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 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. Pfizer-BioNTech COVID-19 vaccine is FDA-authorized under EUA for individuals 5 – 11 years of age as:
   - A 2-dose primary COVID-19 vaccine series.
   - A third primary COVID-19 vaccine series dose for individuals who are moderately or severely immunocompromised.
   - One homologous booster dose for individuals who have completed a primary COVID-19 series with this vaccine. (See Table 1 for dosing intervals.)
2. Pfizer-BioNTech 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 Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 vaccine for individuals 5-11 years of age (multiple dose vials with an **orange cap and label**) is a distinctly different preparation than the other Pfizer-BioNTech/COMIRNATY® COVID-19 vaccines (**maroon cap/label** for 6 months – 4 years of age; **gray cap/label** or **purple cap/label** for adults ≥ 12 years of age).* ***Ensure you are utilizing the correct product and standing order for your patient.***
- *Individuals who will turn from 11 years to 12 years of age between doses in the **primary series** may receive **for any primary series dose**: (1) Pfizer-BioNTech COVID-19 vaccine formulation for use in individuals 5-11 years of age (10mcg/0.2 mL dose from the vial with an **orange cap**);* ***OR*** *(2) Pfizer-BioNTech/COMIRNATY® vaccine authorized for use in individuals ≥ 12 years of age (30mcg/0.3 mL dose from a vial with a **gray cap** or **purple cap**).*

4. Using DHA Form 236, 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).
- **COVID-19 Vaccine Clinical Trial Participants:** Unless they have received or plan to receive a booster dose through a clinical trial, participants 5 – 11 years of age (including moderately or severely immunocompromised people who received an additional primary dose) who completed a primary series of a WHO-EUL COVID-19 vaccine (not a placebo) can receive a single COVID-19 vaccine booster dose. These individuals should confer with their trial POCs before vaccination.

5. Provide all patients (or their parent/legal representative) with a copy of the Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 vaccine as follows:

Table 1. COVID-19 vaccine dosing intervals

Patient Immune Status	# of primary doses	# of booster doses	Interval: 1st and 2nd primary dose	Interval: 2nd and 3rd primary dose	Interval: primary series and booster dose
Pfizer-BioNTech (5 - 11 years)					
Immunocompetent	2	1	3 weeks	NA	≥ 5 months
Immunocompromised	3	1	3 weeks	≥ 4 weeks	≥ 3 months

- Using a sterile needle and 1mL syringe, administer 0.2mL of appropriately diluted vaccine intramuscularly in the deltoid muscle. 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.
- A 2nd or 3rd primary dose administered earlier than allowed by the grace period (17 days for primary dose #2 or 24 days for primary dose #3) 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.
- Booster doses administered prior to the minimum interval do not need to be repeated.

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 - Vaccine Administration: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html

* 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 with **orange caps/labels**:
  - **DILUTE BEFORE USE**.
  - After dilution, one vial contains 10 doses of 0.2mL.
  - 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.
  - Once thawed, **do not refreeze**.
  - Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF) for up to 12 months from the date of manufacture.
  - **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 (see graphic on pages 5-7):
    - 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 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 12 months from the date of manufacture printed on the vial and cartons.

Note:

*The Pfizer-BioNTech COVID-19 vaccine for children ages 5-11 years that is supplied in multiple dose vials with **orange caps/labels** requires a **different dilution volume** than used to dilute the Pfizer-BioNTech/COMIRNATY COVID-19 vaccine used in adults (**purple cap/label** for individuals ≥ 12 years of age). Ensure Pfizer-BioNTech COVID-19 vaccine for children ages 5-11 years that is supplied in multiple dose vials with **orange caps/labels** **is diluted with 1.3mL.***

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.

8. 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 Pfizer-BioNTech COVID-19 vaccine in 5-11 year olds is 218.

9. **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.

10. 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.

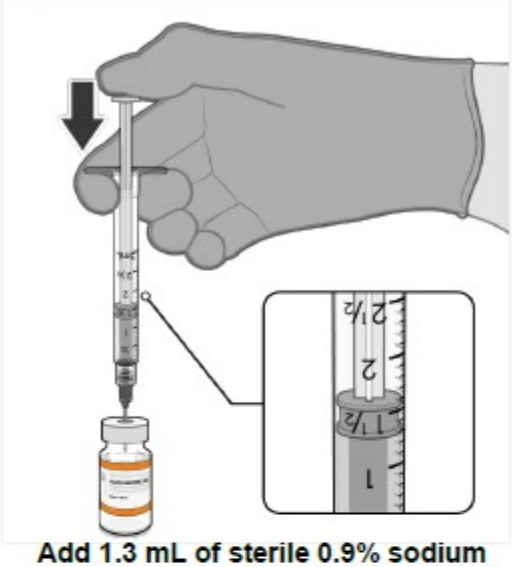
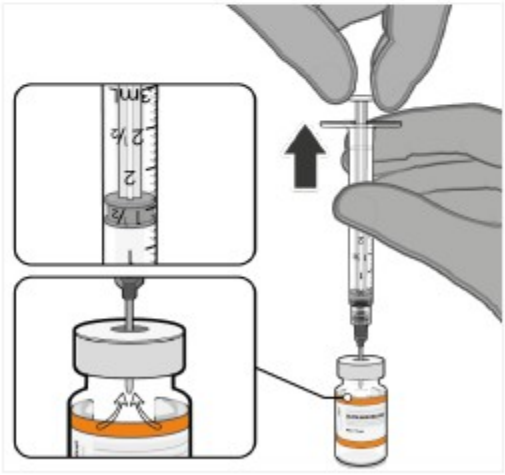
11. It is **MANDATORY** for vaccination providers to file a report with the Vaccine Adverse Event Reporting System (VAERS) for all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome in adults (MIS-A) or children (MIS-C), and hospitalized or fatal cases 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).
12. 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.

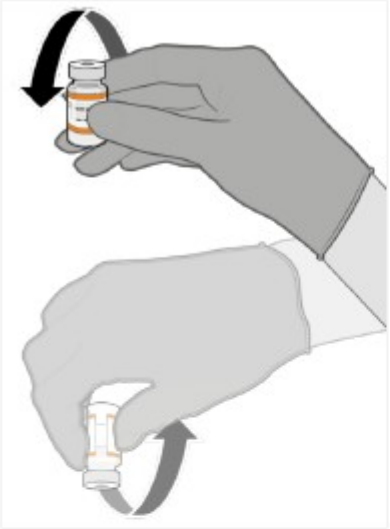
_____ _____

Medical Director's Signature Date

Dilution and Preparation Instructions	
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and a 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 plastic cap and a label with an orange border and states "Age 5y to < 12y."
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: o 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. o Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes. o Vials may be stored at room temperature [up to 25ºC (77ºF)] for up to 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. The liquid 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.

Dilution and Preparation Instructions	
Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and Label with Orange Border - DILUTION	
 **Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.**	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP 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.

Dilution and Preparation Instructions	
 **Gently × 10**	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
 **Use within 12 hours after dilution.**	• Record the date and time of first vial puncture on the vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 12 hours after dilution.