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, 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. For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

2. Screen all patients for contraindications and precautions to the COVID-19 vaccine.

3. COVID-19 and other vaccines may be administered without regard to timing. This includes simultaneous administration of COVID-19 and other vaccines on the same day, as well as co-administration within 14 days.

4. 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.

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 first dose of an mRNA COVID-19 vaccine: until additional safety data are available, these persons should defer the second dose. †
- 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.
- 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 with Moderna COVID-19 vaccine.
- For questions or concerns, consider consulting the DHA Immunization Healthcare Division at (877) 438-8222, Option 1 or DSN 761-4245.

Note:

- *Persons who have a contraindication to an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) may be able to receive the Janssen COVID-19 vaccine.*

- *† In certain circumstances a second dose 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.*

- *Prior to administration of Janssen COVID-19 vaccine, inform women 18-49 years of age of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group. Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.*

Special Populations:

- **Pregnancy/Breastfeeding:** Pregnant, lactating, and post-partum persons are eligible for and can receive any currently authorized COVID-19 vaccine. Pregnant persons 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 persons are limited. Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant person or fetus. The current FDA-authorized COVID-19 vaccines 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 pregnant persons who were vaccinated or for their babies. Clinical trials to evaluate the safety and efficacy of COVID-19 vaccines in pregnant persons are underway or planned.

- **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 authorized COVID-19 vaccines are not live vaccines, therefore can be safely administered to immunocompromised persons. Persons with certain immunocompromising conditions may be eligible for a third dose of mRNA COVID-19 vaccine (see #6).

5. Provide all patients (or their parent/legal representative) with a copy of the 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.

6. Provide vaccine as follows:
   - The Moderna COVID-19 vaccine is a 2-dose series spaced at least 28 days apart (no maximum limit but preferably before 42 days).
   - A third dose of the Moderna COVID-19 vaccine (0.5 mL) administered at least 28 days following the first two doses of this vaccine is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
   - Administer 0.5mL of vaccine intramuscularly in the deltoid muscle.
   - The Moderna COVID-19 vaccine is supplied in two multiple-dose vial presentations:
     - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
     - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
   - 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)

7. 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.

8. 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. Do not restart the primary series for any reason; resume the series with administration of the next dose. COVID-19 vaccines are NOT interchangeable: complete the series with the same product.

9. 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.

10. **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 or Moderna COVID-19 vaccine.
        - History of anaphylaxis due to any cause.
    - **15 minutes**: all other persons.

11. 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.

12. 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.

13. 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