**TITLE: BVP COVID -19 Standard Operating Procedures**

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| **Authorized by** |  |  |
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| **Effective Date** |  |  |

1.0 PURPOSE 1.1

The purpose of this standard operating procedure (SOP) is to establish requirements for ordering, receiving, storing, and administering COVID-19 vaccine

2.0 SCOPE 2.1

This procedure applies to all pharmacy personnel, including but not limited to technicians, externs, and pharmacists, at

3.0 RESPONSIBILITY

3.1 The Vaccine Coordinator shall supervise this procedure.

3.2 The secondary Vaccine coordinator shall supervise if the primary coordinator is unavailable

4.0 REFERENCES

4.1 CPESN - CDC CDC’s Vaccine Storage & Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit. pdf)

5.0 DEFINITIONS

5..1 DDL- Digital Data logger

6.0 FREQUENCY 6.1 The SOP must be reviewed annually, when a new vaccine is ordered, a new employee is hired including temporary staff

**A. Vaccine Coordinator Responsibilities**

1. Designate a **Vaccine Coordinator (Primary and Secondary)**. This person may be a pharmacist, pharmacy technician, or other individual on staff at the pharmacy an overview of responsibilities for the Primary Vaccine Coordinator
   1. Ordering vaccines
   2. Overseeing proper receipt and storage of vaccine deliveries
   3. Documenting vaccine inventory information
   4. Organizing and monitoring vaccines within storage units, including rotating stock and removing expired vaccines
   5. Setting up temperature monitoring devices (TMDs) and recording daily temperatures
   6. Responding to temperature excursions (out-of-range temperatures) and equipment failures
   7. Checking and recording minimum/maximum temperatures at start of each workday‡
   8. Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
   9. Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
   10. Removing expired vaccine from storage units
   11. Responding to temperature excursions (out-of-range temperatures) •
   12. Maintaining all documentation, such as inventory and temperature logs
   13. Organizing vaccine-related training and ensuring staff completion of training
   14. Monitoring operation of vaccine storage equipment and systems •
   15. Overseeing proper vaccine transport (when necessary) —
   16. Tracking inclement weather conditions§ —
   17. Ensuring appropriate handling of vaccines during a disaster or power outage||
   18. Overseeing emergency preparations
2. Checklist for Vaccine Coordinator
   1. Complete the required trainings.
   2. Understand the Distribution of the Vaccine
   3. Become familiar with ancillary supplies and PPE provided by the CDC
   4. Begin to think through other supplies that the pharmacy may need.
   5. Understand the Vaccine Storage requirements.
   6. Review your pharmacy’s storage capabilities.
   7. Create a Storage and Handling Standard Operating Procedure.
   8. Understand Digital Data Logger Requirements
   9. Ensure that all staff are trained on Immtrac 2
   10. Understand how to use the Vaccine Finder,
   11. Determine which individuals will be administering the COVID -19 Vaccine

**B. Staff Training**

* 1. Part of new employee orientation
  2. Annually as a refresher
  3. Whenever new vaccine is added to the inventory
  4. Whenever the recommendations for storage and handling are updated
  5. Training certificates must be sent to Jason Carter

**Required Trainings**

1. You Call the Shots: Vaccine Storage and Handling - Module 10 <https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp>
2. COVID-19 Vaccine Training Module

<https://www2.cdc.gov/vaccines/ed/covid19/SHVA/index.asp>

1. 3 hours of Immunization specific CE annually

**C. Routine Vaccine Storage and Handling**

* Monitoring storage unit and temperature
* Maintaining storage equipment and TMDs
* Responding to storage and handling problems

**Proper Vaccine Storage Temperature ranges**

1. Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F).
2. Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F).
3. Room temperature where unit is stored should be 20° C and 25° C (68° F and 77° F).

Frozen vaccines should never be placed in the freezer compartment of a standalone household-grade unit.

Ensure proper air circulation around the outside of the storage unit, leaving space between the unit, ceiling and wall

For household style units - Place water bottles on the top shelf and floor and in the door racks. Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure. Label water bottles “DO not Drink “

**Power Supply**

1. Plug in only one storage unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power of.
2. Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged
3. Post “DO NOT UNPLUG” warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers not to unplug units
4. Label fuses and circuit breakers to alert people not to turn of power to a storage unit
5. Use caution when using power outlets that can be tripped or switched off

**Digital Data logger DDL**

1. Maintain a current and valid certificate of calibration
2. Maintain a backup DDL in case of a broken or malfunctioning device
3. Maintain a DDL for each transport unit
4. Place the buffered probe of the DDL in the center of the unit with the vaccine surrounding it.
5. Review storage unit temperature readings and review continuous DDL software or website information **weekly** for changes in temperature trends that might require action
6. Check and record storage unit minimum and maximum temperatures **at the start of each workday.** Record:
   1. • Minimum/maximum temperature
   2. • Date • Time
   3. • Name of person who checked and recorded the temperature
   4. • Any actions taken if a temperature excursion occurred
   5. If a reading is missed leave the entry blank
7. Keep the data for **three years** so they can be analyzed for long-term trends and/or recurring problems. Those receiving public vaccine may need to keep records longer as required by state regulations.

Temperature log sheet for refrigerator-<https://www.immunize.org/catg.d/p3037c.pdf>

Temperature log sheet for freezer- <https://www.immunize.org/catg.d/p3038c.pdf>

**Organizing and Storing Vaccine**

To confirm vaccines are stored correctly and to minimize the risk of administration errors, implement the following practices:

1. Store each type of vaccine or diluent in its original packaging and in a separate container.
2. Store vaccines in the middle of the refrigerator Position vaccines and diluents two to three inches from the unit walls, ceiling, floor, and door. If using a household grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in deli, fruit, or vegetable drawers, or on refrigerator door shelves. The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures.
3. Label shelves and containers to clearly identify where each type of vaccine and diluent is stored.
4. Store vaccines and diluents with similar packaging or names or with pediatric and adult formulations on different shelves.
5. » Whenever possible, store diluent with the corresponding refrigerated vaccine. Never store diluent in a freezer.
6. Do not store any food or drink in any vaccine storage unit.
7. Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.
   1. • If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccines. — Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks. — The freezer of a household-grade unit may be used for non-vaccine, medical storage, so long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.
   2. Arrange vaccines and diluents in rows and allow space between them to promote air circulation.
   3. Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates.

**Temperature Excursion**

1. Any staff who hears an alarm or notices a temperature excursion on the DDL should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor.
2. Notify staff by labeling exposed vaccines "DO NOT USE" and placing them in a separate container apart from other vaccines (do not discard these vaccines).
3. The vaccine coordinator, supervisor, or if necessary, the person reporting the problem should begin to document the event with the following information:

* a. Date and time of the temperature excursion
* b. Storage unit temperature as well as room temperature, if available (including minimum/maximum temperatures during the time of the event, if available)
* c. Name of the person completing the report and description of the event||:
  + — General description of what happened
  + — The length of time vaccine may have been affected, if using a DDL
  + — Inventory of affected vaccines
  + — List of items in the unit (including water bottles) other than vaccines
  + — Any problems with the storage unit and/or affected vaccines before the event
  + — Other relevant information

1. Complete your documentation of the event, including:
   1. Action taken — What you did with vaccine and how long it took to act — Whom you contacted, and instructions received — What you did to prevent a similar future event
   2. Results — Final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned) — Other comments

Vaccine storage Troubleshooting form - <https://www.immunize.org/catg.d/p3042.pdf>

**D. Vaccine Inventory Management**

* Ordering and accepting vaccine deliveries
* Unpacking deliveries
* Managing inventory
* Storing each vaccine and diluent
* Placing vaccines and diluents in storage units
* Handling vaccines prior to administration
* Disposing of vaccines and supplies

**1.Vaccine Delivery -**Scheduling and Receiving Deliveries

**Never leave a vaccine shipping container unpacked and unattended**.

* Vaccine deliveries require immediate attention: checked and stored properly upon arrival.
* Maintaining the cold chain is the first step in vaccine inventory management.
* Immediately notify the vaccine coordinator or alternate coordinator when deliveries arrive.

**Unpacking Deliveries**

* Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after they arrive.
* Do not place an unopened and/or unpacked shipment box in a vaccine storage unit

**Immediately examine** shipments for signs of damage and to guarantee receipt of the appropriate vaccine types and quantities

* Examine the shipping container and vaccines for signs of physical damage.
* Check the contents against the packing list to be sure they match. For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date.
* If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents.
* Immediately check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
* Immediately check the cold chain monitor (CCM), a device used to monitor vaccine temperatures during transport (if one was included) for any indication of a temperature excursion during transit

**2.Vaccine Inventory Accounting Stock Counts**

Maintain a vaccine inventory log that will be used to document the following:

a. Vaccine name and number of doses received

b. Date we received the vaccine

c. Condition of vaccine when we received it

d. Vaccine manufacturer and lot number

e. Vaccine expiration date

**3.Vaccine Ordering-**

Order and stock only enough vaccine to meet patient needs.

4. **Stock Rotation** and Removal Vaccine stock should be rotated and checked for expired doses regularly. Any expired vaccines and diluents should be removed immediately to avoid inadvertently administering them

**A Beyond Use Date (BUD) should be written on a vaccine bottle after**

* A diluent is added
* After thawing a frozen or ultra-frozen vaccine
* Refer to the manufactures guide for BUD guidance.

**Vaccine Disposal**

Report to your vaccine or backup vaccine coordinator-

* Expired Vaccine-
* Compromised or broken vaccines bottles
* Empty vaccine vials

**E. Vaccine Preparation**

* Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
* Only prepare vaccines when you are ready to administer them.
* Always check expiration dates and confirm that you have selected the correct vaccine.
* Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration.

**Single Dose vial**

* Only open an SDV when ready to use.
* Before you remove the protective cap, always check the vial to make sure you have the correct vaccine.
* Once you remove the cap, you must use the vaccine because it may not be possible to determine if the rubber seal has been punctured.
* Discard any unused SDVs without a protective cap at the end of the workday.

**Multidose vials**

* Only the number of doses indicated in the manufacturer’s package insert should be withdrawn from the vial.
* After the maximum number of doses has been withdrawn, the vial should be discarded, even if there is residual vaccine or the expiration date has not been reached
* Never use partial doses from two or more vials to obtain a dose of vaccine.

**Manufacturer-Filled Syringes**

* Once the sterile seal has been broken, the vaccine should be used or discarded by the end of the workday.

**Reconstitution of Vaccine**

* Refer to the manufacturer’s package insert for guidance on storage and handling

**Predrawing Vaccine**

* Draw up vaccines only at the time of administration.
* Pre-drawn syringes must be stored at the manufacturer recommended temperatures throughout the clinic day

**Rare instances when the only option is to predraw vaccine.**

* Draw up no more than one MDV or 10 doses at one time
* Predraw reconstituted vaccine into a syringe only when you are ready to administer it.
* If a predrawn vaccine is not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits.
* Discard any remaining vaccine in pre-drawn syringes at the end of the workday.
* Never transfer predrawn reconstituted vaccine back into a vial for storage
* As an alternative to pre-drawing vaccines, use manufacturer filled syringes for large vaccination clinics.

**F. Vaccine Transport**

Transport, as described in this section, involves the movement of vaccine between providers or other locations over a short distance and time frame and is appropriate for events such as an emergency or off-site clinic or to ensure vaccines that are about to expire can be used rather than wasted.

* The total time for transport alone or transport plus clinic workday should be a **maximum of 8 hours** (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).
* Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.
* Your facility should have a sufficient supply of materials needed for vaccine transport of your largest annual inventory. Appropriate materials include:
  + Portable vaccine refrigerator/freezer units (preferred option)
  + Qualified containers and packouts
  + Hard-sided insulated containers or Styrofoam™ (Use in conjunction with the Packing Vaccines for Transport during Emergencies† tool. This system is only to be used in an emergency.)
  + Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to 4° C to 5° C
  + Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container
  + TMDs for each container
* Open unit doors only when necessary and only after completing all preparation for packing and moving vaccines
* Check vaccine temperature upon arrival at the alternative vaccine storage facility and store vaccines at recommended temperatures immediately.
* **Do not use** commercially available soft-sided food or beverage coolers
* **Do not use frozen gel packs or coolant packs** from original vaccine shipments to pack refrigerated vaccines. They can still freeze vaccines even if they are conditioned or appear to be “sweating.”
* **Do not leave** containers in areas where they are exposed to direct sunlight.

**Transporting Frozen Vaccines**

* If frozen vaccines must be transported, use a portable vaccine freezer unit or qualified container, and pack out that maintains temperatures between -50° C and -15° C (-58° F and +5° F).

**Follow these steps for transporting frozen vaccines**:

* Place a TMD (preferably with a buffered probe) in the container as close as possible to the vaccines.
* Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at a temperature range between -50° C and -15° C (-58° F and +5° F). Any stand-alone freezer that maintains these temperatures is acceptable.
* Record the time vaccines are removed from the storage unit and placed in the transport container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.

**Temperature Monitoring During Transport**

* Use a continuous TMD, preferably a DDL, for monitoring and recording temperatures while transporting vaccines:
* The TMD should have an accuracy of +/-0.5° C (+/-1° F).
* Place buffered probe material in a sealed vial directly with the vaccines.
* Keep the TMD display on top of vaccines so you can easily see the temperature.

**Do not use dry ice, even for temporary storage. Dry ice might expose the vaccines to temperatures colder than -50° C (-58° F).**

**G. Emergency Vaccine Storage and handling**

**Emergency Equipment Backup Options Alternative Storage Facility**

* Contact emergency storage facility (closest Best Value Pharmacy) - ensure that you have 24-hour access including after hours
* A generator and backup equipment - checked annually
* Keep on hand and emergency kit with
  + Spare batteries
  + Flashlights
  + Keys
  + Locks
  + Map location of Circuit breakers
  + Emergency transport equipment and materials

1. If vaccines are **exposed to improper storage conditions**, take the following steps:

* Restore proper storage conditions as quickly as possible.
* If necessary, label the vaccine **“Do Not Use”** and move it to a unit where it can be stored under proper conditions.
* Do not discard the vaccine before discussing the circumstances with our state/local health department and/or the appropriate vaccine manufacturers.

b. **Follow the Vaccine Storage Troubleshooting Record’s** (www.immunize.org/catg.d/p3041.pdf) instructions for taking appropriate action and documenting the event. This includes recording details such as the length of time the vaccine was out of appropriate storage temperatures and the current room temperature, as well as taking an inventory of affected vaccines.

c. Contact your Pharmacy Manager to report the incident. Contact the state/local health department and/or the appropriate vaccine manufacturers for consultation about whether the exposed vaccine can still be used.

d. We address the storage units mechanical or electrical problems according to guidance from the unit’s manufacturer or a qualified repair service.

e. In responding to improper storage conditions, we do not make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.

f. We do not use exposed vaccines until our state/local health department immunization program, or the vaccine manufacturer has confirmed that the vaccine is acceptable for use. We review this information with our clinic medical director before returning the vaccine to our supply. If the vaccine is not acceptable for use, we follow our state/local health department instructions for vaccine disposition.

**I. Requirements and Instructions for Reporting ADR and Vaccine Administration Errors**

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for **MANDATORY** reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the **Vaccine Adverse Event Reporting System (VAERS):** Revised: 12/2020 23

* Vaccine administration errors whether associated with an adverse event Serious adverse events\* (irrespective of attribution to vaccination)
* Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults Cases of COVID-19 that result in hospitalization or death
* Serious adverse events are defined as:
  + Death A life-threatening adverse event
  + Inpatient hospitalization or prolongation of existing hospitalization
  + A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  + A congenital anomaly/birth defect
  + An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

1. Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
2. If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or
3. send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

* Patient demographics (e.g., patient name, date of birth)
* Pertinent medical history
* Pertinent details regarding admission and course of illness Concomitant medications
* Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine Pertinent laboratory and virology information
* Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report.
* Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in

* Box 22 provide information on any other vaccines received within one month prior.

2. In Box 18, description of the event:

a. Write “Pfizer-BioNTech COVID-19 Vaccine EUA” as the first line.

* + b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above. Revised: 12/2020 24

3. Contact information:

a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.

b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.

c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider’s office address). Other Reporting Instructions Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above. To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc. Website Fax number Telephone number www.pfizersafetyreporting.com 1-866-635-8337 1-800-438-1985

**V-safe**

Provide all patients with a V-safe information sheet **V-Safe info sheet for the patient-** [**v-safe information sheet**](https://458rl1jp.r.us-east-1.awstrack.me/L0/https:%2F%2Fdshs.texas.gov%2Fimmunize%2Fcovid19%2Fvsafe_info_sheet.pdf/1/010001766734f76b-5ccc6b2d-18b7-43f8-a6cc-7d4c28d9d20b-000000/uMHH5RpKG_us1P6elUXzXruM_-Q=192)

Direct pts to download the V-safe app **V-Safe** [**https://vsafe.cdc.gov/**](https://vsafe.cdc.gov/)

**VEARS online reporting -** [**VAERS-**](https://www2.cdc.gov/vaccines/ed/covid19/SHVA/40000.asp) [**https://vaers.hhs.gov/esub/index.jsp**](https://vaers.hhs.gov/esub/index.jsp)

**J. Preparing for Anaphylaxis**

## **Observation period following COVID-19 vaccination**

CDC currently recommends that persons who receive a Pfizer-BioNTech COVID-19 vaccine be observed after vaccination for the following time periods:

* Persons with a history of anaphylaxis (due to any cause): 30 minutes
* All other persons: 15 minutes

A clinical provider with access to the emergency equipment should be immediately available to assess and manage anaphylaxis.

|  |  |
| --- | --- |
| **Should be available at all sites** | **If feasible, include at sites (not required)** |
| Epinephrine prefilled syringe or autoinjector\* | Pulse oximeter |
| H1 antihistamine (e.g., diphenhydramine) † | Oxygen |
| Blood pressure cuff | Bronchodilator (e.g., albuterol) |
| Stethoscope | H2 antihistamine (e.g., famotidine, cimetidine) |
| Timing device to assess pulse | Intravenous fluids |
|  | Intubation kit |
|  | Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask) |

\*COVID-19 vaccination sites should have at least 3 doses of epinephrine on hand at any given time.

†Antihistamines may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to persons with impending airway obstruction.

## **Management of anaphylaxis at a COVID-19 vaccination site**

If anaphylaxis is suspected, take the following steps:

* Rapidly assess airway, breathing, circulation, and mentation (mental activity).
* Call for emergency medical services.
* Place the patient in a supine position (face up), with feet elevated, unless upper airway obstruction is present, or the patient is vomiting.
* Epinephrine (1 mg/ml aqueous solution [1:1000 dilution]) is the first-line treatment for anaphylaxis and should be administered immediately.
  + In adults, administer a 0.3 mg intramuscular dose using a premeasured or prefilled syringe, or an autoinjector in the mid-outer thigh.
  + The maximum adult dose is 0.5 mg per dose.
  + Epinephrine dose may be repeated every 5-15 minutes (or earlier) as needed to control symptoms while waiting for emergency medical services.
  + Because of the acute, life-threatening nature of anaphylaxis, there are no contraindications to epinephrine administration.

Antihistamines (e.g., H1 or H2 antihistamines) and bronchodilators do not treat airway obstruction or hypotension, and thus are not first-line treatments for anaphylaxis.

## Reporting of anaphylaxis

Any adverse events that occur in a recipient following COVID-19 vaccination, including anaphylaxis, should be reported to the Vaccine Adverse Event Reporting System (VAERS)o

**K. Pfizer and ModernaCOVID-19 Vaccine Information**

**Vaccine video clips -** [**https://www.cvdvaccine-us.com/product-storage-and-dry-ice**](https://www.cvdvaccine-us.com/product-storage-and-dry-ice)

1. **Shipping & Handling,**
2. **Preparation and Administration,**
3. **Returning the Thermal Shipping Container**

**Pfizer -Fact Sheets**

[**Pfizer EUA Fact Sheet for Vaccination Providers**](https://458rl1jp.r.us-east-1.awstrack.me/L0/https:%2F%2Fwww.fda.gov%2Fmedia%2F144413%2Fdownload/1/010001765f3c04b4-b1a149e3-b594-45b2-9de4-7a0ae7b641cf-000000/TVBBHh16c-i44nGjrf5P44xR0Nw=192)

[**Pfizer EUA Fact Sheet for Vaccine Recipients and Caregivers**](https://458rl1jp.r.us-east-1.awstrack.me/L0/https:%2F%2Fwww.fda.gov%2Fmedia%2F144414%2Fdownload/1/010001765f3c04b4-b1a149e3-b594-45b2-9de4-7a0ae7b641cf-000000/db_aWQDXRtYe7qkMe-yOHzIQXUg=192)

## **Moderna COVID-19 Vaccine EUA Fact Sheet** for Healthcare Providers <https://www.fda.gov/media/144637/download>

## Moderna COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers <https://www.fda.gov/media/144638/download>

**ACIP COVID-9 Vaccine Recommendations -https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html**

**V-Safe info sheet for the patient-** [**v-safe information sheet**](https://458rl1jp.r.us-east-1.awstrack.me/L0/https:%2F%2Fdshs.texas.gov%2Fimmunize%2Fcovid19%2Fvsafe_info_sheet.pdf/1/010001766734f76b-5ccc6b2d-18b7-43f8-a6cc-7d4c28d9d20b-000000/uMHH5RpKG_us1P6elUXzXruM_-Q=192)

**V-Safe online** [**https://vsafe.cdc.gov/**](https://vsafe.cdc.gov/)

**VEARS online reporting -** [**VAERS-**](https://www2.cdc.gov/vaccines/ed/covid19/SHVA/40000.asp) [**https://vaers.hhs.gov/esub/index.jsp**](https://vaers.hhs.gov/esub/index.jsp)

**Monitor Pts for the Following ADR**

**Severe ADRS**

Multisystem inflammatory Syndrome (MIS), Bell’s Palsy, Appendicitis

**Non-Severe ADRS**

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

**Management of Acute Allergic Reactions**

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction VID-19 Vaccine. See CDC specific guidance for Provider response to Anaphylaxis.

The [Pfizer-BioNTech COVID-19 Vaccine Standing Orders Template](https://458rl1jp.r.us-east-1.awstrack.me/L0/https:%2F%2Fwww.texaspharmacy.org%2Fresource%2Fresmgr%2Fpractice%2F321570-H_Pfizer_StandingOrde.pdf/1/0100017676609aa2-a0037b15-22bf-461b-96af-1d2b3a0b663c-000000/ln_QTRA-8C7w9Ywb5Y2Bk9vnSiE=193) includes the anaphylaxis guidance.

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>

**Workflow Process y** that occur in a recipient following COVID-19 vaccination, including a

**Online Screening**

* Direct pts to fill out an online COVID-19 screening form which will include the following
  + COVID-19 specific VAR
  + HIPPA consent forms
  + Vaccine immTrac Consent forms
  + Insurance card
  + EUA Fact sheet

**Appointment**

* Direct pts to make an appointment no sooner than 3 days for the 1st dose and 21 days (or 28) thereafter for the 2nd dose

**Responsibilities -Technician**

* Enters the vaccine information on CRX

**Responsibilities - Pharmacists**

* Reviewing the VAR screening form
* Preparation and Administration of the vaccine using proper technique

**Documentation**

* Technician enters the information on ImmTrac with 24 hours