Standing Order for Administering Moderna COVID-19 Vaccine
(COVID-19 mRNA-1273 Vaccine)

Purpose: To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all persons 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) Emergency Use Authorization (EUA), and the Department of Defense (DoD).

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

Procedure:

1. Moderna COVID-19 Vaccine is allowed under EUA for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.
2. A third primary series dose of Moderna COVID-19 vaccine given at least 1 month after the second dose is allowed under EUA for individuals 18 years of age and older who are moderately or severely immunocompromised.
3. A single booster dose of Moderna COVID-19 vaccine given at least 5 months after completion of a primary series of the Moderna COVID-19 vaccine is allowed under EUA for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.
4. Moderna COVID-19 vaccine and other vaccines may be co-administered without regard to timing. This includes simultaneous administration with other vaccines on the same day, as well as co-administration within 14 days. Separate injection sites by 1 inch or more and if possible, administer COVID-19 vaccines and vaccines that may be more likely to cause a local reaction in different limbs. The one exception to simultaneous vaccine administration is with ACAM2000™ smallpox vaccine. Per DoD policy, ACAM2000™ vaccine must be separated from any COVID-19 vaccine by at least 28 days.
5. Defer vaccination with Moderna COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
6. 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 product fact sheet for complete list of excipients).

Precautions:

- Moderate or severe acute illness with or without fever.
- Allergies: Persons with a history of severe allergic reaction (e.g. anaphylaxis) to an injectable medication should use caution when receiving the vaccine, and be observed by medical personnel for 30 minutes following administration.
- Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine: until additional safety data are available, these individuals should defer additional (2nd, additional [3rd] or booster) doses. †
- Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid a falling injury (e.g. 15-minute 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:

† In certain circumstances a subsequent dose or alternative COVID-19 vaccine may be considered, but should be based on shared clinical decision-making and is not covered under these standing orders. Patients must obtain a written order from a privileged provider for this situation.

Special Populations:

- **Pregnancy/Breastfeeding**: Pregnant, lactating, and post-partum women are eligible for and can receive any currently approved or authorized COVID-19 vaccine to include any additional or booster doses. Pregnant women who contract COVID-19 have an increased risk of adverse pregnancy complications, severe illness, or death, though the absolute risk for these outcomes is low.

  Data on the safety of COVID-19 vaccines in pregnant women is limited. Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant woman or fetus. Moderna COVID-19 Vaccine cannot cause infection in either the mother or the fetus. Early data from vaccine- safety-related databases (VAERS and V-SAFE) did not identify any safety concerns for vaccinated pregnant women or for their babies. Clinical trials to evaluate the safety and efficacy of Moderna COVID-19 Vaccine in pregnant women are underway or planned. There is an exposure registry that monitors outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866- MODERNA (1-866-663-3762).
- **Fertility:** COVID-19 vaccination is recommended for all women trying to get pregnant now or who might become pregnant in the future. **There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine.** Those who are trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination. There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems. Many women have become pregnant after receiving COVID-19 vaccine. However, results from ongoing long-term fertility studies are not yet available.
- **Immunocompromised:** Persons with immunocompromising conditions or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. No data are available to establish COVID-19 vaccine safety and efficacy or optimal dose timing in these groups. However, the currently approved and authorized COVID-19 vaccines are not live vaccines, therefore can be safely administered to immunocompromised persons. A third dose of Moderna COVID-19 Vaccine is allowed under EUA for persons with certain immunocompromising conditions (see # 8). Immunocompromised patients should discuss COVID-19 vaccine receipt timing and medication management with their primary or specialty healthcare provider.
- **Booster doses:** A single booster dose **(0.25mL)** of Moderna COVID-19 Vaccine at least 5 months after the primary series is allowed under EUA for individuals 18 years and older.

- **COVID-19 Vaccine Clinical Trial Participants**: anyone who reports they are in a clinical trial for a COVID-19 vaccine candidate needs to confer with their trial POCs before vaccination. However, unless they have received or plan to receive a booster dose through a clinical trial, clinical trial participants aged ≥12 years (including moderately or severely immunocompromised people who received an additional primary dose) are eligible to receive a single booster dose. Clinical trial participants ages 12 years and older should receive a booster dose of Pfizer-BioNTech COVID-19 vaccine (30 µg formulation) at least 5 months after completing their primary series. Please see Pfizer-BioNTech/COMIRNATY® COVID-19 vaccine Standing Orders for additional guidance.

7. Provide all patients (or their parent/legal representative) with a copy of the Moderna COVID-19 Vaccine Emergency Use Authorization (EUA) fact sheet for recipients and caregivers. Provide non-English speaking patients with a copy in their native language, if available and preferred.

8. Provide Moderna COVID-19 vaccine as follows:
   - A 2-dose primary series (0.5mL each) spaced at least 1 month apart (no maximum limit but preferably before 42 days).
   - A third primary series dose (0.5mL) administered at least 1 month following the first two doses of this vaccine is authorized for administration to certain immunocompromised individuals at least 18 years of age.
   - A single booster dose **(0.25 mL)** at least 5 months after completing the primary series of the Moderna COVID-19 vaccine to individuals 18 years and older.
   - A single booster dose **(0.25mL)** to eligible individuals who have completed primary vaccination with a different authorized or approved COVID-19 vaccine, at least 5 months after completion of an mRNA primary series or 2 months after receiving the Janssen vaccine. Eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.
   - Using a sterile needle and 1mL syringe, administer the appropriate dose (0.5mL or 0.25mL) intramuscularly in the deltoid muscle.

Note: The booster dose of the Moderna COVID-19 Vaccine is 0.25 mL.

- The Moderna COVID-19 vaccine is supplied in two multiple-dose vial presentations:
  - A 5.5mL multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
  - A 7.5mL multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
  - When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses.
  - **Do not puncture the vial stopper more than 20 times.**
- Vials must be stored frozen at -50°C to -15°C and protected from light, in the original cartons, until ready to use: do not store on dry ice or below -50ºC.
- Thaw in a refrigerator at 2° to 8°C for at least 2 hours and 30 minutes (11-dose vial) or 3 hours (15-dose vial).
- Thawed vials can be stored refrigerated at 2° to 8°C for up to 30 days prior to first use.

- Alternatively, thawed vials may be stored refrigerated at 8° to 25°C for up to 24 hours.
- Let thawed vials stand at room temperature for 15 minutes before administering.
- For immediate use, thaw vials at room temperature (15ºC to 25ºC) for one hour (11-dose vial) or 1 hour and 30 minutes (15-dose vial).
- Swirl vial gently after thawing and before/between each withdrawal. **Do not shake; do not dilute.**
- After the first puncture, vials should be marked with the date and time.
- Punctured vials must be stored at 2° to 25°C and discarded after 12 hours.
- Once thawed, **do not refreeze**.
- Do not pool excess vaccine from multiple vials.

IM Needle Length and Injection Site for Adolescents & Adults		
Use a 22 – 25 gauge needle. Choose needle gauge and length appropriate to administration route and the patient's age and body mass.		
Patient sex and weight	**Needle Length**	**Injection Site**
All patients 12 – 18 years of age	1 inch	Deltoid Muscle of Arm
Men and Women (<130 lbs)	1 inch†	
Men and Women (130-152 lbs)	1 inch	
Men (152-260 lbs)	1-1.5 inches	
Women (152-200 lbs)	1-1.5 inches	
Men (> 260 lbs)	1.5 inches	
Women (>200 lbs)	1.5 inches	

Adapted from General Best Practice Guidelines for Immunization: Vaccine Administration
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html
† Some experts recommend a 5/8 inch needle for men and women who weigh <130 lbs: stretch skin tightly (do not bunch subcutaneous tissue)

9. Provide all patients with the V-safe enrollment sheet and strongly encourage them to enroll in the program. V-Safe is a smart phone-based tool that uses text messaging and web surveys to provide personalized health check-ins after a patient receives a COVID-19 vaccination. It also reminds the patient of additional dose timing, when applicable.

10. Observe a minimum interval of 28 days between the 1st and 2nd dose of the Moderna COVID-19 vaccine. DO NOT compress the minimum interval between doses. The minimum interval between dose 1 and dose 2 of the primary series is 24 days (INCLUSIVE of the 4-day grace period). Should dose #2 be administered earlier than 24 days from dose #1, the dose should be repeated. The repeat dose should be spaced after the improperly spaced dose by at least 28 days. COVID-19 vaccines are NOT interchangeable: complete the **primary series** with the same product.

11. 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 person administering the vaccine. If vaccine was not given, record the reason for non-receipt. The CVX code for Moderna COVID-19 vaccine is

207.

12. **Mandatory observation.** All persons who receive any COVID-19 vaccine will be observed post-administration according to the following guidelines:
    - **30 minutes** - persons with:
        - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy.
        - Contraindication to Janssen COVID-19 vaccine who receive Pfizer-BioNTech/COMIRNATY® or Moderna COVID-19 vaccine.
        - History of anaphylaxis due to any cause.
    - **15 minutes**: all other persons.

13. 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.

14. 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, by fax, or by mail. Additional information about VAERS is available by telephone (800-822-7967) or online at https://vaers.hhs.gov.

15. 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