Standing Order for Administering COVID-19 Vaccine (Pediatric)

Purpose: To reduce morbidity and mortality from SARS-CoV-2 infection by vaccinating all individuals 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) product labeling, and the Department of Defense (DOD).

Policy: Under this standing order, eligible health care professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Procedure:

- 1. Identify individuals 6 months 17 years of age who are eligible for 2024-2025 Formula COVID-19 vaccine.
- 2. Using <u>DD Form 3110</u>, screen all patients for contraindications and precautions to COVID-19 vaccine:

Contraindications:

- History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine is a contraindication to the same type of COVID-19 vaccine. These patients may be eligible to receive the alternate COVID-19 vaccine type with provider consultation.
- For information on vaccine components, refer to the package inserts or FDA Fact Sheets for <u>Moderna/Spikevax</u>, <u>Novavax</u>, <u>Pfizer-BioNTech/Comirnaty</u>, or <u>CDC guidance</u>.

Precautions:

- Moderate or severe acute illness with or without fever.
- History of a non-severe, immediate (onset < 4 hours) allergic reaction after a dose of COVID-19 vaccine or a diagnosed non-severe allergy to a COVID-19 vaccine component.
 - Allergic reactions are defined as:
 - ✓ Severe: known or possible anaphylaxis (e.g., urticaria, wheezing, difficulty breathing, or low blood pressure); airway angioedema (i.e., visible swelling of tongue, uvula, or larynx); diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome).
 - ✓ Non-severe: urticaria beyond the injection site; angioedema anywhere other than as described above.
 - These patients may receive the alternate COVID-19 vaccine type, if available.
- History of Multisystem Inflammatory Syndrome in Children (MIS-C).
- History of myocarditis or pericarditis within 3 weeks after a dose of any 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., 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 312-761-4245.

Special Populations:

• **Pregnancy and lactation:** COVID-19 vaccination is recommended for individuals who are pregnant, trying to get pregnant, might become pregnant in the future, and those who are breastfeeding.

Routine pregnancy testing before COVID-19 vaccine receipt is not required, and pregnancy need not be delayed after vaccination.

- **Immunocompromise:** Individuals who are or become <u>moderately or severely immunocompromised</u> should receive the COVID-19 vaccine and dosage appropriate for their age and immune status on the day of vaccination. COVID-19 vaccination should not be delayed in patients taking immunosuppressive therapies, however whenever possible:
 - Administer vaccine \geq 2 weeks before initiation or resumption of immunosuppressive therapies
 - For those receiving B-cell-depleting therapies on a continuing basis, administer vaccine approximately 4 weeks before the next scheduled therapy
- Received COVID-19 vaccine outside the U.S.: Everyone ≥ 6 months of age vaccinated outside the U.S. with any previous formulation should receive at least 1 age-appropriate dose of 2024-2025 Formula COVID-19 vaccine.
- 3. Prior to vaccine administration, provide all patients (or their parent/legal representative) with a copy of the current federal <u>Vaccine Information Statement (VIS)</u> or appropriate EUA-Fact Sheet for Vaccine Recipients and Caregivers. Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred.
- 4. Provide vaccine as follows:
 - Prior to administration, consult the manufacturer's package insert or EUA Fact Sheet for Healthcare Providers for storage, handling, and preparation instructions.
 - Administer the appropriate 2024-2025 Formula COVID-19 vaccine dose intramuscularly (IM) according to tables 1-3. [Although vial images are shown in these tables, many 2024-2025 Formula COVID-19 vaccines are only available in prefilled syringes.]
 - Interchangeability:
 - All individuals 6 months–4 years should receive all doses of 2024-2025 mRNA vaccine from the same manufacturer.
 - Ages 5 years and older who are unvaccinated and are moderately or severely immunocompromised should receive a 3-dose 2024-2025 mRNA initial series from the same manufacturer.
 - Ages 12 years and older who start their series with Novavax COVID-19 vaccine should complete the 2-dose initial series with Novavax. However, if > 8 weeks have elapsed since receipt of the first Novavax dose, any 2024-2025 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered.
 - COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended. A different, age-appropriate vaccine may be given when:
 - ✓ Same vaccine not available
 - ✓ Previous dose unknown
 - ✓ Person would otherwise not receive a recommended dose
 - ✓ Person now has a contraindication to the previous product
 - COVID-19 vaccine and other vaccines may be given simultaneously if there are no contraindications at the time of the healthcare visit, with one exception:
 - Smallpox/mpox vaccine (JYNNEOS) should be spaced from any mRNA COVID-19 vaccine dose by ≥ 28 days. However, if a patient's risk for mpox or severe disease due to COVID-19 is increased, administration of JYNNEOS and COVID-19 vaccines should not be delayed.
 - Additional vaccine doses for moderately or severely immunocompromised individuals:
 - Age 6 months to 4 years may receive 1 additional dose of 2024–2025 mRNA vaccine (from the same manufacturer as their initial series) ≥ 2 months following the last recommended 2024-2025 dose.
 - Age 5-17 years may receive 1 additional dose of 2024-2025 mRNA vaccine (regardless of the

manufacturer of the initial series) \geq 2 months following the last recommended 2024-2025 dose.

- Certain situations are not covered under this standing order. These patients must obtain a written order from a privileged provider:
 - History of MIS-C, myocarditis, or pericarditis
 - Vaccination of patients taking immunosuppressive therapies outside the dosing intervals described in "Special Populations".
 - Revaccination of immunocompromised patients who received COVID-19 vaccine during treatment (e.g., recipients of HCT, CAR-T-cell, or limited B-cell-depleting therapy).
 - Additional mRNA vaccine dose(s) may be considered for other persons with moderate or severe immunocompromise, spaced at least 2 months apart, in consultation with their healthcare providers.
 - Administration of > 4 doses of 2024-2025 Formula COVID-19 vaccine to any individual.

| TABLE 1. IM Needle Length and Injection Site Guide | | |
|---|--------------------------|------------------------|
| Use a 22 – 25-gauge needle. Choose needle gauge and length appropriate to the patient's age | | |
| Patient Age | Needle Length | Injection Site |
| Infants (1-12 months) | 1 inch (25 mm) | Anterolateral thigh |
| Toddlers (1-2 years) | 1-1.25 inch (25-32 mm) | Anterolateral thigh* |
| | 5/8†-1 inch (16-25 mm) | Deltoid muscle of arm |
| Children (3-10 years) | 5/8†-1 inch (16-25 mm) | Deltoid muscle of arm* |
| | 1-1.25 inches (25-32 mm) | Anterolateral thigh |
| Adolescents (11-17 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: <u>https://www.cdc.gov/vaccines/hcp/imz-best-practices/vaccine-administration.html</u>. * Preferred site

† If skin is stretched tightly and subcutaneous tissues are not bunched.

TABLE 2.* COVID-19 Vaccine Schedule by Age and History, 6 mos – 17 years of age, NOT immunocompromised







* Although vial images are shown in these tables, many 2024-2025 Formula COVID-19 vaccines are only available in prefilled syringes † If more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered.

TABLE 3.* COVID-19 Vaccine Schedule by Age and History, 6 mos – 17 years of age, immunocompromised



TABLE 3.* COVID-19 Vaccine Schedule by Age and History, 6 mos – 17 years of age, immunocompromised



* Although vial images are shown in these tables, many 2024-2025 Formula COVID-19 vaccines are only available in prefilled syringes † People in this age group who have received 1 dose of any Novavax vaccine should complete the 2-dose initial series with Novavax (dose 2 should be received 3 weeks after dose 1.). However, if more than 8 weeks have elapsed since receipt of the first dose of Novavax, any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) may be administered.

- 5. Document all immunizations 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, Vaccine Information Sheet (VIS) or VIS-equivalent date, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.
- 6. Observation all individuals who receive any COVID-19 vaccine must be monitored as follows:
 - **30 minutes:** individuals with:
 - Contraindication to a different type of COVID-19 vaccine
 - Non-severe, immediate (onset < 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
 - Diagnosed non-severe allergy to a component of the COVID-19 vaccine
 - Anaphylaxis after non-COVID-19 vaccines or injectable therapies
 - 15 minutes: all other individuals
- 7. 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.

- 8. Adverse Events Following Immunization
 - These events are **required** to be reported in the Vaccine Adverse Event Reporting (VAERS):
 - Shoulder Injury Related to Vaccine Administration within 2 days after vaccination
 - Vasovagal syncope within 1 hour after vaccination
 - Any severe allergic reaction, including anaphylaxis, after vaccination
 - Any acute complication or sequelae (including death) after vaccination
 - In addition, the following events are required to be reported in VAERS after any COVID-19 vaccination administered under EUA:
 - Vaccine administration errors, whether or not associated with an adverse event
 - Serious adverse events regardless of causality; these include death, life-threatening event, inpatient hospitalization, any event that disrupts ability to conduct normal life functions, congenital anomaly/birth defect, any event that may require medical or surgical intervention to prevent one of the outcomes listed above
 - Multisystem Inflammatory Syndrome (MIS) in children and adults
 - Myocarditis or pericarditis
 - SARS-CoV-2 infection that results in hospitalization or death
 - All other adverse events or vaccination errors are encouraged to be reported in VAERS, although not required to be reported in VAERS
 - VAERS reports are submitted <u>online</u>.
 - Vaccination errors must additionally be reported to Joint Patient Safety Reporting (JPSR) system.
 - Questions about response to adverse events or vaccination errors may be directed to DHA Immunization Healthcare Support Center at 877-438-8222 or DSN 312-761-4245.
- 9. V-safe option
 - Persons who receive COVID-19 vaccines may optionally self-enroll in <u>CDC's v-safe program</u>, a smartphone-based system for monitoring vaccine safety.
- 10. This standing order must be signed by a privileged physician with medical oversight over the clinic or activity administering immunizations. It is valid for one year from the date of signature and remains in effect for all patients of the ______ until rescinded, expired, or upon a change in the privileged physician, whichever is earlier.

Privileged Physician's Signature

Date