CoVP

Connecticut COVID-19 Vaccine Program

COVID-19 Vaccine Provider Manual

Keeping Connecticut Healthy
DPH
Connecticut Department of Public Health

Contents

Key COVID-19 Vaccination Planning Assumptions

The National COVID-19 Vaccine Program is planning three phases of vaccination response.

Phase 1: Potentially Limited COVID-19 Vaccine Doses Available
In Phase 1 of the COVID-19 vaccination response, the initial doses of vaccine will be limited in supply and targeted to critical healthcare personnel, essential workers, and high-risk populations with the goal of maximizing vaccine acceptance and public health protection.

Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand
In Phase 2 of the COVID-19 vaccine response, the supply of available vaccine increases. The distribution will be expanded to include the remainder of Phase 1 populations and the general population.

Phase 3: Likely Sufficient Supply, Slowing Demand
In Phase 3 of the COVID-19 vaccination response, COVID-19 vaccine will be widely available, integrated into routine vaccination programs, and run by both public and private partners. The goal will be to vaccinate all remaining populations.

Many COVID-19 vaccine candidates are in development and large-scale manufacturing is being conducted. It is not known which vaccines will be approved. COVID-19 Vaccination Program plans must be flexible and accommodate multiple scenarios. Due to the uncertainty of COVID-19 vaccine approval, the Department of Public Health

Immunization Program is operating under the following additional planning assumptions:

- Limited COVID-19 vaccine doses may be available as early as the December 2020. Vaccine may be available to the general public in the spring of 2021.
- Prioritization of recipient populations will be made based on the recommendations of the Advisory Committee on Immunization Practices (ACIP) and will be dependent on factors including vaccine supply and disease epidemiology.
- Phase 1 vaccine administration will be performed at limited access clinics held by hospitals, local health departments, selected pharmacies and other health care providers that can achieve high throughput. Many other providers be needed in Phases 2 and 3 when vaccine becomes available to the general public.
- Two doses of COVID-19 vaccine, separated by 21–28 days depending on the vaccine, may be needed for immunity, requiring the ability to track vaccine administration and provide patient reminders.
- COVID-19 vaccination is likely to occur during active community COVID-19 transmission; vaccine clinics will need to incorporate prevention measures, such as social distancing, universal face coverings and vaccination by appointment.
- Routine immunization will continue throughout the COVID-19 vaccination response.

Requirements for Participating in the COVID-19 Vaccination Program

COVID-19 Vaccination Program Enrollment

Providers that wish to receive COVID-19 vaccines must enroll in the COVID-19 Vaccination Program (CoVP). The enrollment process is described on the CT DPH COVID-19 Vaccine Providers webpage.

COVID-19 Vaccination Program Provider Agreement

Enrolled COVID-19 vaccine providers must be licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement. Failure of any enrolled COVID-19 vaccine provider organization or vaccination location under its authority to meet the conditions of the agreement may impact whether COVID-19 vaccine product orders are fulfilled and may result in legal action by the federal government. A Provider Profile indicating key attributes of the organization is also required to accompany the Agreement (see Section B of the CDC COVID-19 Vaccination Program Provider Agreement). The Provider profile will be retained on file for a minimum of 3 years and made available to CDC upon request.

Patient Eligibility

Information on the current phases of COVID-19 vaccination response is available at https://portal.ct.gov/Coronavirus/COVID-19-Vaccination---Phases.

Providers must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees.

Supplemental COVID-19 Vaccine-Redistribution Agreement

Vaccine ordered by a CoVP enrolled provider will be sent from the central distributor or manufacturer (for ultra-cold vaccine) to the delivery location specified in CT WiZ for that provider under the agreement. Under limited circumstances, a provider that receives vaccine may redistribute it to another CoVP enrolled provider. This means that custody of the vaccine will be transferred from one CoVP enrolled provider to another. For example, vaccine may be delivered to a Local Health Department (LHD) and some portion of that order may be redistributed to another LHD or vaccinator, such as a Visiting Nurse Association (VNA). This may occur when a jurisdiction's needs fall below the minimum allowable order or because COVID-19 vaccination by LHDs is organized regionally. For transfer of COVID-19 vaccine, the entity that ordered the vaccine will be required to sign a CDC Supplemental COVID-19 Redistribution Agreement. Each site receiving redistributed vaccine must sign a COVID-19 Vaccination Program Provider Agreement and complete the required trainings.

When redistributing vaccines, appropriate precautions should be taken. Vaccine should only be transported using appropriate packing materials that provide maximum protection refer to the Vaccine Storage for Transport . Follow specific jurisdiction and federal direction for transporting COVID-19 vaccine products. Please see the Connecticut COVID-19 Vaccine Transfer Form .

It is always safest to have vaccines delivered directly to a facility with a vaccine storage unit ready to receive the shipment, but this is not always possible. If necessary, vaccines may be transported using a portable vaccine refrigerator or freezer with a digital data logger placed with the vaccines. Vaccines should only be transported using appropriate packing materials that provide the maximum protection.

If a portable vaccine refrigerator or freezer is not available, qualified containers and pack outs with a TMD in each container can be used. For transport to an off-site clinic, bring only what is needed for the workday. Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially

available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures.

Laws and Regulations

Public Readiness and Emergency Preparedness Act (PREP Act)

The Public Readiness and Emergency Preparedness Act (PREP Act) added new legal authorities to the Public Health Service (PHS) Act to provide liability immunity related to the manufacture, testing, development, distribution, administration and use of medical countermeasures against chemical, biological, radiological and nuclear agents of terrorism, epidemics, and pandemics. It also added authority to establish a program to compensate eligible individuals who suffer injuries from administration or use of products covered by the PREP Act's immunity provisions.

The PREP Act and DHHS Secretary declarations provide immunity for the administration or use of a covered countermeasure (which includes vaccines) to, among others, "a qualified person who prescribed, administered, or dispensed such countermeasure" and their agents and employees under 42 U.S.C. sec. 247d-6d.

Acts or omissions which are willful are not protected by immunity. The federal law specifically defines willful as a standard for liability that is more stringent than a standard of negligence in any form or recklessness. Willful acts or omissions are those intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

Connecticut General Statutes and the Governor's Executive Order 7V

While the PREP Act immunity will govern vaccinator's liability, they are also protected under state law. Conn. Gen. Stat. § 19a-131f provides that the Commissioner may authorize any qualified person to administer vaccinations. Under Conn. Gen. Stat. § 19a-131i, the immunity provided to State employees is provided to any person acting on behalf of the state pursuant to the public health emergency statutes, within the scope of such person's practice or profession, including those acting under § 19a-131f. In addition, the Governor's Executive Order 7V provides immunity to health care providers and facilities for acts or omissions undertaken in good faith while providing health care services in support of the State's COVID-19 response

Countermeasures Injury Compensation Program (CICP)

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the covered countermeasures. The CICP can also provide benefits to certain survivors of individuals who die as a direct result of the administration or use of covered countermeasures identified in a PREP Act declaration. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are any antiviral medication, any other drug, any biologic, any diagnostic, any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, the transmission of SARS-CoV–2 or a virus mutating from SARS-CoV-2, or any device used in the administration of and all components and constituent materials of any such product.

The CICP is administered by the Health Resources and Services Administration within the Department of Health and Human Services. Information about the CICP and filing a claim is available by calling 1-855-266-2427 or visiting CICP.

Vaccine Administration

Best Practice

The following are considered best practices when administering vaccine.

- Only prepare vaccines when you are ready to administer them.
- Always check the lot number and expiration date and confirm that you have selected the correct vaccine.
- Only administer vaccines you have prepared as a matter of quality control and patient safety.
- When administering an FDA approved vaccine, providers must make a Vaccine Information Sheet (VIS) available to each vaccine recipient or legal guardian accompanying the recipient. The fact sheet may be made available as a hard copy or via a website URL.

COVID-19 Vaccine Program

Clinicians administering specific COVID-19 vaccines should follow manufacturer instructions and the recommendations of ACIP.

Under the COVID-19 vaccine program:

- Providers of COVID-19 vaccine are required to report all doses administered electronically directly to CT WiZ or indirectly via the VAMS platform.
- COVID-19 vaccine providers must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay any COVID-19 vaccine administration fees.
- When administering COVID-19 vaccine under an FDA Emergency Use Authorization (EUA), providers must make available an EUA fact sheet to each vaccine recipient or legal guardian accompanying the recipient. The fact sheet may be made available as a hard copy or via a website URL.

Vaccine Adverse Event Reporting System

The Vaccine Adverse Event Reporting System (VAERS) is a program for vaccine safety, co-managed by the U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Reports should be submitted online under the circumstances listed below.

Healthcare providers are **required by law** to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations.
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

Healthcare providers are strongly **encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event.
- Vaccine administration errors.

The VAERS table of Reportable Events and the list of contraindications are vaccine specific and will be updated to include COVID-19 when a vaccine has been authorized or approved by the FDA. Adverse events to COVID-19 vaccines should be reported electronically through VAERS.

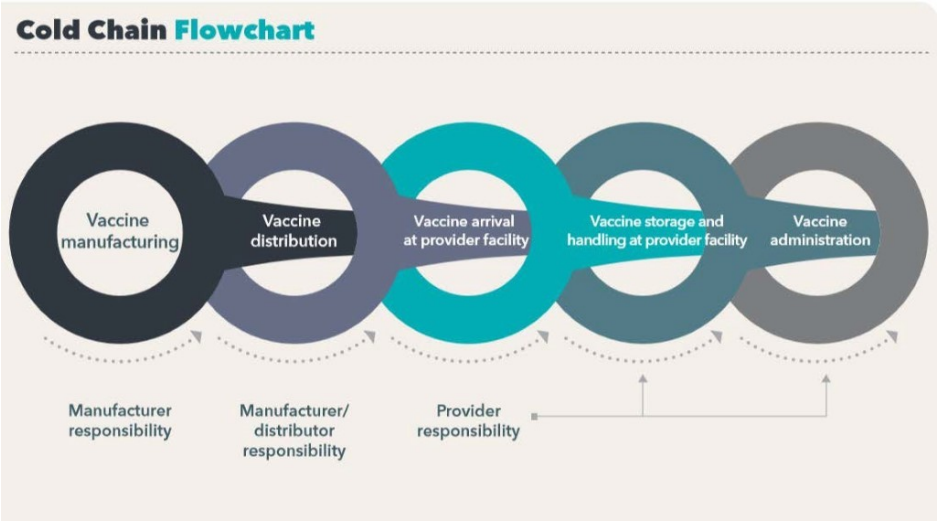
The CT Immunization Program encourages providers to promote V-safe among recipients by posting registration materials at all vaccination locations.

Other reporting requirements specific to COVID-19 vaccines may be put in place when they become available.

Storage and Handling Guidance

The CDC Vaccine Storage and Handling Toolkit outlines CDC recommendations for vaccine storage and handling. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness. A vaccine provider is responsible for maintaining appropriate cold chain storage, monitoring and handling from the time the vaccine arrives at the facility until it is administered.

Storage, handling, and transport guidance for specific COVID-19 vaccines will become available as vaccines are authorized or approved by the FDA.



Vaccine Coordinator Role and Responsibilities

The CoVP requires enrolled COVID-19 vaccination providers to designate a vaccine coordinator role at each location as well as a back-up vaccine coordinator. A vaccine coordinator is the point of contact with DPH and is responsible for receiving vaccine shipments, monitoring storage unit temperatures, managing vaccine inventory, etc. The coordinator responsibilities may be completed by the coordinator or delegated to appropriate staff. The coordinator must ensure that all delegated staff have been trained appropriately for all tasks assigned to them. CDC Storage and Handling Toolkit (See page 7.)

The back-up coordinator would assist or assume the vaccine coordinator role when the vaccine coordinator is not available. (*Note: This person will be responsible for ensuring all vaccines are stored and handled correctly and should be an expert on your facility's storage and handling Standard Operating Procedures.)*

Vaccine Storage Units

CDC recommends the use of stand-alone refrigerator and stand-alone freezer units; meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit. The following storage units are deemed appropriate types to store COVID-19 vaccines:

- Pharmaceutical/medical/laboratory grade refrigerator or freezer
- Stand-alone refrigerator or freezer

Placement of your Storage Unit

The following guidelines are recommended for placement of your storage unit:

- Good air circulation around the outside of the storage units is important.
- Storage units should be in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment.
- Most units work best when placed in an area with standard indoor room temperature between 68° F and 77° F (20° C and 25° C).
- Comply with the manufacturer-supplied owner's manual for additional guidance on placement and spacing.
- Each vaccine storage unit MUST be plugged directly into a wall outlet. It CANNOT be plugged into an outlet controlled by a light switch or into a surge protector with an on/off switch extension cord.

Temperature Monitoring Equipment

Every vaccine storage unit must have a continuous temperature monitoring device also known as a digital data logger (DDL). An accurate temperature history that reflects actual vaccine temperatures is critical for protecting vaccines.

All COVID-19 vaccine providers **MUST** use a working, digital, downloadable DDL with a current and valid certificate of calibration in all storage units that are used to store vaccine. The DDL must be calibrated to monitor at the intended temperature of the storage device. The DDL should be placed centrally in the storage unit.

When selecting a DDL, CDC/CT Immunization Program recommends the following features:

- A detachable, buffered probe (i.e. glycol, ethanol, glycerin, sand, glass beads or a solid block of Teflon or aluminum)
- Alarm for out-of-range temperatures set to 15 minutes or less
- Current, minimum, and maximum temperature displays
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings
- Logging intervals (or reading rate) that can be programed by the user to measure and record temperature at least every 5 minutes or less
- Document temperatures using the appropriate log and must be saved for 3 years.

Temperature Ranges

- Refrigerators should maintain temperatures between 2°C and 8°C (36°F and 46°F).
- Freezers should maintain temperatures between -50°C and -15°C (-58°F and +5°F).
- Ultra-Cold freezers should maintain temperatures between -60°C and -80°C (-76°F to -112°F).
- Refrigerator or freezer thermostats should be set at the factory set or midpoint temperature, which will decrease the likelihood of temperature excursions.
- Consult your owner's manual for instructions on how to operate the thermostat.
- Thermostats are marked in various ways and, in general, show levels of coldness rather than temperatures.
- The only way to know the temperature of stored vaccines is to measure and monitor the temperature with a temperature monitoring device.

- Never expose refrigerated vaccine to freezing temperatures

CoVP Provider Responsibilities for Temperature Monitoring

1. Ensure there is a digital data logger (DDL) monitoring and recording device for each vaccine storage unit storing COVID-19 vaccine.

2. Assess and record temperatures twice a day (AM/PM) (See log sheets below).
3. Document minimum/maximum temperature at least once a day [preferably twice a day]
4. Name (or initials) of the person who assessed/and recorded these temperature readings, time, and date of each reading.

5. Download DDL Data Report, Evaluate Daily, Weekly and Monthly temperatures; for any changes in temperature trends that might require corrective action.

6. If a temperature excursion occurs/DDL alarms out of range for 15 minutes or less:

a. Refer to *Temperature Excursion* section below.
b. Document information about any excursion and what steps were taken to correct any issues.
c. Contact the Immunization Program/or Manufacturers for guidance on vaccine viability.

See below for details on temperature excursions

Temperature Log Sheets

Refrigerator

- Fahrenheit - https://www.immunize.org/catg.d/p3037c.pdf
- Celsius - https://www.immunize.org/catg.d/p3037c.pdf

Freezer

- Fahrenheit - https://www.immunize.org/catg.d/p3038f.pdf
- Celsius - https://www.immunize.org/catg.d/p3038c.pdf

Ultra-Cold Freezer (Pfizer-BioNtech mRNA COVID-19 Vaccine)

- Celsius - https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/temp-log-ultra-cold-storage-celsius.pdf

Temperature Excursion

A temperature excursion refers to when a storage device goes out of the temperature range required for the storage of vaccine. If a storage unit experiences a temperature excursion, corrective action must be taken as soon as it is detected.

Corrective actions

Storage unit temperatures may need to be adjusted over time. In some situations, thermostats may need to be reset in summer and winter, depending on room temperature. If you confirm that an adjustment is needed:

1. Refer to your manufacture storage unit manual for detailed instructions.
2. Make small adjustments toward warmer or colder settings to avoid going outside the correct temperature range.
3. Once the adjustment is made, allow the air space within the unit to stabilize for 30 minutes and keep the door closed.
4. Recheck the temperature every 5 minutes.
5. Repeat these steps as needed until the temperature has stabilized for the unit
    a. Refrigerator between 2° C and 8° C (36° F and 46° F) or

b. Freezer between -25° C and -15° C (-13° F and +5° F) or
c. Ultra-Cold freezers should maintain temperatures between -60°C and -80°C (-76°F to -112°F).

Address the root cause of the temperature excursion

1. Confirm that the unit is securely plugged into a power source; unit doors are closed; thermostat settings are correct, and placement of the buffer probe is place appropriately in the center.
2. Check seals and door hinges.
3. Use your backup device to confirm the temperature/compare to the DDL in the unit.
4. Implement the emergency back-up plan if the storage unit has failed. Never allow vaccines to remain in a non-functioning unit.

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in the unit or temperatures in the unit are fluctuating between extreme highs or lows, the vaccine supply is at risk. Use your Emergency Vaccine Backup Plan Template to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

Providers must document information about all excursions and what steps were taken to correct any issues on the Temperature Troubleshooting Record. These corrective actions include but are not limited to the following:

1. Quarantine and label vaccines exposed to an excursion as "DO NOT USE".
2. Place vaccines in a unit where they can be stored under proper conditions.
3. Contact the Immunization Program to report a temperature excursion (860-509-7929)
4. Contact the vaccine manufacturer to obtain documentation supporting the usability of the vaccine.

COVID-19 Vaccine Storage Back-Up Plan (see Appendix A)

Every facility that administers vaccines **MUST** have a plan in place to protect the vaccines when there is a temperature excursion, loss of power to the refrigerator and /or freezer unit(s) that houses the vaccines. An emergency vaccine storage vaccine plan template can be seen in the Appendix. This plan should be posted on or near vaccine storage unit or where it can be easily accessed in the event of an emergency. All office staff should know the emergency back-up procedure to follow and where/how the individual vaccines are to be stored.

Vaccine Deliveries*

- Maintaining the cold chain is the first step in vaccine inventory management. Staff members who might accept vaccine deliveries should be trained to immediately notify the vaccine coordinator or alternate coordinator when deliveries arrive.
- Vaccines must always be immediately checked and stored properly upon arrival.
- Check DDL upon shipment to ensure cold chain.
- Check for discoloration of vial/contamination.
- Check invoice against what is shipped.
- COVID-19 vaccine diluent and ancillary supplies will be shipped separately.
- The practice needs to make sure that someone is available to accept the shipment during the days and hours you have designated for deliveries under your COVID-19 Vaccination Program Provider Agreement.
- If the practice will be closed for any day or time other than what is listed on your provider profile, it is the responsibility of the provider to contact the Immunization Program to let us know.
- Delivery hours can also be updated in CT WiZ.

Thawing Frozen Vaccine Recommendations:

Always follow the vaccine manufacturer's directions when thawing frozen vaccine prior to administration.
Pfizer mRNA COVID-19 Vaccine
Moderna mRNA COVID-19 Vaccine

NEVER refreeze thawed vaccine.

Procedures for Handling Unused doses

The process for returning (e.g. unused) the COVID-19 vaccine is currently unknown. Information on returns will be communicated to COVID-19 vaccine providers when they become available.

Process for Completing Storage and Handling Requirements

Please complete the CoVP Vaccine Storage and Handling Readiness Checklist (Appendix D) document and email to dph.immunizations@ct.gov.

Resources

- CT DPH COVID-19 Vaccine Providers webpage
- Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations
- CDC Interim Guidance for Routine and Influenza Immunization Services During the COVID-10 Pandemic
- AAP Storage Unit Guidance
- AAP Data Logger Guidance

CONNECTICUT VACCINE PROGRAM (CoVP)

Emergency Vaccine Storage Backup Plan Template

*Facility Name*_____ *PIN*_____ *City/Town*____ *Phone*_____

_____ *Person Completing Form*_____ *Date*_____

_____

Date Reviewed	*Initials*

THE BACK- UP PLAN MUST BE REVIEWED ANNUALLY AND UPDATED WHENEVER PERSONNEL

RESPONSIBLE FOR VACCINE CHANGES. PLEASE RECORD THE DATE IN THE SPACE ABOVE EACH TIME THE FORM IS REVIEWED.

This document offers guidance for developing a vaccine recovery plan. Included are steps to follow when your refrigerator or freezer malfunctions due to mechanical failure or natural disaster. This plan should be posted near the vaccine storage unit or easily accessible in case of an emergency. All appropriate staff should review and understand the standard operating procedure for handling emergencies and safeguarding the vaccine inventory. ***If you have any questions about vaccine transportation or stability call (860) 509-7929.***

VACCINE RECOVERY PLAN

Designate a Vaccine Coordinator and a Back-up person within your practice to:

✓ Monitor the operation of the vaccine storage equipment and systems daily.

✓ Track inclement weather conditions. Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create a shut down in power. An alarm/notification system is a requirement for receipt of COVID-19 vaccines.

✓ Assure the appropriate handling of the vaccine during the disaster or power outage.

✓ Ensure procedures are in place to notify the Vaccine Coordinator and/or Back-up person if power is lost and that they have access on weekends and off hours.

Names of designated employees:

NAME/TITLE	CELL PHONE	HOME PHONE

Back-Up Systems

✓ If you do not have a back-up generator, identify a location with one. This may be the local hospital, pharmacy, fire station, another practice, or an employee's home. When weather prediction calls for inclement conditions (severe ice, snowstorms, hurricanes, etc.), arrange with the site to store your vaccine.

✓ If you have a generator, check with building maintenance to make sure it is running when a power outage occurs.

✓ If a vaccine storage unit is not maintaining the appropriate temperature, move vaccines to an alternate

storage device on site or if this is not possible to the back up location. Never allow vaccines to remain in a nonfunctioning unit.

✓ In situations where a location with a back-up generator cannot be identified within a reasonable distance, preparations should be made to have coolers, and frozen ice packs available to temporarily and safely store your vaccine.

Alternative Location:

Document the alternative location(s), contact person and phone number of your back-up system/generator:

LOCATION NAME/PHONE #	CONTACT PERSON	HOME PHONE

Document type of storage units used at alternative site (ex. Pharmaceutical / Stand-alone units)

#	Unit Type (Fridge/Freezer)	Location	Brand	Model #	Serial #
1.					
2.					

The use of any household combination refrigerator/freezer unit for storage of CoVP vaccines including temporary storage is strictly prohibited.

Vaccine Transportation Procedures:

✓ Contact the Immunization Program whenever you are considering transporting COVID-19 vaccines outside of your facility to ensure you have the most relevant guidance and advice for your specific situation.

✓ Conduct an inventory before you transport vaccine.

✓ Package vaccine in a well-insulated container with phase change materials [gel packs, conditioned frozen water bottles, or ice packs] appropriate for type of vaccines being transported.

✓ Use separate packing containers for refrigerator stored vaccines and freezer stored vaccines. Label outside of packing container 'Must Store in Refrigerator' or 'Must Store in Freezer'.

Refrigerated Vaccines: CDC recommends condition frozen water bottles should be placed in the container used to transport refrigerated vaccines. Never place frozen gel packs or ice packs with refrigerated vaccines.

Appendix B: Pfizer mRNA COVID-19 Vaccine

Shipment Information:

The Pfizer vaccine will be shipped straight from the manufacture to the facility packed with dry ice. This vaccine requires ultra-cold storage (-60°C to -80°C).

Each thermal shipping container contains:

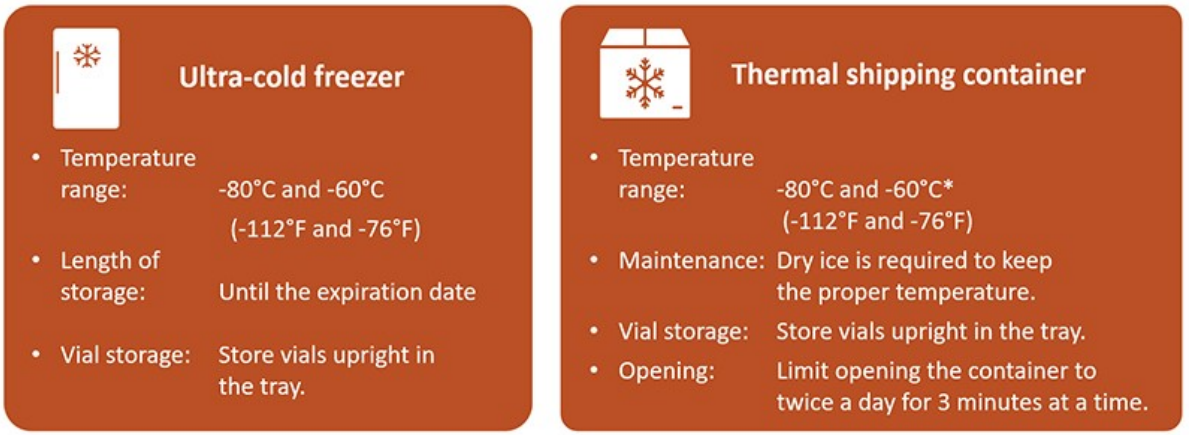
- Up to 5 trays of vaccine
  - Each tray contains 195 multidose vials.

Preparing for a Delivery/Dry Ice Safety

Before opening the thermal shipping container, make sure the area has proper ventilation.

- Do not use or store dry ice in confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation. Manufacturer's Guidance on Unpacking a Delivery and the Thermal Shipping Container CDC Dry Ice Safety for Healthcare Professionals

Storing Vaccine at Ultra-Cold Temperatures



Considerations When Storing Vaccine in Ultra-Cold Temperatures:

- **Do not open the vial trays or remove vials** until ready to thaw/use the vaccine.
- Once a vial is **touched and removed from a tray**, it begins to thaw and must be stored in the refrigerator.
- **Once thawed the vials cannot be re-frozen.**
- The vial must be used within 120 hours (5 days).
- Determine the number of doses/multidose vials needed for the day.
- Use vaccine vials stored in the refrigerator before removing additional vials from frozen storage.

Opened trays exposed to room temperature:

- Must be returned to ultra-cold temperatures within **3 minutes**.
- Should remain at ultra-cold temperatures for **2 hours** before they can be removed again.
- Vaccine is light sensitive.

Appendix C: Moderna mRNA COVID-19 Vaccine

Shipment Information:

Moderna vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F). Each shipment contains 100 doses of vaccine. **Moderna vaccine should be stored in a freezer until date of a clinic** to avoid vaccine wastage in the case of a temperature excursion. Moderna vaccine can be used for 30 days if the temperature rises in a freezer just above acceptable range; no leeway exists for excursion from refrigerator to room temperature. It will be shipped directly from McKesson. Upon arrival vaccine must be:

- Unpack immediately upon arrival
- Store at recommended temperatures in a freezer
- Document in the inventory
- Vaccine is movement and light sensitive and must be stored in the original package/carton.
- **Thawed vials cannot be re-frozen.**
- Do not store with/on dry ice.
- When transporting Moderna vaccine, it is recommended to transport in the frozen state using the appropriate equipment (portable freezer or manufacture pack out).

Moderna COVID-19 Vaccine Information | CDC

Appendix D: CoVP Vaccine Storage and Handling Readiness Checklist

Vaccines must be kept in a storage unit that can maintain the temperature range specified by the vaccine manufacturer. Vaccines that can be kept in a freezer should be kept frozen until needed. Thaw frozen vaccine as needed for administration. NEVER refreeze thawed vaccine.

Please refer to the CDC Vaccine Storage and Handling Toolkit and its vaccine-specific appendices for details on CoVP storage and handling requirements (Vaccines Storage and Handling Toolkit | CDC).

Specific training requirements:

☐ CDC's COVID-19 Vaccine Training ☐ ModulesDPH CoVP Provider Manual

Available Storage Units (Please check all that will be used to store COVID-19 Vaccine):

☐ Stand-alone Freezer ☐ Stand-alone Refrigerator ☐ Ultra-Cold Freezer

*Dorm style compact refrigerator unit with an embedded freezer is NOT acceptable storage unit

Each of the following items must be in place before a CoVP Provider is authorized to order COVID-19 vaccine. Please put a check in the box next to each item that is in place:

☐ Digital data logger used to monitor temperature for **each** vaccine storage unit, including portable units, with a valid certificate of calibration.

This digital data logger must have a temperature display, record temperature at least every 15 minutes or less and have an alarm that sound immediately when temperatures are out of range.

☐ Download of digital data logger showing at least 72 hours of in range temperatures for **each** storage device.

☐ Completed Vaccine Emergency Backup Plan Template (See appendix A.)

☐ Up-to-date Managed Assets section of CT WiZ (i.e.: Storage Units, DDLs)

All storage equipment's MUST be entered in CT WiZ Managed Assets prior to receiving COVID vaccines. Please see page 6 CT WiZ COVID-19 Vaccine Provider Enrollment Training Guide.

Date: ____/____/ _____

PIN: _____ Clinic Name: _____

Signature _____

Please retain all documents and have them available for review by DPH upon request.

When completed, email the document to dph.immunizations@ct.gov. The subject line should read **CoVP Vaccine Storage and Handling Readiness Checklist and include your PIN.**