Standing Order for Administering Moderna /SPIKEVAX® COVID-19 Vaccine (Adult ≥ 18 years of age)

Purpose: To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all individuals ≥ 18 years of age who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (FDA) licensure or Emergency Use Authorization (EUA), and the Department of Defense (DOD).

Policy: Under these standing orders, eligible healthcare professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Procedure:

1. Moderna/SPIKEVAX® COVID-19 vaccine in a vial with a **red cap and a label with light blue border** is:
   - FDA-licensed as a 2-dose primary COVID-19 vaccine series for individuals ≥ 18 years of age.
   - FDA-authorized under EUA as a third primary COVID-19 vaccine series dose for individuals ≥ 12 years of age who are moderately or severely immunocompromised.
2. Moderna Bivalent COVID-19 vaccine in a vial with a **dark blue cap and a label with a gray border** is FDA-authorized under EUA as a single booster dose for individuals ≥ 6 years of age. See Table 1 for all dosing intervals.
3. Individuals vaccinated outside the United States who received all or some of:
   - An FDA-licensed or FDA-authorized COVID-19 vaccine, a World Health Organization emergency use listed (WHO-EUL) COVID-19 vaccine not FDA-licensed or FDA-authorized, or a heterologous (mix and match) series from those two groups: do not restart the series in the U.S. Receive subsequent doses according to Table 1.
   - A non WHO-EUL COVID-19 vaccine primary series: doses do not count towards U.S. vaccination. Start a primary series ≥ 28 days after the last dose and receive subsequent doses according to Table 1.
4. Moderna/SPIKEVAX® COVID-19 vaccine and other vaccines may be co-administered without regard to timing, including same-day administration, with one exception: per DoD policy, ACAM2000™ smallpox vaccine must be separated from any mRNA COVID-19 vaccine by ≥ 28 days.
5. If an orthopoxvirus vaccine is recommended in the setting of an outbreak (e.g., monkeypox), it should not be delayed because of recent receipt of an mRNA or Novavax COVID-19 vaccine; no minimum interval between these vaccines is necessary.
6. Defer receipt of tixagevimab/cilgavimab (EVUSHELD™) for ≥ 2 weeks after vaccination with Moderna/SPIKEVAX® COVID-19 vaccine. There is no recommended vaccination deferral period after receipt of passive antibody therapy (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma).

Notes:

- *The Moderna Bivalent COVID-19 vaccine can be used for **booster doses only**.*
- *The Moderna COVID-19 vaccines for individuals ≥ 18 years of age are distinctly different formulations than the Moderna COVID-19 vaccines for other age groups. Ensure you are utilizing the correct standing order and product for your patient.*

- *Individuals who will move from a younger to an older age group between primary series doses or between the primary series and a booster dose should receive the vaccine and dosage appropriate for their age on the day of vaccination.*

7. Using DHA Form 207, screen all patients for contraindications and precautions to the COVID-19 vaccine:

Contraindications:

- History of a serious allergic reaction (e.g., anaphylaxis) or diagnosed allergy to a previous dose or component of a Moderna COVID-19 vaccine, to include polysorbate (see the FDA fact sheets for Moderna/SPIKEVAX® and Moderna Bivalent for complete lists of excipients).

Precautions:

- History of anaphylaxis after any vaccine **other** than COVID-19 or any injectable medication (excluding allergy shots).
- Allergy-related contraindication to another **type** of COVID-19 vaccine (e.g., protein subunit [Novavax] or adenovirus vector [Janssen]).*
- History of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine is a precaution to the **same type** of COVID-19 vaccine.
- Moderate or severe acute illness with or without fever.
- History of Multisystem Inflammatory Syndrome (MIS).
- Myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine.*
- Syncope (fainting) can occur in association with administration of injectable vaccines. Have procedures in place to avoid a falling injury (e.g., observation after administration) and to restore cerebral perfusion following syncope.
- For questions or concerns, consider consulting the DHA Immunization Healthcare Support Center at (877) 438-8222, Option 1 or DSN 761-4245.

* ***Note:*** *A subsequent dose or alternative COVID-19 vaccine may be considered using shared clinical decision-making but is not covered under these standing orders: these patients must obtain a written order from a privileged provider.*

Special Populations:

- **Pregnancy/Lactation:** Individuals who are pregnant, postpartum, or breastfeeding may receive any current FDA-licensed or FDA EUA-authorized COVID-19 vaccine, to include additional primary or booster doses. Data on the safety of COVID-19 vaccines in pregnancy is limited, but reassuring. Encourage individuals vaccinated during pregnancy to enroll in the Moderna/SPIKEVAX® COVID-19 Pregnancy Registry by calling 1-866-MODERNA (1-866-663-3762). Routine pregnancy testing before receipt of COVID-19 vaccine is not indicated, and pregnancy need not be delayed after vaccination.
- **Immunocompromised:** Individuals who are moderately or severely immunocompromised may be at increased risk for severe COVID-19. These individuals should discuss COVID-19 vaccine receipt timing and medication management with their primary or specialty healthcare provider. These conditions can include (but are not limited to):
  - Generalized malignancy.
  - Solid organ or stem cell transplant.
  - Congenital or acquired immunodeficiencies (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome, HIV/AIDS, or lymphocyte or complement deficiencies).
  - Iatrogenic immunosuppression (e.g., treatment with immunosuppressive drugs, including long-term systemic corticosteroids, biologics, or radiation therapy).
- **COVID-19 Vaccine Clinical Trial Participants:** Unless they have received or plan to receive additional doses through a clinical trial, participants (including moderately or severely immunocompromised people who received an additional primary dose) who

completed a primary series of a WHO-EUL COVID-19 vaccine (not a placebo) can receive additional age-appropriate mRNA COVID-19 vaccine doses as indicated. These individuals should confer with their trial POCs before vaccination.

8. Provide all patients (or their parent/legal representative) with a copy of the product-specific EUA Fact Sheet for Recipients and Caregivers, or the VIS, as applicable. Provide non-English speaking patients with a copy in their native language, if available and preferred.
9. Provide Moderna COVID-19 vaccine as follows:

Table 1: Dosing intervals				
COVID-19 Vaccine Product	**Number of primary doses**	**Interval: 1st and 2nd primary dose***	**Interval: 2nd and 3rd primary dose**	**Interval: primary series or last monovalent booster and bivalent booster dose†**
Moderna/SPIKEVAX® & Moderna Bivalent	**≥ 18 years**			
• **Immunocompetent**	2	4-8 weeks	**NA**	≥ 2 months
• **Immunocompromised**	3	4 weeks	≥ 4 weeks	≥ 2 months

* An 8-week interval may be optimal for some individuals 6 months - 64 years of age, especially for males 12 - 39 years of age. A shorter interval (4 weeks for Moderna/SPIKEVAX®) between the 1st and 2nd doses remains the recommended interval for immunocompromised individuals, adults ≥ 65 years of age, and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

† Bivalent booster recommended for all individuals ≥ 6 years of age, regardless of the number of previous monovalent booster doses received.

- Using a sterile needle and 1mL syringe, administer the appropriate vaccine and dose intramuscularly according to Table 2. Separate multiple injection sites by 1 inch or more and if possible, administer COVID-19 vaccines and vaccines that may be likely to cause a local reaction in different limbs.
  - Primary series and bivalent booster dose (≥ 18 years): **0.5mL**
- **DO NOT** compress minimum intervals for clinic convenience. However, doses administered ≤ 4 days (the "grace period") before the minimum interval (e.g., prior to imminent travel, immunosuppressive therapies, etc.) are considered valid.
- Any COVID-19 vaccine dose administered earlier than allowed by the grace period is invalid and should be repeated. Space the repeat dose after the dose given in error by at least the minimum interval.
- COVID-19 vaccines are NOT interchangeable for initial vaccination: complete the **primary series** with the same product. Individuals may receive any homologous or heterologous bivalent mRNA vaccine booster that is FDA-authorized for their age.

Table 2. IM Needle Length and Injection Site Guidelines		
• Use a 22 - 25 gauge needle • Use gauge & length appropriate to product, administration route & site, and the patient's sex & body mass		
Adults (≥ 18 years)	**Needle length**	**Injection site**
Men and Women < 60 kg (<130 lbs)	5/8*-1 inch (16-25 mm)	Deltoid muscle of arm †
Men and Women 60-70 kg (130-152 lbs)	1 inch (25 mm)	
Men 70-118 kg (152-260 lbs)	1-1.5 inches (25-38 mm)	
Women 70-90 kg (152-200 lbs)		
Men > 118 kg (> 260 lbs)	1.5 inches (38 mm)	
Women > 90 kg (>200 lbs)		
Men and women, any weight	1*-1.5 inches (38 mm)	Anterolateral thigh

Adapted from CDC General Best Practice Guidelines for Immunization: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html
* If the skin is stretched tightly and subcutaneous tissues are not bunched.

† Preferred site: the alternate site may be used if the muscle mass at the preferred site is inadequate. Do not administer vaccine into the gluteal muscle.

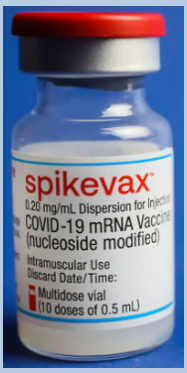
10. Storage and use of vials (see graphic on last page):
    - **DO NOT DILUTE BEFORE USE**.
    - Primary series vials (**red cap/light blue label**) are supplied in two volumes:
        - A 5.5mL multiple-dose vial
        - A 7.5mL multiple-dose vial
    - Bivalent booster doses (**dark blue cap/gray label**) are supplied in a 2.5mL multiple-dose vial.
    - Store frozen vials at -50ºC to -15ºC (-58ºF to 5ºF) until the expiry date.
    - Alternatively, vials may also be thawed and stored in a refrigerator at 2°C to 8°C (35ºF to 46ºF) for up to 30 days before first use. At this temperature, thaw 2.5mL vials for ≥ 2 hours, 5.5mL vials for ≥ 2.5 hours, and 7.5mL vials for 3 hours. Allow vials to stand at room temperature (15°C to 25°C [59°F to 77°F]) for 15 minutes prior to use.
    - If not previously thawed at 2°C to 8°C, vials may be thawed at room temperature for 45 minutes (2.5mL), 1 hour (5.5mL), or 1.5 hours (7.5mL).
    - Thawed vials may be stored in a refrigerator at 8°C to 25°C (46ºF to 77ºF) for a **total** of 24 hours.
    - Once thawed, **do not refreeze.**
    - Swirl vial gently after thawing and between each withdrawal: **do not shake**.
    - Mark vials with the date and time of first use.
    - Do not pool excess vaccine from multiple vials.
    - Store punctured vials at 2°C to 25°C (35°F to 77°F) and discard after 12 hours.
11. Provide all individuals (or their parent/legal representative) with information on the v-safe program and strongly encourage them to enroll. V-safe is a CDC app that provides personalized health check-ins and dose reminders after receipt of a COVID-19 vaccine.
12. Document all immunizations administered in the patient's electronic health record and the appropriate immunization tracking system. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, and the identification of the individual administering the vaccine. If vaccine was not given, record the reason for non-receipt.
13. **Mandatory observation.** Observe all individuals who receive any COVID-19 vaccine post-administration according to the following guidelines:
    - **30 minutes** - individuals with:
        - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy.
        - History of anaphylaxis due to any cause.
    - **15 minutes**: all other individuals.
14. Be prepared to manage a medical emergency related to the administration of vaccines by having a written emergency medical protocol available, as well as equipment and medications.
15. It is **MANDATORY** for vaccination providers to file a report with the Vaccine Adverse Event Reporting System (VAERS) for all vaccine administration errors; all serious adverse events; cases of myocarditis, pericarditis, or Multisystem Inflammatory Syndrome (MIS) in adults or children; and hospitalized or fatal cases of COVID-19 following vaccination with any COVID-19 Vaccine**.** Reports can be submitted to VAERS online at https://vaers.hhs.gov. Additional information about VAERS is also available by telephone (800-822-7967).
16. This standing order shall remain in effect for all patients of the _____ _____ until rescinded and/or upon a change in the Medical Director, whichever is earlier.

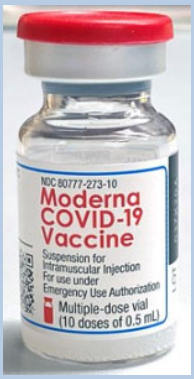
_____ _____

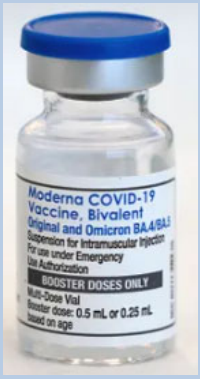
Medical Director's Signature Date

Moderna COVID-19 vaccine

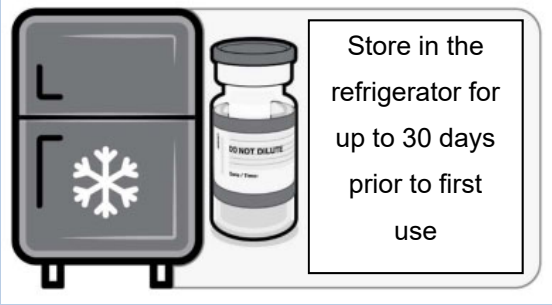
Verification:
Products FDA-licensed or FDA-authorized under EUA for individuals ≥ 18 years of age







Storage / Thawing Prior to Use



- Frozen between -50°C to -15°C (-58°F to 5°F): until expiry date
- In a refrigerator at 2°C to 8°C (36°F to 46°F): up to 30 days
- In a refrigerator at 8°C to 25°C (46°F to 77°F): up to 24 hours
- Thaw in a refrigerator at 2°C to 8°C (36°F to 46°F):
  - 2.5mL vial: 2 hours
  - 5.5mL vial: 2 hours and 30 minutes
  - 7.5mL vial: 3 hours
- Thaw at room temperature at 15°C to 25°C (59°F to 77°F):
  - 2.5mL vial: 45 minutes
  - 5.5mL vial: 1 hour
  - 7.5mL vial: 1 hours and 30 minutes
- Let refrigerated vials stand at room temperature (15°C to 25°C [59°F to 77°F]) for 15 minutes before administering

Preparation / Storage After Puncture

- **DO NOT DILUTE**
- Swirl vial gently after thawing and between each withdrawal: **do not shake**
- Vaccine should appear as a white to off-white suspension, and may contain white or translucent product-related particulates: do not administer if vaccine is discolored or contains other particulate matter
- Mark vials with date and time of first use
- Store punctured vials at 2°C to 25°C (35°F to 77°F) and discard after 12 hours