



**NC State Health Director's Statewide Standing Order
for Moderna mRNA COVID-19 Vaccine Administration
Revised March 31, 2022**

Purpose: To meet the goal of administering FDA Approved Moderna COVID-19 vaccine/SPIKEVAX 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 245](#), 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.

COVID-19 Vaccination

**Condition/Situation:
Non-immunocompromised
patients (most patients)**

Patients who self-attest to **not** being [moderately to severely immunocompromised](#), who present requesting and have legal capacity to consent, shall receive:

➤ **Primary Series (2-Dose Moderna/ SPIKEVAX):**

18 years and older, who present requesting Moderna vaccine for the first or second dose of their 2-dose primary series. The second dose shall be given at least 28 days after the first dose and up to 8 weeks per patient request.

Intervals for Doses in Primary Series: (Table 1)

Dose 1 to Dose 2 of Moderna/SPIKEVAX	4 – 8 weeks*
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*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.

➤ **1st Booster Dose (Moderna/ SPIKEVAX) scenarios (based on primary series):**

- Moderna/ SPIKEVAX COVID-19 Vaccination primary series:
18 years of age and older, who present requesting a booster dose at least 5 months after completion of their primary series with Moderna/SPIKEVAX.
- Pfizer/COMIRNATY COVID-19 Vaccination primary series:
18 years of age and older, who present requesting a booster dose at least 5 months after completion of their primary series with COMIRNATY/Pfizer. Anyone aged 12-17 years who presents is not eligible for a Moderna/SPIKEVAX vaccine booster.
- Janssen COVID-19 Vaccination primary series:
18 years and older, who received primary COVID-19 vaccination with Janssen at least 2 months ago.
(See Table 2)



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Heterologous use of vaccine product and intervals for primary dose to 1st booster dose: (Table 2)

Primary Series Vaccine	Age for vaccine booster	Interval between final primary dose and booster dose	COVID-19 product that may be given as a 1 st booster dose
Pfizer/COMIRNATY	≥ 18 years*	≥ 5 months	Pfizer Moderna Janssen
Pfizer/COMIRNATY	12-17 years	≥ 5 months	This age group only eligible for Pfizer
Moderna/SPIKEVAX	≥ 18 years*	≥ 5 months	Pfizer Moderna Janssen
Janssen	≥ 18 years*	≥ 2 months	Pfizer Moderna Janssen

*Regarding booster doses: Upon their request, patients 18 years of age and older can receive any brand of COVID-19 vaccine for their booster shot.

**For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who present requesting booster dose of Moderna/SPIKEVAX, refer to section on “Special Circumstances.”

➤ **2nd Booster Dose (Moderna/ SPIKEVAX) scenarios:**

- **Moderna/ SPIKEVAX COVID-19 1st Booster Vaccination:**
50 years of age and older, who present requesting a 2nd booster dose at least 4 months after 1st booster dose with Moderna/SPIKEVAX.
- **Pfizer/COMIRNATY COVID-19 1st Booster Vaccination:**
50 years of age and older, who present requesting a 2nd booster dose at least 4 months after 1st booster dose with COMIRNATY/Pfizer.
- **Janssen COVID-19 1st Booster Vaccination:**
 - ***18-49 years, who received Janssen COVID-19 vaccine as **both** their primary series and first booster dose who present requesting a 2nd booster at least 4 months after their first booster dose
 - ***50 years and older, who received a mRNA vaccine as primary series and a Janssen as 1st booster, present requesting a 2nd booster dose at least 4 months after 1st booster dose of Janssen



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Heterologous use of vaccine product and interval from 1st booster dose to 2nd booster dose: (Table 3)

1 st Booster Dose	Age for 2 nd Booster	Interval between 1 st and 2 nd Booster dose	COVID-19 product that may be given for 2 nd booster dose
Pfizer/ COMIRNATY	≥ 50 years*	≥ 4months	Pfizer Moderna
Moderna/ SPIKEVAX	≥ 50 years*	≥ 4 months	Pfizer Moderna
Janssen	18-49***	≥ 4 months	Pfizer Moderna
Janssen	≥ 50 years***	≥ 4 months	Pfizer Moderna

*Regarding booster doses: Upon their request patients 18 years of age and older can receive either mRNA brand of COVID-19 vaccine for their 2nd booster shot.
 **For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who present requesting 2nd booster dose of Moderna/SPIKEVAX, refer to section on “Special Circumstances.”
 ***See Janssen 2nd Booster criteria above.

**Condition/Situation:
Moderately to Severely
Immunocompromised
patients**

Patients who self-attest to being [moderately to severely immunocompromised](#), who present requesting and have legal capacity to consent, shall receive:

➤ **Primary Series (3-dose Moderna/SPIKEVAX):**
 18 years and older, requesting Moderna/SPIKEVAX vaccine for the first, second, or third dose of their 3-dose primary series of mRNA vaccine. (See appropriate interval between doses in table below).

(Table 4)

Intervals for Doses in the Primary Series: Moderately to Severely Immunocompromised People	
Dose 1 to Dose 2 of Moderna/SPIKEVAX	4 weeks*
Dose 2 to Dose 3 Moderna/SPIKEVAX	4 weeks

*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 dose 1 and dose 2.



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➤ **Additional (2nd) Dose after receiving Janssen vaccine (Moderna/SPIKEVAX):**

18 years and older, presenting for Moderna/SPIKEVAX vaccine at least 28 days after receiving their first dose of Janssen COVID-19 vaccine.

**The additional dose is NOT a booster dose; See Table F below for appropriate intervals for booster dose.

(Table 5)

Intervals for Doses in the Primary Series: Moderately to Severely Immunocompromised People

1st dose of Janssen vaccine to additional dose of Moderna/SPIKEVAX	4 weeks
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*For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who self-identify as moderately to severely immunocompromised and present requesting an additional dose of Moderna/SPIKEVAX, refer to section on “Special Circumstances.”

➤ **1st Booster Dose scenarios -based on primary series(Moderna/SPIKEVAX):**

- Moderna/SPIKEVAX COVID-19 Vaccination primary series:
18 years of age and older, requesting a booster dose at least 3 months after completion of their primary series with Moderna/SPIKEVAX.
- Pfizer/COMIRNATY COVID-19 Vaccination primary series:
12 years of age and older, requesting a booster dose at least 3 months after completion of their primary series with Pfizer/COMIRNATY.
- Janssen COVID-19 Vaccination primary series & additional dose of mRNA vaccine:
18 years and older, who received their first dose of COVID-19 vaccination with Janssen, followed by an additional dose of mRNA vaccine (see criteria above). The patient should have received their additional dose of mRNA vaccine at least 2 months ago.

Heterologous use of vaccine product as noted in table below:(Table 6)

Intervals for 1st Booster Doses: patients who are Moderately to Severely Immunocompromised

Primary Series Vaccine	Age for vaccine booster	Interval between final primary dose and booster dose	COVID-19 product that may be given as a 1st booster dose
Pfizer/COMIRNATY	≥ 18 years*	≥ 3 months	Pfizer Moderna Janssen



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Pfizer/COMIRNATY	12-17 years	≥ 3 months	This age group only eligible for Pfizer
Moderna/SPIKEVAX	≥ 18 years*	≥ 3 months	Pfizer Moderna Janssen
Janssen *** (1 dose, followed by additional dose of mRNA vaccine)	≥ 18 years*	≥ 2 months after additional dose of mRNA vaccine	Pfizer Moderna Janssen

*Regarding booster doses: Upon their request, patients 18 years of age and older can receive any brand of COVID-19 vaccine for their booster shot.

**For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who present requesting booster dose of COMIRNATY/Pfizer, refer to section on “Special Circumstances.”

***For patients who received an additional Janssen dose following their primary Janssen dose or who received 50 mcg dose of Moderna as their 2nd dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine (100 mcg)as the 3rd dose at least 2 months after dose 2. For further guidance see CDC Interim Clinical Considerations, Appendix D.

➤ **2nd Booster Dose scenarios: (Moderna/SPIKEVAX)**

- Moderna/SPIKEVAX COVID-19 1st Booster Vaccination:
18 years of age and older, requesting a 2nd booster dose at least 4 months after 1st booster dose with Moderna/SPIKEVAX.
- Pfizer/COMIRNATY COVID-19 1st Booster Vaccination:
12 years of age and older, requesting a 2nd booster dose at least 4 months after 1st booster dose with Pfizer/COMIRNATY.
- Janssen COVID-19 1st Booster Vaccination:
18 years and older, who received their first dose of COVID-19 vaccination with Janssen, followed by an additional dose of mRNA vaccine (see criteria above). The patient should have received their 1st booster dose of mRNA vaccine at least 4 months ago.

Heterologous use of vaccine product and interval between booster doses: (Table 7)

Primary Series Vaccine	Age for vaccine booster	Interval between 1st and 2nd booster	COVID-19 product that may be given as a 1st booster dose
Pfizer/COMIRNATY	≥ 18 years*	≥ 4 months	Pfizer Moderna



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Pfizer/COMIR NATY	12-17 years	≥ 4 months	This age group only eligible for Pfizer
Moderna/SPIK EVAX	≥ 18 years*	≥ 4 months	Pfizer Moderna
Janssen ***	≥ 18 years*	≥ 4 months	Pfizer Moderna

*Regarding booster doses: Upon their request, patients 18 years of age and older can receive either brand of mRNA COVID-19 vaccine for their 2nd booster shot.

**For patients who received their primary series of COVID-19 vaccination with a non-FDA authorized or approved vaccine who present requesting booster dose of COMIRNATY/Pfizer, refer to section on “Special Circumstances.”

*** For further guidance on booster doses for patients who have received Janssen, see [CDC Interim Clinical Considerations, Appendix D.](#)

Assessment Criteria

Assessment Criteria

Patients shall be vaccinated with Moderna/SPIKEVAX 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, third, additional dose, 1st or 2nd booster dose of Moderna/ SPIKEVAX : ensure that the minimum interval between doses has been met (see appropriate Tables above or [CDC Clinical Considerations](#) for further guidance).
4. Moderately and severely immunocompromised people aged 12 and older who qualify for a third dose of an mRNA primary series may receive up to 2 mRNA COVID-19 booster doses (as appropriate based on conditions and criteria noted above). These patients **may receive a total of five (5) COVID-19 vaccine doses.**
5. Patients aged 50 or older who are not immunocompromised may receive a 2nd mRNA COVID-19 booster dose (as appropriate based on conditions noted above). These patients **may receive a total of four (4) 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. Review [CDC Pre-Vaccination Checklist for COVID-19 Vaccine](#)
2. If the patient is presenting for dose 1 of their primary series; provide education on optimal vaccine intervals so that the patient can choose when they would like to return for their second shot.



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- a. A four-week interval between dose 1 and dose 2 is the minimum interval between these doses and provides more rapid protection against COVID-19. A four-week interval is recommended for:
 - i. People who self-attest to being moderately to severely immunocompromised
 - ii. Adults aged 65 and older
 - iii. People who self-attest to having an underlying medical condition which may put them at higher risk of severe COVID-19; such as the examples from the [CDC'S list of People with Certain Medical Conditions](#)
- b. An 8-week interval between dose 1 and dose 2 may reduce the risk of myocarditis and may increase peak antibody response/ vaccine effectiveness. An 8-week interval may be optimal for:
 - i. Males aged 12-39, who do not fall into one of the above categories.
 - ii. All patients, aged 12-64, who do not fall into one of the above categories.
3. [Fact Sheet for Recipients and Caregivers for SPIKEVAX and 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/ SPIKEVAX.
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.



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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.
 - 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. 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.

Vaccine Product & Preparation:

1. **Vaccine 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
2. **Dosing:**
 - a. Administer 0.5 mL Moderna COVID-19 vaccine in the following situations:
 - i. First, second or third dose of the primary series
 - ii. Additional dose after receiving Janssen vaccine for moderately to severely immunocompromised patients
 - b. Administer 0.25 mL Moderna COVID-19 vaccine in the following situations:
 - i. Booster dose

(Table 8)

Moderna/SPIKEVAX COVID-19 Vaccine Dosing	
Primary series: Dose 1, 2 or 3	100 mcg, 0.5 mL injection (red top)



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		<table border="1"> <tr> <td>Additional dose after receiving Janssen vaccine (for immunocompromised patients)</td> <td>100 mcg, 0.5 mL injection (red top)</td> </tr> <tr> <td>1st and 2nd Booster Doses</td> <td>50 mcg, 0.25 mL injection (red top) 0.5ml injection (blue top)</td> </tr> </table>	Additional dose after receiving Janssen vaccine (for immunocompromised patients)	100 mcg, 0.5 mL injection (red top)	1st and 2nd Booster Doses	50 mcg, 0.25 mL injection (red top) 0.5ml injection (blue top)	<p>c. <u>In patients who have initiated an mRNA COVID-19 vaccine (Pfizer/COMIRNATY or Moderna/SPIKEVAX) primary series:</u> 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.</p> <p>d. When a patient inadvertently receives an incorrect/ inappropriate dose of COVID-19 vaccine, review Interim Clinical Considerations, Appendix C for COVID-19 vaccine errors and deviations, and take action as directed.</p> <p>3. <u>Timing:</u></p> <p>a. All recommended doses of Moderna/SPIKEVAX 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)</p> <p>b. Timing (interval) of 1st booster dose is determined by what brand of COVID-19 Vaccine was administered for Primary Series (See Table 3 above). Timing (interval) of 2nd booster dose is same regardless of primary or 1st booster dose (see Table 7 above). Also, see CDC Clinical Considerations for further guidance.</p> <p>c. See Interim Clinical Considerations, Appendix C for information on COVID-19 vaccine errors and administration deviations.</p> <p>4. <u>Administration:</u></p> <p>a. Route of Administration: Administer Moderna/ SPIKEVAX 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.</p> <p>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</p>
Additional dose after receiving Janssen vaccine (for immunocompromised patients)	100 mcg, 0.5 mL injection (red top)						
1st and 2nd Booster Doses	50 mcg, 0.25 mL injection (red top) 0.5ml injection (blue top)						



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	<p>weight. Patients may self-report their weight for needle selection purposes. See needle sizing chart below:</p>			
	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
	<p>* 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).</p> <p>c. 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</p> <p>d. 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.</p> <p>5. Documentation:</p> <p>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.</p> <p>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.</p> <p>c. Electronic Medical Record: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.</p> <p>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.</p>			



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	<p>e. Counsel when and how patient needs to schedule return appointment for follow up of COVID-19 vaccine, if applicable.</p>
	<p>Moderna/ SPIKEVAX COVID-19 Vaccination Observation and Follow-Up</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> a. 30 minutes: <ol style="list-style-type: none"> 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.
<p>Special Circumstances</p>	<p>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.</p> <p>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</p>



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	<p>independently confirmed efficacy are considered fully vaccinated. *These persons require medical consultation.</p> <ul style="list-style-type: none"> Moderately or severely immunocompromised clinical trial participants should receive an additional dose of Pfizer-BioNTech COVID-19 Vaccine (ages 12 years and older) or Moderna COVID-19 Vaccine (ages 18 years and older) 28 days after receiving the second vaccine dose of a primary series as detailed above, unless they have received or plan to receive an additional or booster dose through a clinical trial. Clinical trial participants (including moderately or severely immunocompromised people who received a 3-dose primary series) should receive a single booster dose of Pfizer-BioNTech COVID-19 Vaccine (ages 12 years and older) or Moderna COVID-19 Vaccine (ages 18 years and older), unless they have received or plan to receive a booster dose through a clinical trial. <p>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)</p>
<p>Follow-up</p>	<p>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:</p> <ul style="list-style-type: none"> Vaccine administration errors <p>Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix A. Administration errors should be reported to VAERS.</p> <ul style="list-style-type: none"> Serious adverse events Cases of Multisystem Inflammatory Syndrome Cases of COVID-19 that result in hospitalization or death <p>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.</p>
<p>Precautions for Use of this Order</p>	<p>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.</p>



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	<ol style="list-style-type: none"> 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/SPIKEVAX) 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.
<p>Contraindications for Use of this Order</p>	<p>Do not administer the COVID-19 Vaccine to individuals with a history of:</p> <ul style="list-style-type: none"> • 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. <p>See Appendix A: Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Approved or Authorized in the United States</p>
<p>Criteria or Circumstances for Notifying Medical Provider</p>	<ol style="list-style-type: none"> 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. <p>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.</p>



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Handwritten signature of Elizabeth Cuervo Tilson in black ink.

Approved by: _____
Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

Date Signed: 3-31-22

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 245](#).