose for Immunocompromised** Boosters are NOT authorized or recommended at this time for any persons 6 mos through 17 years who have completed the Moderna COVID-19 primary series.
Condition	In addition to criteria above, the following conditions regarding consent must be met: • Patients (recipients of vaccine) 6 through 11 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 (immunocompromised) dose of primary series of Moderna, ensure that the minimum interval between doses has been met (see appropriate Tables above or CDC Clinical Considerations for further guidance). 4. Boosters are NOT authorized or recommended at this time for any persons 6 months through 17 years who have completed the Moderna COVID-19 primary series.
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 through 11 years COVID-19 Vaccine 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.

Moderna 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 Moderna Fact Sheets for Healthcare Providers Administering Moderna COVID-19 vaccine pediatric formulation for ages 6 through 11 years.
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:

Moderna currently has one available presentation of COVID-19 Vaccine authorized for primary series doses to individuals 6 years through 11 years of age. It is the **"Booster Doses Only"** formulation - vial and label shown below.

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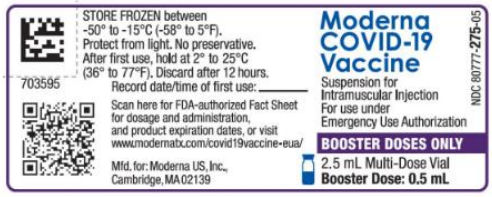

This presentation is supplied in a multi-dose vial with a **dark blue cap** and **purple border.** Note that **c**artons and vial labels state **"BOOSTER DOSES ONLY"**, however, this presentation can be used to provide **Primary Series doses ONLY**, to individuals 6 years through 11 years of age. **It is not authorized for use as a booster dose in those 6 through 11 years of age. Consult Appendix C. Vaccine administration errors and deviations for more information.

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:**

Moderna (6 through 11 years) COVID-19 Vaccine Dosing	
Primary series: **Dose 1, 2, or 3**	**BLUE** top with **Purple** border: 0.5 mL 50mcg 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. If this occurs, consult Appendix C. Vaccine administration errors and deviations, and take action as directed.

3. **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. (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.

4. See Appendix C. Vaccine administration errors and deviations for information on COVID-19 vaccine errors and administration deviations. **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
Children, 3-10 years	22-25	5/8 –1 inch (16–25 mm)	Deltoid muscle
	22-25	1–1.25 inches (25–32 mm)	Anterolateral thigh
Children 11-18 years	16-25 mm	*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**).

5. **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.
6. **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.
7. **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 through 11 years Primary Series: 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 CDC Interim Considerations - Routine observation periods following COVID-19 vaccination and Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination 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. See Early Recognition and Management of 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 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 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) • 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 A (People who received COVID-19 vaccine as part of a clinical Trial) outside the United States)
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. Click to find Information on how to submit a report to VAERS or call 1-800-822-7967.

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Precautions for Use of this Order	Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine. See CDC Contraindications and Precautions for COVID-19 Vaccination 1. Immediate allergic reaction‡ to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]) a. This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown 2. Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine 3. Contraindication to one type of COVID-19 vaccine (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen) 4. Moderate to severe acute illness, with or without fever 5. History of MIS-C or MIS-A » History of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine
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 Contraindications and Precautions for COVID-19 Vaccination and Appendix C. Vaccine administration errors and deviations
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.

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Approved by: _____ 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.