Standing Order for Administering Moderna COVID-19 Vaccine
(Pediatric 6 months – 5 years of age)

Purpose: To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all individuals 6 months – 5 years of age (6m - 5y) 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), 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 Monovalent COVID-19 vaccine is FDA-authorized under EUA for individuals 6m – 5y as:
   - A 2-dose primary series.
   - A third primary series dose for individuals who are moderately or severely immunocompromised.
2. Moderna Bivalent COVID-19 vaccine is FDA-authorized under EUA as a single booster dose for individuals 6m – 5y of age after completion of a Moderna COVID-19 primary series. See Table 1 for 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, including a bivalent mRNA booster if eligible.
   - 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, including a bivalent mRNA booster if eligible.
4. Moderna 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.

Notes:

- *The Moderna Bivalent COVID-19 vaccine can be used for **booster doses only**.*
- *The Moderna COVID-19 vaccines for individuals 6m – 5y of age are distinctly different preparations 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 turn from 5 years to 6 years of age between doses (primary or booster) should receive the vaccine and dosage appropriate for their age on the day of vaccination.*

5. Using DHA Form 236, screen all patients for contraindications and precautions to the COVID-19 vaccine:

Contraindications:

- A 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 Monovalent 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 MIS-C.
- 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:

- **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 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 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.

6. Provide all patients (or their parent/legal representative) with a copy of the 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.
7. Provide Moderna COVID-19 vaccine as follows:

Table 1: Dosing intervals, 6m – 5y

COVID-19 Vaccine Product	Number of primary doses	Interval: 1st and 2nd primary dose	Interval: 2nd and 3rd primary dose	Interval: primary series and booster dose
Moderna & Moderna Bivalent				
• **Immunocompetent**	2	4 - 8 weeks*	**NA**	≥ 2 months
• **Immunocompromised**	3	4 weeks	≥ 4 weeks	≥ 2 months

* An **8-week** interval between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines might be optimal for some as it may reduce the small risk of myocarditis and pericarditis associated with these vaccines. A 4-week interval (Moderna) is still recommended for moderately or severely immunocompromised individuals, and in situations when the fullest possible protection is needed quickly.

- Using a sterile needle and 1mL syringe, administer 0.25mL (monovalent primary dose) or 0.2 mL (bivalent booster dose) of the appropriate vaccine 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.
- **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.

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 age & body mass		
Age group	**Needle length**	**Injection site**
Infants, 1-12 months	1 inch (25 mm)	Anterolateral thigh
Children, 3-10 years	5/8*-1 inch (16-25 mm)	Deltoid muscle of arm†
	1-1.25 inches (25-32 mm)	Anterolateral thigh

Adapted from the 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.

8. Storage and use of vials (vial pictures on page 4):
   - **DO NOT DILUTE BEFORE USE.**
   - Moderna Monovalent: one vial contains 10 doses of 0.25 mL.
   - Moderna Bivalent: one vial contains 2 doses of 0.2 mL.
   - Store frozen vials at -50ºC to -15ºC (-58ºF to 5ºF).
   - Vials may be thawed:
     - In a refrigerator at 2°C to 8°C (36ºF to 46ºF) for 2 hours (monovalent) or 45 minutes (bivalent). Let vials stand at room temperature (8°C to 25°C [46°F to 77°F]) for 15 minutes before administering.
     - Between 15°C to 25°C (59°F to 77°F) for 45 minutes (monovalent) or 15 minutes (bivalent).
   - After thawing, vials of both products may be stored:
     - In a refrigerator at 2°C to 8°C for up to 30 days.
     - At room temperature (8°C to 25°C) 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 puncture.
   - Do not pool excess vaccine from multiple vials.
   - After the first puncture, store vials at 2°C to 25°C (36°F to 77°F) and discard after **12** hours (monovalent) or **8** hours (bivalent).

9. 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.

10. 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.

11. **Mandatory observation.** Observe all individuals who receive any COVID-19 vaccine post-administration according to the following guidelines:
    - **30 minutes** - individuals with:
      - Allergy-related contraindication to a different type of COVID-19 vaccine.
      - 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.

12. Be prepared to manage a medical emergency related to the administration ofvaccines by having a written emergency medical protocol available, as well as equipment and medications.

13. 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).
14. 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