Standing Order for Administering Pfizer-BioNTech COVID-19 Vaccine (Pediatric 5 - 11 years of age)

Purpose: To reduce morbidity and mortality from COVID-19 caused by SARS-CoV-2 by vaccinating all individuals 5 -11 years of age (5-11y) 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. Pfizer-BioNTech Monovalent COVID-19 vaccine is FDA-authorized under EUA for individuals 5-11y as:
   - A 2-dose primary series.
   - A third primary series dose for individuals who are moderately or severely immunocompromised.
2. Pfizer-BioNTech Bivalent COVID-19 vaccine is FDA-authorized under EUA as a single booster dose for individuals 5-11y after completion of either a primary series with any authorized or approved COVID-19 vaccine, or receipt of a monovalent booster with any authorized or approved COVID-19 vaccine. 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. Pfizer-BioNTech 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 Pfizer-BioNTech Bivalent COVID-19 vaccine for individuals 5-11y can be used for **booster doses only**.*
- *The Pfizer-BioNTech COVID-19 vaccines for individuals 5-11y are distinctly different preparations than the Pfizer-BioNTech COVID-19 vaccines for other age groups. Ensure you are utilizing the correct standing order and product for your patient.*
- *CDC's standard guidance to administer the vaccine product and dosage based on age on the day of vaccination does **NOT** apply to this age group. Individuals who transition from 4 years to 5 years of age during the Pfizer-BioNTech primary series must complete the series they start, and may receive either:*
  - *The 3-dose primary series recommended for children ages 6m - 4y **or***
  - *The 2-dose primary series recommended for children ages 5 - 11y*
- *Individuals who will transition from 11 years to 12 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 Pfizer-BioNTech COVID-19 vaccine, to include polysorbate (see the FDA fact sheets for Pfizer-BioNTech and Pfizer-BioNTech 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:

- **Pregnancy & Lactation:** Staying up to date with COVID-19 vaccination (completed a primary series and received the most recent recommended booster dose) is recommended for individuals who are pregnant, trying to get pregnant, might become pregnant in the future, and who are breastfeeding. Data on the safety and effectiveness of COVID-19 vaccination indicates that the benefits of vaccination outweigh any potential risks during pregnancy. Encourage individuals vaccinated during pregnancy to enroll in the Pfizer-BioNTech/COMIRNATY® COVID-19 Pregnancy Registry (see registry information in Section 8.1 on page 18 of the package insert) and the CDC v-safe surveillance system. Routine pregnancy testing before receipt of COVID-19 vaccine is not required, and pregnancy need not be delayed after vaccination.
- **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 Pfizer-BioNTech COVID-19 vaccine as follows:

Table 1: Dosing intervals, 5-11y				
COVID-19 Vaccine Product	**Number of primary doses**	**Interval: 1st and 2nd primary dose**	**Interval: 2nd and 3rd primary dose**	**Interval: primary series or last monovalent booster and bivalent booster dose***
Pfizer-BioNTech & Pfizer-BioNTech Bivalent				
• **Immunocompetent**	2	3 - 8 weeks†	NA	≥ 2 months
• **Immunocompromised**	3	3 weeks	≥ 4 weeks	≥ 2 months

* Bivalent booster recommended for all individuals ≥ 5 years of age, regardless of the number of previous monovalent booster doses received.

† 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 3-week interval (Pfizer) 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 0.2mL 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**
Children, 3-10 years	5/8*-1 inch (16-25 mm)	Deltoid muscle of arm†
	1-1.25 inches (25-32 mm)	Anterolateral thigh
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: 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 (see graphics on page 5):
   - **DILUTE BEFORE USE.**
   - After dilution, one vial contains 10 doses of 0.2mL.
   - Frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF) for up to 18 months from the date of manufacture.
   - Alternatively, undiluted vials may be thawed and stored in a refrigerator at 2°C to 8°C (35ºF to 46ºF) for up to 10 weeks. Cartons may take up to 4 hours to thaw at this temperature.
   - Once thawed, **do not refreeze.**
   - **Do not store vials at -25°C to -15°C (-13°F to 5°F).**
   - If not previously thawed at 2ºC to 8ºC, allow vials to thaw at room temperature (8°C to 25°C [46°F to 77°F]) for 30 minutes prior to use: vials must reach room temperature before dilution.
   - Vials may be stored at room temperature for a total of 12 hours prior to dilution.
   - Dilute vaccine as follows:
     - Allow thawed vial to sit at room temperature (up to 25ºC) for 30 minutes.
     - Gently invert vaccine vial 10 times prior to dilution; **do not shake**.

- Withdraw **1.3mL** of diluent (use sterile non-bacteriostatic 0.9% sodium chloride injection USP only) using a 21 gauge or narrower needle and aseptic technique.
- Add diluent to the vaccine vial; equalize vial pressure before removing the needle by withdrawing 1.3 mL of air into the empty diluent syringe.
- Gently invert the vaccine vial 10 times; **do not shake.**

- Mark vials of diluted vaccine with the dilution date and time.
- Diluted vaccine should be stored at 2°C to 25°C (35°F to 77°F) and discarded 12 hours after dilution.
- Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the product-specific EUA Fact Sheet supersedes the number of hours printed on vial labels and cartons.
- Do not pool excess vaccine from multiple vials.
- Regardless of storage condition, vaccines should not be used beyond 18 months from the date of manufacture printed on the vial and cartons.

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 of vaccines by having a written emergency medical protocol available, as well as equipment and medications.

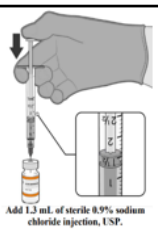
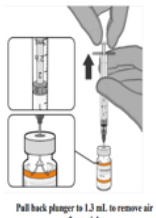
13. It is **MANDATORY** for vaccination providers to file a report with the Vaccine Adverse Event Reporting System (VAERS) for all vaccine administration errors; all serious adverse events; cases of myocarditis, pericarditis, or Multisystem Inflammatory Syndrome (MIS) in adults or children; and hospitalized 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

Dilution and Preparation Instructions	
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – VIAL VERIFICATION	
 ✓ **Orange plastic cap and label with orange border.**	Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine: • has an orange cap and a label with an orange border, • states "Age 5y to < 12y.", and • states "Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)" if administering a booster dose
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border – THAWING PRIOR TO DILUTION	
 **Store in the refrigerator for up to 10 weeks prior to use.**	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: ○ Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks. ○ Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes. ○ Vials may be stored at room temperature [up to 25ºC (77ºF)] for 12 hours prior to use.

Dilution and Preparation Instructions	
 Gently × 10	• Before dilution, mix by inverting vaccine vial gently 10 times: **do not shake** • Inspect the liquid in the vial prior to dilution: it is a white to off-white suspension and may contain opaque amorphous particles • Do not use if liquid is discolored or if other particles are observed
 Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.	• Use only sterile 0.9% Sodium Chloride Injection, USP as the diluent • Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (using a 21-gauge or narrower needle) • Cleanse the vaccine vial stopper with a single-use antiseptic swab • Add 1.3 mL of diluent into the vaccine vial
 Pull back plunger to 1.3 mL to remove air from vial.	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe • Gently invert the vial and inspect as above: **do not shake**
 Record the date and time of dilution. Use within 12 hours after dilution.	• Record the date and time of dilution on the vial label • Store between 2°C to 25°C (35°F to 77°F) • Discard any unused vaccine 12 hours after dilution