NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
for Moderna mRNA COVID-19 Vaccine Administration
Revised November 19th, 2021

Purpose: To meet the goal of administering FDA-Emergency Use Authorization Moderna COVID-19 vaccine and to protect and save lives in the COVID-19 pandemic by vaccinating persons who meet the criteria set-forth by the Food and Drug Administration.

Policy: This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Executive Order 236, or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA through an Emergency Use Authorization (EUA) per conditions of this order.

COVID-19 Vaccination	
Condition or Situation	Patients 18 years and older who present requesting and have legal capacity to consent to first or second dose of Primary Series, third dose of Primary Series or Booster dose of Moderna COVID-19 Vaccine, will be vaccinated under the FDA-EUA status. **Primary 2-Dose Series administered under the following conditions:** • 18 years and older, who present requesting Moderna vaccine for the first or second dose of their 2-dose primary series. **3rd Dose Primary Series administered under the following conditions:** • 18 years and older, who self attest to: ○ Being moderately to severely immunocompromised, who present at least 28 days after their second dose of Moderna vaccine and are requesting the third dose of their three-dose primary series. **Moderna Booster Dose Situations** Persons who completed series of COVID-19 vaccination with Janssen: Anyone 18 years and older, who received primary COVID-19 vaccination with Janssen at least 2 months ago. Persons who completed series of COVID-19 Vaccination with Moderna or Pfizer/COMIRNATY: • Anyone 18 years of age and older, who present requesting a booster dose at least 6 months after completion of their primary series. • Regarding booster doses: patients 18 years of age and older can receive any brand of COVID-19 vaccine for their booster shot, upon their request.
Assessment Criteria	
Assessment Criteria	Patients shall be vaccinated with Moderna COVID-19 Vaccine based on: 1. the conditions of this order 2. If patient is presenting for first dose of Moderna: ensure there is no history of previous COVID-19 vaccination, regardless of brand.

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3. **If patient is presenting for second, third, or booster dose of Moderna:** ensure that the minimum interval between doses has been met. **Timing (interval) of booster dose is determined by what brand of COVID-19 Vaccine was administered for Primary Series**.

See the below chart for minimum intervals between doses:

Dose 1 to Dose 2 of Moderna	*Dose 2 to Dose 3 of Moderna	** +End of 2 OR 3-dose mRNA series (Moderna or Pfizer/ COMIRNATY) to booster dose of Moderna	Single dose series Janssen to booster dose of Moderna
28 days	28 days	6 months	2 months

***see the section above on third doses to determine if a three-dose primary series is appropriate.

**see the section above on booster doses to determine if a booster dose is appropriate after completion of the Moderna, Pfizer/COMIRNATY or Janssen primary series.

+ Moderately and severely immunocompromised people aged ≥18 years who completed an mRNA COVID-19 vaccine primary series and received an additional mRNA vaccine dose **may** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose. In such situations, people who are moderately and severely immunocompromised **may receive a total of four COVID-19 vaccine doses**.

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. Where, how, and when to obtain follow up COVID-19 vaccinations.
2. CDC Pre-Vaccination Checklist for COVID-19 Vaccine
3. Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine
4. Patient should consult primary care or other health care provider if they have questions regarding which COVID-19 vaccine they should receive for a booster dose. 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 Vaccine (Vaccination Providers) for Moderna.

3. Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA COVID-19 vaccine.
4. A medical provider, defined as a physician, physician assistant, nurse practitioner, or a pharmacist authorized to order COVID-19 vaccines by the PREP Act must be accessible to provide medical supervision of the vaccination site/service, to assess and evaluate individuals who present with contraindications or precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.
5. Review *Special Circumstances*, *Precautions*, *Contraindications*, *and Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine.
6. Following the current *CDC Pre-Vaccination Checklist for COVID-19 Vaccines*. instruct patients accordingly or consult with overseeing provider.
7. Consent must be obtained from the patient or the patient's legally authorized representative prior to vaccine 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.
9. **Vaccine Administration:**
    a. **Preparation**: Mix, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine. Refer to: Moderna COVID-19 Vaccine Preparation and Administration Summary
    b. **Vaccine Product and Dosing:**
        i. **First Dose of Moderna: Administer 0.5 mL Moderna COVID-19** Vaccine. This vaccine is administered in a 2 -dose series. Second doses should be scheduled at least 28 days after first dose.
        ii. **Second dose**: **Administer 0.5 mL Moderna COVID-19** Vaccine. Patients shall receive the second COVID-19 vaccine dose of the same brand as first administered. If two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. See CDC Interim Clinical Considerations for Use of COVID-19 Vaccines ("Vaccine Administration" and "Interchangeability of COVID-19 vaccine products" headers).
        iii. **Third dose of Moderna of mRNA COVID-19 vaccine for moderately to severely immunocompromised people: Administer 0.5 mL Moderna COVID-19** Vaccine. Patients who self-attest to being moderately to severely immunocompromised

and have completed a 2-dose mRNA COVID-19 vaccine series can receive a third mRNA COVID-19 vaccine dose of the same product as the primary vaccine series. If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered.

iv. **Booster dose of Moderna**: **Administer 0.25ml Moderna COVID-19 Vaccine**. Single booster dose should be administered to individuals 18 years of age and older no sooner than six 6 months after primary 2-dose series of Moderna or Pfizer/COMIRNATY. Single booster dose of Moderna COVID-19 Vaccine should be administered to individuals 18 years of age and older no sooner than two 2 months after primary vaccination with Janssen COVID-19 Vaccine. (See chart below for dosing)

Moderna COVID-19 Vaccine Dosing	
Primary series: Dose 1, 2 and *3	0.5ml injection
**Booster Dose	**0.25 ml injection

v. + Moderately and severely immunocompromised people aged ≥18 years who completed an mRNA COVID-19 vaccine primary series and received an additional mRNA vaccine dose **may** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose. In such situations, people who are moderately and severely immunocompromised may receive a total of four COVID-19 vaccine doses.

c. **<u>Route of Administration</u>:** Administer Moderna vaccine via intramuscular (IM) injection in the deltoid muscle of the arm to patients 18 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used.

d. **<u>Needle Gauge</u>**: 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. Patients may self-report their weight for needle selection purposes. See needle sizing chart below:

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site*
Female or male fewer than 130 lbs.	22–25	5/8 ** –1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm

Female 152–200 lbs.	22–25	1-11/2"	Deltoid muscle of arm
Male 153–260 lbs.	22–25	1-11/2"	Deltoid muscle of arm
Female 200+ lbs.	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	11/2"	Deltoid muscle of arm

* Alternatively, the anterolateral thigh also can be used.

** Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

e. **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

f. **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.

g. **Timing**:

i. **Second dose** of Moderna COVID-19 Vaccine should be administered as close to the recommended interval (28 days) as possible, but not earlier than recommended. However, individuals who receive the second dose up to 4 days before or at any time after the recommended date can be considered fully vaccinated.

ii. **Third dose** of Moderna COVID-19 Vaccine for moderately and severely immunocompromised people shall be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine series. Third doses administered at least 24 days after completion of the primary series are considered valid and do not need to be repeated.

iii. **Booster dose** of Moderna COVID-19 Vaccine (per conditions above). should be administered at least 6 months after primary vaccination of Moderna or Pfizer/COMIRNATY vaccine or at least 2 months after Janssen single dose vaccination. There is a 4-day grace period for booster doses; booster doses administer 4 days before the required interval are considered valid and do not need to be repeated.

10. **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**: Document vaccine record in CVMS **within 24 hours** after vaccine administration per system guidelines found at: https://immunize.nc.gov/providers/covid-19training.htm. If vaccine is documented in the EHR within 24 hours, providers have **no more than 72 hours** from administration to also enter data in CVMS.

	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 vaccine recipients and/or their legal representative 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 Vaccination Observation and Follow-Up 1. **Post-vaccination Observation**: Nurses, EMS, or other individuals who are trained and supervised by clinical staff shall observe patients post-vaccination for immediate allergic reactions according to the Centers for Disease Control and Prevention guidelines for the following time periods: a. 30 minutes: i. Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine ii. Persons with a history of anaphylaxis due to any cause iii. People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to a viral vector vaccine-Janssen/Johnson and Johnson who receive a mRNA vaccine-COMIRNATY/Pfizer or Moderna) should be observed for 30 minutes following vaccination. iv. Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy b. 15 minutes: All other persons 2. **Anaphylaxis Management**: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis. 3. **Syncope:** Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.
Special Circumstances	1. **People who were vaccinated outside the United States with a currently FDA-approved or FDA-authorized COVID-19 vaccine:** a. If they received all of the recommended doses of a single dose or 2-dose primary COVID-19 vaccine series, they are considered fully vaccinated. People who are moderately or severely immunocompromised and were

vaccinated with a 2-dose mRNA COVID-19 vaccine primary series should receive an additional primary dose as detailed in Considerations for COVID-19 vaccination in moderately or severely immunocompromised people. People vaccinated with an FDA-approved or FDA-authorized COVID-19 vaccine outside the United States should also follow guidance for booster doses as detailed in Considerations for use of a COVID-19 booster dose.

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

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

	~~b.~~ After completion of primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine, these individuals are considered fully vaccinated. ***These persons require medical consultation** **4. Participants in clinical trials within or outside the United States who received all of the recommended "active" (not placebo) primary series doses of a WHO-EUL COVID-19 vaccine that is not FDA-approved or FDA-authorized or a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy (e.g., Novavax COVID-19 vaccine, Moderna COVID-19 vaccine in children aged 6-17 years)**: a. Are considered fully vaccinated. b. Unless they have received or plan to receive an additional dose through a clinical trial, under EUI, moderately or severely immunocompromised clinical trial participants aged ≥12 years should receive an additional primary dose of **Pfizer-BioNTech COVID-19** vaccine (30 µg formulation [purple cap]) at least 28 days after receiving the second vaccine dose of their primary series as detailed in the Considerations for COVID-19 vaccination in moderately or severely immunocompromised people. c. Unless they have received or plan to receive a booster dose through a clinical trial, under EUI, clinical trial participants aged ≥18 years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation [purple cap]) at least 6 months after completing their primary series, if they fall into one of the groups at increased risk for serious complications of COVID-19 or exposure to SARs-CoV-2 as detailed in Considerations for use of a COVID-19 booster dose. d. If clinical trial participants have questions about whether they should receive an additional and/or booster dose outside of the clinical trial, they should consult with their healthcare provider. ***Clinical trial participants who did not receive all of the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series.
Follow-up	Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA: • Vaccine administration errors

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	Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix A. Administration errors should be reported to VAERS. • Serious adverse events • Cases of Multisystem Inflammatory Syndrome • Cases of COVID-19 that result in hospitalization or death Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.govexternal icon or by calling 1-800-822-7967.
Precautions for Use of this Order	1. Persons with a history of an immediate allergic reaction to any other vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]). This includes people with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, even if it is unknown which component elicited the immediate allergic reaction. 2. Persons with a contraindication to one type of a COVID-19 vaccine (e.g., viral vector – Janssen/Johnson and Johnson) have a precaution to another (e.g., mRNA – COMIRNATY/Pfizer or Moderna) because of potential cross-reactive hypersensitivity. Consultation with an allergist-immunologist should be considered prior to vaccination and patients with this precaution should be vaccinated in a health care setting where allergic reactions can be immediately managed and under the supervision of a health care provider experienced in the management of severe allergic reactions. 3. Patient 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. 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 C: Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Approved or Authorized in the United States
Criteria or Circumstances for Notifying Medical Provider	1. Allergic reaction: Call 911, implement medical emergency protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service. 2. Patient 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.

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	6. Patient reports they are a HCT or CAR-T cell recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred. 7. Notify the Medical Provider from the organization providing clinical supervision of the vaccination site/service at any time there are questions or problems with carrying out this standing order. Note: Healthcare providers or health departments in the United States can request a consultation from CISA COVIDvax for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines.

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

Elizabeth Cuervo Tilson, MD, MPH
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This order is effective immediately upon signing and may be revised or revoked by the State Health Director according to his/her discretion. This order will expire upon rescission off the State of Emergency Executive Order Number 116. Legal Authority Executive Order 236.