Standing Order for Administering Moderna COVID-19 Vaccine
(Pediatric 12 through 17 years of age)

Purpose: To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all individuals 12 through 17 years of age (12y - 17y) 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 COVID-19 vaccine with a **red cap** and a **label with a light blue border (100mcg/0.5mL)** is FDA-authorized under EUA for individuals 12y – 17y of age as:
   - A 2-dose primary COVID-19 vaccine series for individuals who are NOT moderately or severely immunocompromised (aka immunocompetent)
   - A 3-dose primary COVID-19 vaccine series for individuals who are moderately or severely immunocompromised
2. Moderna COVID-19 vaccine and other vaccines may be co-administered without regard to timing, including simultaneous/same-day administration.
3. Defer receipt of tixagevimab/cilgavimab (EVUSHELD™) for ≥ 2 weeks after vaccination with Moderna COVID-19 vaccine. There is no recommended deferral period for vaccination after receipt of passive antibody therapy (e.g., anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma).

Notes:

- *The Moderna COVID-19 vaccine for individuals 12y – 17y of age (vials with a **red cap** and a **label with a light blue border**) is a distinctly different formulation than the other Moderna COVID-19 vaccines (vials with a **dark blue cap** and a **label with a magenta border**, vials with a **dark blue cap** and a **label with a purple border**, and vials with a **dark blue cap** and a **label with a teal border**).* ***Ensure you are utilizing the correct product and standing order for your patient.***
- *This Standing Order is specific to Moderna COVID-19 vaccine for individuals 12y - 17y of age (vial with a **red cap** and a **label with a light blue border**). Administration of other Moderna COVID-19 vaccine formulations is NOT covered under these standing orders.*

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

Contraindications:

- A history of a serious reaction (e.g., anaphylaxis) after vaccination or to any vaccine component to include polyethylene glycol (see the package insert for a complete list of excipients).

Precautions:

- Moderate or severe acute illness with or without fever.
- History of severe allergic reaction (e.g. anaphylaxis) to any injectable medication.
- Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine: defer additional primary or booster doses.*
- 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 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).

5. Provide all patients (or their parent/legal representative) with a copy of the Moderna COVID-19 vaccine Information 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.

6. Provide Moderna COVID-19 vaccine as follows (see Table 1):
    - Using a sterile needle and 1mL syringe, administer 0.5mL of Moderna COVID-19 vaccine (vial with a **red cap** and a **label with a light blue border**) 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 up to 4 days (the "grace period") before the minimum interval (e.g., prior to imminent travel, immunosuppressive therapies, etc.) are considered valid.
    - A 2nd or 3rd primary dose administered earlier than allowed by the grace period (23 days or less) is invalid and should be repeated. The repeat dose should be given ≥ 28 days after the invalid dose. Invalid doses do not count towards a series or the maximum number of doses.
    - Although FDA EUA allows for different dosing for certain age transitions (e.g., individuals who turn from 11 to 12 years of age during their primary series), per ACIP:
        - Individuals should receive the recommended age-appropriate vaccine product and dosage based on their age on the day of vaccination.
        - If a person moves from a younger age group to an older age group during the primary series, they should receive the vaccine product and dosage for the older age group for all subsequent doses.
    - If an individual is given a product for a different age group in accordance with the FDA EUA, it is not considered a vaccine administration error and does not need to be reported to the Vaccine Adverse Event Reporting System (VAERS).

Table 1. COVID-19 vaccine dosing intervals for patients 12 through 17 years of age					
COVID-19 Vaccine Product	**# of primary doses**	**# of booster doses**	**Interval: 1st and 2nd primary dose**	**Interval: 2nd and 3rd primary dose**	**Interval: primary series and booster dose**
Moderna red cap and a label with a light blue border (0.5mL/dose)					
• **Immunocompetent**	2	0	4 – 8 weeks	**NA**	**NA**
• **Immunocompromised**	3	0	4 weeks	≥ 4 weeks	**NA**

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**
Children/Adolescents, 11-18 years	5/8*-1 inch (16-25 mm)	Deltoid muscle of arm†
	1-1.5 inches (25-38 mm)	Anterolateral thigh

Adapted from the CDC General Best Practice Guidelines for Immunization - Vaccine Administration: 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.

- Storage and use of vials Moderna COVID-19 vaccine with a **red cap** and a **label with a light blue border**:
  - **DO NOT DILUTE BEFORE USE**.
  - Vials are supplied in two volumes:
    - A 5.5mL multiple-dose vial containing 11 doses of 0.5mL
    - A 7.5mL multiple-dose vial containing 15 doses of 0.5mL
  - Store frozen vials at -50ºC to -15ºC (-58ºF to 5ºF)
  - Vials may 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 5.5mL vials for 2 hours and 30 minutes and 7.5mL vials for 3 hours.
  - Thawed vials may be stored in a refrigerator at 8°C to 25°C (46ºF to 77ºF) for a **total** of 24 hours.
  - Alternatively, vials may be thawed at room temperature (15°C to 25°C [59°F to 77°F]): 5.5mL vials for 1 hour and 7.5mL vials for 1 hour and 30 minutes.
  - Once thawed, **do not refreeze.**
  - Allow refrigerated thawed vials to stand at room temperature (15°C to 25°C [59°F to 77°F]) for 15 minutes prior to use.
  - Swirly 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.
  - Do not puncture the vial stopper more than 20 times.
  - Store punctured vials at 2°C to 25°C (35°F to 77°F) and discard after 12 hours.

7. Provide all individuals (or their parent/legal representative) with information on the v-safe program and strongly encourage them to enroll. V-safe is an app that provides personalized health check-ins and dose reminders after receipt of a COVID-19 vaccine.
   - 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. The CVX code for Moderna COVID-19 vaccine for 12y – 17y of age with a **red cap** and a **label with a light blue border** is 207.

8. **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.

9. 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.

10. 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 Multisystem Inflammatory Syndrome in adults (MIS-A) or children (MIS-C), 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).

11. This policy and procedure 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