NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
Administration of SPIKEVAX (COVID-19 Vaccine, mRNA) in Individuals 18 Years of Age and Older

Purpose: To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the US Food and Drug Administration (FDA).

Policy: This standing order authorizes an immunizing pharmacist licensed with the NC Board of Pharmacy and practicing in North Carolina in accordance with the conditions of their licensure to administer COVID-19 Vaccines approved by the FDA per the conditions of this order. This standing order aligns with provisions regarding prescribing of the COVID-19 Vaccine set out in the Declaration Under the Public Readiness and Emergency Preparedness (PREP) Act for Medical Countermeasures Against COVID-19 and the conditions of the FDA approval of the COVID-19 Vaccine.

SPIKEVAX® (COVID-19 Vaccine, mRNA) 2025-2026 Formula	
Condition/Situation	**Individuals 65 years of age and older** who present requesting a vaccination will receive the following, regardless of previous COVID-19 vaccine history: • 1 dose 0.5 mL SPIKEVAX, administered as an IM injection **Individuals 18 years through 64 years of age who self-attest to at least one underlying condition* that puts them at high risk for severe outcomes from COVID-19** and present requesting vaccination will receive the following, regardless of previous COVID-19 vaccine history: • 1 dose 0.5 mL SPIKEVAX, administered as an IM injection For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of SPIKEVAX at least 2 months after the last dose of COVID-19 vaccine. ***Underlying Conditions and Higher Risk for Severe COVID-19** • Asthma • Cancer • Cerebrovascular disease • Chronic kidney disease • Chronic lung diseases, limited to bronchiectasis, COPD (Chronic Obstructive Pulmonary Disease), interstitial lung disease, pulmonary embolism, pulmonary hypertension • Chronic liver diseases, limited to cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease, autoimmune hepatitis • Cystic fibrosis • Diabetes mellitus, type 1 and type 2 • Disabilities, including Down syndrome (complete list included here) • Epilepsy • Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies) • Hemophilia • HIV (human immunodeficiency virus) • Mental health conditions, limited to mood disorders (including depression), schizophrenia spectrum disorders

	• Neurologic conditions, limited to dementia and Parkinson's Disease • Overweight (BMI ≥25 kg/m^2) • Physical inactivity • Pregnancy or recent pregnancy • Primary immunodeficiencies • Sickle cell disease • Smoking, current or former • Solid organ or blood stem cell transplantation • Substance use disorders • Tuberculosis • Use of corticosteroids or other immunosuppressive medications
Assessment Criteria	
Assessment Criteria	Patients 18 years through 64 years of age who self-attest to at least one underlying condition that puts them at high-risk for severe COVID-19 and patients 65 years of age and older shall be vaccinated with SPIKEVAX based on: 1. The conditions/situations of this order (see above).
Plan of Care	
Actions	**Patient Education and Data Collection** Prior to patients receiving the SPIKEVAX 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. A review of the Screening Checklist for Contraindications to Vaccination for Adults 2. Review of the SPIKEVAX Information for Recipients and Caregivers
	Administration Procedures: 1. Review the SPIKEVAX package insert. The vaccinator shall be familiar with procedures for preparation and storage & handling of SPIKEVAX according to the package insert. 2. 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. *3.* Review *Precautions, Contraindications, and Notification of Medical Provider* sections of this standing order **before** administering SPIKEVAX.

4. Following the current Screening Checklist for Contraindications to Vaccination for Adults, instruct patients accordingly or consult with a provider.
5. Personal Protective Equipment: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per CDC guidelines for COVID-19 vaccinations.

Vaccine Product Storage, Preparation, and Administration:

For intramuscular injection only.

Storage Prior to Use

- Store frozen between -50ºC to -15ºC (-58ºF to 5ºF). During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- After thawing, SPIKEVAX may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 60 days or up to the expiration date printed on the carton, whichever comes first.
- After thawing, SPIKEVAX may be stored between 8°C to 25°C (46°F to 77°F) for up to 12 hours.
- **Do not refreeze once thawed.**
- Thawed syringes can be handled in room light conditions.

Preparation for Administration

- Select the SPIKEVAX Single-Dose Prefilled Syringe containing 1 dose of 0.5 mL.
- Verify that the label on the pre-filled syringe states 2025-2026 Formula.
- If pre-filled syringes of SPIKEVAX are frozen, thaw before use following the instructions below.

	Thaw in Refrigerator 2°C to 8°C (36°F to 46°F)	**Thaw at Room Temperature 15°C to 25°C (59°F to 77°F)**
Carton of 10 syringes	Thaw for 2 hours and 40 minutes	Thaw for 1 hour and 20 minutes
Carton of 2 syringes	Thaw for 1 hour and 40 minutes	Thaw for 40 minutes
One syringe (removed from carton)	Thaw for 1 hour and 40 minutes	Thaw for 40 minutes

- After thawing, do not refreeze.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

- SPIKEVAX is a white to off-white suspension. It may contain white or translucent product-related particulates. Do not administer if vaccine is discolored or contains other particulate matter.
- **Do not shake.**
- With tip cap upright, remove tip cap by twisting counterclockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.

Administration

Administer SPIKEVAX intramuscularly. Discard after single use.

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
18 years	22-25-gauge	*5/8 inch-1 inch	Deltoid muscle
Adults, 19 years and older 1. 130 lbs or less 2. 130-152 lbs 3. Men, 152-200 lbs 4. Women 152-200 lbs 5. Men, 260 lbs or more 6. Women, 200 lbs or more	22-25-gauge • 1 inch • 1 inch • 1-1.5 inches • 1-1.5 inches • 1.5 inches • 1.5 inches	1-1.25 inch	Deltoid muscle

Needle Gauge: Patient may self-report weight for needle selection purposes. *If a 5/8-inch needle is used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

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.

Multiple vaccinations: Administration of multiple vaccines should be in accordance with guidance in the CDC Interim Clinical Considerations on Simultaneous administration of COVID-19 vaccines with other vaccines.

Administration Errors: If a patient inadvertently receives an incorrect/inappropriate dose of COVID-19 vaccine, review Appendix: Vaccine administration errors and deviations, and take action as directed.

	Documentation • Patient or caregiver attestation to severe or moderate immunocompromise should be documented within the patient's electronic health record or other documenting system. • **NCIR**: Document vaccine record in NCIR at the time of administration or by close of business day, after vaccine administration. • Provide a signed immunization record, at no charge, each time an immunization is given and when immunization records are needed.

	Observation and Follow-Up
	
	Post-vaccination Observation: Observe patients post-vaccination for immediate allergic reactions according to the Centers for Disease Control and Prevention guidelines for the following time periods:
	• **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
	• **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 severe allergic reactions and anaphylaxis.
	
	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.

Follow-up	Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Reporting is encouraged for any 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.

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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 also 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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Notification of Medical Provider	Pharmacists shall ask **ALL** individuals assessed under this standing order to provide the name and contact information of their medical provider. **<u>If an individual identifies a medical provider</u>:** The pharmacist shall provide the individual's medical provider a summary of the encounter within **72 hours**. At a minimum, the summary should include the individual's name & date of birth, vaccination provided. **<u>If an individual does NOT identify a medical provider:</u>** The pharmacist shall counsel on the benefits of establishing care with a medical provider, **AND** Provide information on accessible care options, such as private practices, federally qualified health centers (FQHCs), free clinics, and local health departments serving the patient's area.

Signed by:
Lawrence Greenblatt
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09/12/25 | 11:48 AM EDT

Lawrence Greenblatt, MD

Date Signed

National Provider ID: 1629019971

This standing order signed by the North Carolina State Health Director is effective immediately and may be revised or revoked by the State Health Director according to his/her discretion. This statewide standing order will expire on August 31, 2026. This order will be renewed upon changed in the State Health Director, if needed, or updated if any relevant information regarding COVID-19 vaccine necessitates a change.