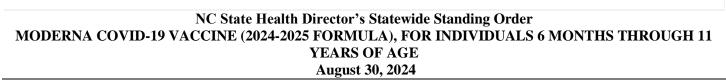




Purpose: To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and to administer Moderna COVID-19 vaccine to persons who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

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 <u>Session Law 2022-74</u>, <u>Sec. 9G.7.(a)-(e)</u> and <u>Session Law 2023-65</u>, <u>Sec. 9G.7</u> (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.

	CO	VID-19 Vaccination	
Condition/Situation:	Patients present requesting authorized caregiver:	vaccination will receive, with	appropriate written consent from an
	Individuals 6 Months Th	rough 4 Years of Age by Mod	lerna COVID-19 Vaccination Status
	 Vaccine (2024-2025 Fe first. Individuals who have a single dose 0.25 mL after the initial dose of Individuals who have including at least 1 de Moderna COVID-19 V Moderna COVID-19 V 	received 1 dose of any Mode of Moderna COVID-19 Vaccin Moderna COVID-19 Vaccine. received ≥2 doses of Modern se 2024-2025 Moderna: Adm accine (2024-2024=5 Formula accine.	
	Number of Previous Doses of Moderna COVID-19	Status Moderna COVID- 19 Vaccine (2024- 2025 Formula) Dosing Regimen, Dose and Schedule ^b	^a Previous dose(s) of Moderna COVID-19 vaccine(s) refers to dose(s) of any prior Moderna COVID-19 Vaccine that is no longer authorized
	$\frac{\text{COVID-19}}{\text{Vaccine}(s)^a}$	2 doses, ^d 0.25 mL each Dose 1: week 0 Dose 2: 4-8 weeks	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
	1	Single Dose, 0.25 mL Four to eight weeks after receipt of a previous dose of Moderna COVID-19 vaccine ^a	^a Not previously vaccinated with any COVID-19 vaccine. ^d Individuals turning from 4 years to 5 years of age during the vaccination series should



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≥2	Single dose, 0.25 mL At least 8 weeks after rece of the last previous dose of Moderna COVID-19 vaccine ^a	
 Administer a sin Formula). If prev weeks after receiption 	gle dose 0.25 mL of Moderna viously vaccinated with any C pt of the last previous dose of	
		Vho Are Unvaccinated or Have cluding 1 Dose of any 2024-2025
Formula) Dos Schedule ^a	9 Vaccine (2024-2025 sing Regimen, Dose and dosin	ndividuals with certain kinds of nocompromise, see below for further g information.
1 0	d, at least 8 weeks after vacc	ious dose refers to any prior COVID-19 ne that is no longer authorized for use in inited States.
Immunocompromised i	ndividuals 6 months throug	11 years of age:
years of age show refers to individu diagnosed with c	ald follow the schedule below tals who have undergone solic conditions that are considered	munocompromised 6 months through Certain kinds of immunocompromise organ transplantation, or who are to have an equivalent level of ical consideration <u>here</u> for more detail
	Immunocompromised Indiv D-19 Vaccination Status	iduals 6 Months Through 4 Years o
Vaccine (2024-2025 weeks, and the third Individuals who ha two doses 0.25 mL of should be administer	Formula). The interval betwee dose should be given at least 4 ve received 1 dose of any Mo	derna COVID-19 Vaccine: Administ e (2024-2025 Formula), the first dose



Previous Doses of Moderna COVID-19 Vaccine(s)a19 Vaccine (2024- 2025 Formula) Dosing Regimen, Dose and SchedulebCOVID-19 vaccine(s) refers to dose(s) of any prior Moderna COVID-19 Vaccin that is no longer authorized for use in the United States. b For individuals with certain indis of immunocompromis previously vaccinated with a weeks0°3 doses, d 0.25 mL each Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: at least 4 weeksb For individuals with certain indis of immunocompromis previously vaccinated with a dose1Dose 1: 4 weeks after last dose0 cose 1 and Dose 2: at least 4 weekscovID-19 vaccine a information. covID-19 vaccine2Single dose, 0.25 mL of the last previous dose of Moderna COVID-19 vaccine ^a covID-19 vaccine a (2024- 2025 Formula).	wioderater	of Age	Immunocompromised Indivi by Moderna COVID-19 Va	
0°3 doses, d 0.25 mL each Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: at least 4 weeksFor individuals with certain 		Previous Doses of Moderna COVID-19	19 Vaccine (2024- 2025 Formula)	Moderna COVID-19 Vaccine that is no longer authorized for use in the United States.
1Dose 1: 4 weeks after last dose° Not previously vacinated wi any COVID-19 vacine.1Dose 1: 4 weeks after last dose° Not previously vacinated wi any COVID-19 vacine.2Dose 1 and Dose 2: at least 4 weeks° Individuals turning from 4 years to 5 years of age durin the vaccination series shoul receive both doses with Moderna COVID-19 Vaccin (2024- 2025 Formula).2At least 4 weeks after receipt of the last previous dose of Moderna COVID-19 vaccineªModerna COVID-19 (2024- 2025 Formula).			Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: at least 4 weeks	kinds of immunocompromise previously vaccinated with a Moderna COVID-19 vaccine, see below for dosing
2 At least 4 weeks after receipt of the last previous dose of Moderna COVID-19 vaccine ^a Moderna COVID-19 (2024- 2025 Formula).		1	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: at least 4 weeks	 ^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
Single dose 0.25 mI		2	At least 4 weeks after receipt of the last previous dose of Moderna COVID-19	Moderna COVID-19 Vaccine
≥3 At least 8 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	

3

administered at least 4 weeks after the first.



	• Individua	ale who have	received 2 deses of any Med	ma COVID 10 Vaccing	· Administor
	• Individuals who have received 2 doses of any Moderna COVID-19 Vaccine: Administer a single dose 0.25 mL of Moderna COVID-19 Vaccine (2024-2025 Formula), at least 4				
	weeks after the last dose of Moderna COVID-19 Vaccine (2024-2025 Formula), at least 4				
	 Individuals who have received ≥3 doses of any mRNA COVID-19 Vaccine, NOT 				
			se any 2024-2025 mRNA vac		
			D-19 Vaccine (2024-2025 Form		
			D-19 Vaccine.	india), at least o weeks are	
	Moderate	•	y Immunocompromised Indi	6	h 11
		Number of	e Regardless of COVID-19 V	accination Status	
		Previous	Moderna COVID-	^a Previous dose(s) of Moderna	
		Doses of	19 Vaccine (2023-	COVID-19 vaccine(s) refers to dose(s) of any prior	
		Moderna	2024 Formula)	Moderna COVID-19 Vaccine	
		COVID-19	Dosing Regimen, Dose and Schedule ^b	that is no longer authorized	
		Vaccine(s) ^a		for use in the United States. ^b For individuals with certain	
			3 doses, ^d 0.25 mL each	kinds of immunocompromise	
		0c	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: at least 4 weeks	previously vaccinated with a Moderna COVID-19 vaccine,	
			2 doses, ^d 0.25 mL each	see below for dosing information.	
		1	Dose 1: 4 weeks after last	^c Not previously vaccinated with	
		-	dose	any COVID-19 vaccine. ^d Individuals turning from 4	
			Dose 1 and Dose 2: at least 4 weeks	years to 5 years of age during the vaccination series should	
			Single dose, 0.25 mL	receive both doses with	
		2	At least 4 weeks after receipt	Moderna COVID-19 Vaccine (2024- 2025 Formula).	
		2	of the last previous dose of	(2021 2023 Formula).	
			Moderna COVID-19		
			vaccine ^a Single dose, 0.25 mL		
			At least 8 weeks after receipt		
		3 or more any mRNA	of the last dose a^{a}		
Condition	In addition to criteria above, the following conditions regarding consent must be met:			et:	
	• Patients (recipients of vaccine) 6 months through 11 years of age presenting for			g for	
	vaccination whose parent or legal guardian has provided written consent to the vaccine				
	will be vaccinated under FDA-Emergency Use Authorization (EUA) status.				
			ssessment Criteria		
Assessment Criteria	Patients shall	be vaccinated	with Moderna COVID-19 Va	ccine (2023-2024 Formul	a), 6 mos11
	years based or	n:			
	1. The c	onditions/situa	ations of this order (see above)).	
			Plan of Care		



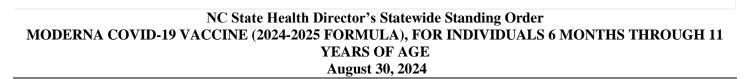
Drion to	a nation to magining the COVID 10 headter vegating the vegatington on designed (if
	patients receiving the COVID-19 booster vaccine, the vaccinator or designee (if tion permitted by licensure and/or law) shall provide anticipatory guidance regarding
Ū.	ation to the patient, which at a minimum shall include:
	Review <u>CDC Screening Checklist for Contraindications</u>
2.	Fact Sheet for Recipients and Caregivers for Moderna COVID-19 Pediatric vaccine 6
	months through 11-years
Model	na COVID-19 Vaccine, 6 months through 11 years
Admir	nistration 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 (2024-2025 Formula), is supplied in a single dose pre- filled syringe of 0.25 mL.
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.	
	Circumstances for Notifying Medical Provider sections of this standing order before
	administering the COVID-19 vaccine (2024-2025 Formula).
8.	Following the current <u>CDC Screening Checklist for Contraindications</u> , 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 <u>NC General</u>
	Statute. 90-21.13.
10	. <u>Personal Protective Equipment:</u> Before administering the COVID-19 vaccination, don
	appropriate personal protective equipment (PPE) per <u>CDC guidelines for COVID-19</u>
	vaccinations to protect against the transmission of COVID-19.
Vaccir	ne Product & Preparation:



Moderna COVID-19 Vaccine (2024-2025 Formula) is a suspension for intramuscular
injection
• <u>Vaccine Preparation</u> : 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 (<u>CDC Interim Clinical Considerations for COVID-19 Vaccine</u>
Administration Appendix B).
c. When a patient inadvertently receives an incorrect/inappropriate dose of
COVID-19 vaccine, review <u>Appendix B. Vaccine administration errors and</u>
deviations, and take action as directed.
• <u>Timing:</u> 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 <u>Transitioning from a younger to older age group.</u>
<u>Administration:</u>
a. Route of Administration: Use the chart below to determine appropriate needle
gauge and site of intramuscular injection.
Suage and site of intrainascular injection.



			T • 4• 0•
Age of Patient	Needle Gauge	Needle Length	Injection Site
Infants, 6-12 months	s 22-25-gauge	1 inch	Vastus lateralis
			muscle of the
Talilare 1 America	22.25	1 1 25 in th	anterolateral thigh
Toddlers, 1-2 years	22-25-gauge	1-1.25 inch	Vastus lateralis muscle of the
	22-25-gauge	*5/8 inch-1 inch	anterolateral thigh Deltoid muscle
Children, 3-10 years		*5/8 inch-1 inch	Deltoid muscle
Children, 5-10 years			Vastus lateralis
	22-25-gauge	1-1.25 inch	muscle of the
Children 11 years	22.25 20000	*5/Qinch 1 inch	anterolateral thigh
Children, 11 years	22-25-gauge	*5/8 inch-1 inch	Deltoid muscle
patient based child's weigh stretched tigh • Multiple vac administer ea Interim Clinic • Bleeding Ris the vaccine us site, without r • Documentati a. Patie shoul docum b. NCII close c. Elect docum agend d. Provi patien when immu e. Coum	on their reported weight t for needle selection p tly (do not bunch sub ection cinations: If multiple weight ch injection in a different cal Considerations on k : Patients with blood of sing a 23 gauge or small rubbing, for at least 2 m tor caregiver attestation d be documented within menting system. R : Document vaccine re- of business day, after weight romic Medical Record ment patient COVID-19 cy policy. de a signed immunization needed for schools, chinization records are re-	nt. Patient's authorize urposes. *If a 5/8-inc cutaneous tissue). vaccines are administe ent injection site follor disorders or who are of ler caliber needle, fol- ninutes. on to severe or moder n the patient's electro ecord in NCIR at the vaccine administration I: If necessary for bill 9 vaccination in agene ion record, at no char, zation is given as spe ildcare facilities, coll quired. ent needs to schedule	wing guidance in the CDC on blood thinners: administer llowed by firm pressure on the rate immunocompromise onic health record or other time of administration or by n ing or other purposes, cy electronic health record per ge, to the parent, guardian, or ecified in G.S. 130A-154 and eges/universities, or wherever return appointment for



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	Moderna COVID-19 Vaccine 6 months through 11 years: Observation and Follow-Up
	 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 <u>Centers for Disease Control and Prevention guidelines</u> 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 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 <u>severe allergic reactions and anaphylaxis</u>. 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	People who received COVID-19 vaccination outside the United States: Everyone ages 6
Circumstances	months and older vaccinated outside the U.S. should receive at least 1 dose of an updated (2024-2025 formula) mRNA COVID-19 vaccine regardless of past COVID-19 vaccination history (e.g., vaccine type(s), vaccine manufacturer(s), number of doses) unless they received an updated (2024-2025 formula) mRNA COVID-19 vaccine that is FDA-approved or FDA-authorized (i.e., Moderna or Pfizer-BioNTech), or prequalified or listed for emergency use by the World Health Organization (WHO). COVID-19 vaccines that are pre-qualified or listed for emergency use by WHO, but are not approved or authorized by FDA, have not been evaluated for efficacy or safety by CDC or ACIP. Children ages 6 months – 4 years and those who are moderately or severely immunocompromised may be recommended to receive more than 1 dose of an updated (2024-2025 formula) mRNA vaccine depending on vaccination history as noted within this standing order. See <u>Appendix A</u> in the Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for more information.
Follow-up	 Adverse events that occur in a recipient following COVID-19 vaccination should be reported to <u>VAERS</u>. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA: Vaccine administration errors Serious adverse events Cases of myocarditis, cases of pericarditis, and cases of Multisystem Inflammatory Syndrome (MIS) Cases of COVID-19 that result in hospitalization or death.



	Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain
	whether the vaccine caused the event. Information on how to submit a report to VAERS is
	available at https://vaers.hhs.gov or by calling 1-800-822-7967.
Precautions for Use of this Order	1. Persons with a history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine.*
	2. Persons with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine.**
	3. Patient self-reported moderate to severe acute illness, with or without fever.
	4. Persons with a history of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine.
	5. Persons with a history of MIS-C or MIS-A.
	*Persons with a precaution to vaccination must be counseled about the unknown risks of experiencing a severe allergic reaction and balance these risks against the benefits of vaccination.
	**Persons with an allergy-related precaution to one COVID-19 vaccine type may receive the alternative COVID-19 vaccine type in the usual vaccination setting. Vaccination with the same COVID-19 vaccine type may be considered on an individual basis; the same vaccine type should be administered in an appropriate setting and under the supervision of a health care provider experienced in the management of severe allergic reactions. An observation period of 30 minutes post-vaccination should be followed. Referral to an allergist-immunologist should be considered.
Contraindications	Do not administer the COVID-19 vaccine to individuals with a history of:
for Use of this	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the
Order	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 <u>Considerations for people with a history of allergies or</u>
	allergic reactions.



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Criteria or	1. Allergic reaction: Call 911, implement medical emergency protocols and immediately notify
Circumstances for	the medical provider providing clinical supervision of the vaccination site/service.
Notifying Medical	2. Patient reports a precaution for the vaccine.
Provider	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 <u>CISA COVID</u> 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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Elizabeth Cuervo Tilson, MD, MPH

Approved by: _

___ Date Signed: _8-30-2024_

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 <u>Session Law 2022-74</u>, <u>Sec. 9G.7.(a)-</u> (e) and <u>Session Law 2023-65</u>, <u>Sec. 9G.7</u> (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.