

COVID-19 Vaccine Management

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Massachusetts Department of Public Health

Immunization Division

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- Requirements to receive COVID-19 vaccine.
- Methods for ordering COVID-19 vaccine.
- COVID-19 vaccine storage and handling (including transport requirements).
- Planned redistribution from depots to individual locations and from larger to smaller locations.
- Managing vaccine inventory, including accessing and managing product expiration dates.
- Reporting vaccine inventory.
- Managing temperature excursions.
- Document and report vaccine wastage/spoilage.

Learning Objectives


COVID-19 Vaccine Eligibility Considerations

- Decisions about which eligible patients receive the COVID Vaccine should be based on the clinical judgement of hospitals and providers, consistent with the terms of the EUAs and with this guidance.
- Provider criteria for the COVID Vaccine use should be as clear, transparent, and objective as possible, and be based on biological factors related only to the likelihood and magnitude of benefit from the medical resources and should at all times minimize inequitable outcomes.
- Factors that have no bearing on the likelihood or magnitude of benefit, include but are not limited to, race, disability, gender, sexual orientation, gender identity, ethnicity, ability to pay or insurance status, socioeconomic status, English language proficiency, perceived social worth, perceived quality of life, immigration status, incarceration status, homelessness or past or future use of resources.

Evolving Recommendations

Always check the websites below and other websites provided within this presentation for the latest guidance and information.

- Pfizer EUA Webpage: <https://www.cvdvaccine-us.com>
- CDC's Healthcare Professionals: Preparing for COVID-19 Vaccination: <https://www.cdc.gov/vaccines/covid-19/hcp/index.html>
- CDC's COVID Vaccination Training and Education: <https://www2.cdc.gov/vaccines/ed/covid19/>



Requirements to receive COVID-19 vaccine

1. Registered with the Massachusetts Immunization Information System (MIIS).
2. Submit a unique **Massachusetts COVID-19 Vaccine Program (MCVP)** agreement.
 - The MCVP Agreement is emailed as a link to contacts associated with the MIIS and State Vaccine Program.

MCVP Agreement

Providers agree to:

- Follow state prioritization guidelines for vaccinating populations.
- Agree to report immunization administration data within 24 hours of administration.
- Organization must not sell or seek reimbursement for COVID-19 vaccine or ancillary supplies.
- Must administer regardless of ability to pay.
- Must provide Emergency Use Authorization fact sheet.
- Must comply with CDC and manufacturer guidance for vaccine management.
- Comply with MDPH guidance for handling temperature excursions.

When completing the MCVP Agreement, sites are also completing the redistribution agreement.

Training

- All facilities designated a primary and back-up COVID-19 Vaccine coordinator when completing the MCVP agreement.
- COVID-19 Vaccine Coordinators will ensure that COVID-19 vaccines are stored and handled correctly.
- All staff members who receive vaccine deliveries, handle or administer vaccines must be trained in vaccine related practices and procedures.

Ordering and Receiving COVID- 19 Vaccine



Ordering

- In the initial phases of distribution, MDPH Immunization Division will allocate and order COVID-19 vaccine for providers.
 - When an order is created, the Primary and Back-Up Vaccine Coordinators will receive an email advising of the order.
 - Sites should review this order and ensure that there is space for this vaccine.
 - Sites will have a short window to have the order cancelled.
 - Vaccine will arrive within 48-72 hours of this order being created.
- Eventually, sites will be able to place orders for COVID-19 vaccine directly in the MIIS.

Shipment

- Once an order is received, it will be fulfilled by CDC distributor and/or vaccine manufacturer.
 - Accurate contact information is necessary, providing an unmonitored email in your MCVP Agreement can result in a rejected order.
- Depending on the vaccine product ordered, sites will receive the following shipments:
 - COVID-19 vaccine
 - Ancillary kit
 - Dry Ice replenishment


Critical system email addresses to accept for vaccine distribution and ancillary kits.

Address	Purpose
SNSSupport@McKesson.com	Communization about ancillary kits
Pfizer.logistics@controllant.com	Communization from Controlant including: <ul style="list-style-type: none">• Notice at time of vaccine shipment with tracking information.• Exceptions for either shipment delay or cancellation.• Delivery Quality Report
donotreply@Pfizer.com	Confirmation of the ancillary kit shipment
cvgovernment@Pfizer.com	Pfizer customer service.

Contact Information

It is incredibly important to provide email addresses that will continue to be monitored.

Unmonitored emails will result in rejected orders.



Pfizer COVID-19 Vaccine

Tray Dimensions: 229mm x 229mm x 40mm (approx. 9in x 9in x 1.5 in)

Minimum Order: 975 dose

On Site Vaccination Storage:

- -80°C to -60°C in ultra cold storage unit for up to 6 months
- -80°C to -60°C in the original thermal shipping container for up to 30 days, if replenished with dry ice upon receipt and every 5 days.
- 2°C to 8°C in a storage unit for up to 120 hours (5 days)

Thawing

- A tray of 195 vials may take up to 3 hours to thaw in the refrigerator (2°C to 8°C)
- Vials needed for immediate use may be thawed at room temperature (30 minutes). Can be at room temperature for no more than 2 hours.

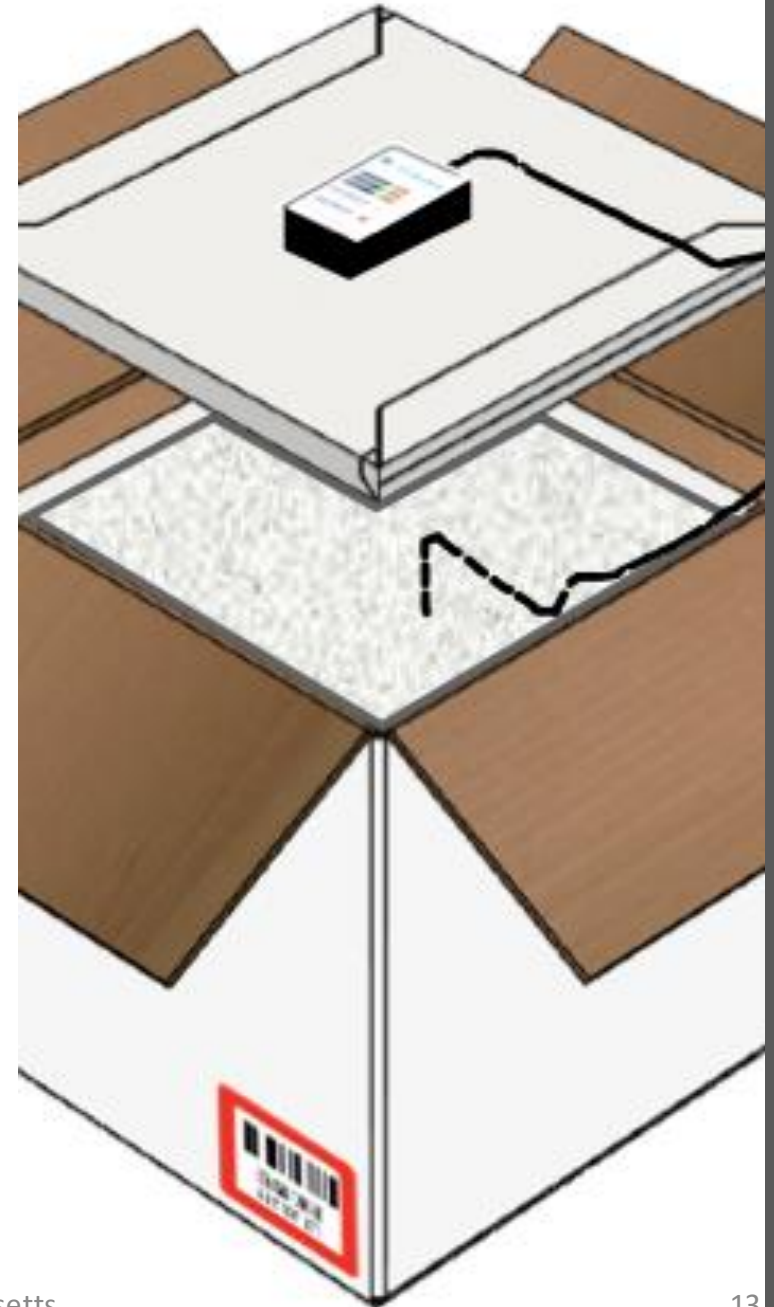
Diluted product must be used in 6 hours from the time of dilution, stored between 2°C to 25°C .

Pfizer COVID-19 Vaccine – Thermal Shipper

- Vaccine is shipped directly from Pfizer.
- Vaccine is shipped in a container that includes dry ice and digital data logger to monitor temperature.
- Thermal shipping container dimensions – 400mm x 400mm x 560mm (approx. 15 ¾ in x 15 ¾ in x 22in).
- Container holds a maximum of 5 cartons/trays (4,875 doses).
- If using thermal shipping container to store vaccine, add dry ice pellets (9mm to 16mm) within 24 hours of delivery and every 5 days or as needed to maintain temperatures for up to 30 days.
- Dry ice will be delivered within 24 hours of vaccine delivery to refill the thermal shipping container for the first re-ice only.
- Do Not Use or Store dry ice or liquid nitrogen in confined areas, walk-in refrigerators, or rooms without ventilation.
- A full shipping container with vaccine and dry ice weighs approximately 70 pounds.

12/14/20

<https://www.mass.gov/covid-19-vaccine-in-massachusetts>



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Pfizer COVID-19 – Product Packaging


Vials

- 2mL Type 1 glass preservative-free
- MDV has 0.45 mL frozen liquid product
- 5 doses per vial after dilution

Trays

- Single tray holds 195 vials
- 975 doses per tray





Pfizer Vaccine - Ancillary Kits

The ancillary kits shipped for the Pfizer vaccine are combined kits with syringes for vaccine administration, mixing supplies and diluent.

Supports administration of 975 doses and includes 0.9% preservative-free normal saline diluent.

Dimensions: 214in x 20 in x 24 in (40lbs)

Includes:

- 829 needles (22-25G x 1")
- 200 needles (22-25G x 1.5")
- 205 mixing needles (21 - 25G x 1.5")
- 1024 syringes (1mL)
- 205 syringes (3mL or 5mL)
- 200 diluent vials
- 2458 alcohol pads
- 1000 vaccination record cards
- 10 needle gauge and length charts
- 20 face shields



Dry Ice Kit

If Pfizer COVID-19 vaccine is ordered, the US Government will supply an initial replenishment of Dry Ice.

- Dry Ice replenishment will arrive within 24 hours of vaccine delivery.
- Dry Ice Kit contents will include
 - Gloves
 - 1 Face Shield
 - 1 Ice scoop
 - OSHA dry ice safety card

Moderna COVID-19 Vaccine

Manufacturer: Moderna

Carton Dimensions: 53mm x 53mmX137mm (2in x 2in X 5 3/8in)

Minimum Order: 100 doses

Presentation: 10-dose multidose vial/10 MDV per carton

Distribution: Centrally distributed, will come from CDC distributor McKesson

On Site Vaccine Storage for **unopened (non-punctured)** vials:

- -25°C to -15°C in vaccine storage unit up to 6 months.
- 2°C to 8°C in vaccine storage unit for up to 30 days as long vial has not been entered.
- 15°C to 25°C for 12 hours after removed from refrigeration.

On Site Vaccine Storage for **Open (needle-punctured) multi-dose vials:**

- 2°C to 25°C for a maximum of 6 hours. **Discard any punctured vial after 6 hours.**

Considerations: Freezer temperature settings will require adjustment if this vaccine and varicella-containing vaccines are in the same unit. The temperature range for this vaccine is limited compared to varicella-containing vaccines.

Moderna Vaccine – Ancillary Kit

When a site receives Moderna vaccine they will receive a standard syringe kit for vaccine administration

Dimensions: 14inx13inx9in (3.5lbs) – supports 100 doses (plus overage)

Contents:

- 85 safety needles (22-25G x 1")
- 20 safety needles (22-25G x 1.5")
- 105 syringes (1mL or 3mL)
- 210 alcohol pads
- 100 vaccination record cards
- 1 needle gauge and length chart
- 2 face shields
- 4 surgical masks

Considerations: products and brand may vary.

COVID-19 Vaccine Storage and Handling - EUA

Since COVID-19 vaccines may initially be authorized for use under an Emergency Use Authorization (EUA), providers should refer to the EUA fact sheet for Healthcare providers and manufacturer information for detailed storage and handling information for each vaccine.

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>

Vaccine Storage Units

Temperature Range	Storage Unit
2°C to 8°C	<ul style="list-style-type: none">• As a best practice, vaccines should be stored in purpose-built units or pharmaceutical-grade units. They are designed specifically for the storage of vaccines.• Household-grade units can be an acceptable alternative, but the freezer must not be used, and temperature must be monitored closely.
-15°C to -50°C	<ul style="list-style-type: none">• Standalone freezers should be used for storage.• Freezer compartments of Household units are not acceptable.• Freezer temperature settings will require adjustment if Moderna COVID-19 vaccine and varicella-containing vaccines are in the same unit.
-60°C to -80°C	<ul style="list-style-type: none">• Freezers designed to reach ultra-cold temperatures should be used.• Vaccines that require ultra-cold temperature storage cannot be stored in a standard freezer.• Neither CDC nor MDPH recommend that providers purchase ultra-cold storage units. Vaccines requiring ultra-cold storage conditions will be shipped in containers that can maintain ultra-cold temperatures for an extended time.

Temperature Monitoring

It is essential that providers continuously monitor vaccine storage unit temperatures. CDC and MDPH recommend that a **digital data logger** (DDL) is used.

DDLs:

- Provide the most accurate storage unit temperature information by using a buffered probe.
- Records temperatures continuously.
- Identifies alarms and how long vaccine storage units have been out of range (temperature excursion).

* Not all DDLs can measure ultra-cold temperatures. Sites may use monitoring equipment that uses an air-probe or a probe designed specifically for ultra-cold temperatures.

Temperature Monitoring

Storage units must be monitored regularly. Even using a continuously monitoring temperature device like a DDL, providers must also record the following at least twice a day:

1. Minimum and Maximum Temperature
 2. Date/Time
 3. Name of person checking and recording temperatures
 4. Actions taken if a temperature excursion occurred.
- Some DDLs keep a record of this information.
 - Temperature records must be kept for a minimum of three years.

Pfizer-BioNTECH COVID-19 Vaccine

Temperature Log for Ultra-Cold Vaccine Storage (Fahrenheit) Days 1-15



Store COVID-19 vaccine (Pfizer) between -112°F and -76°F . Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See *CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum*, for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures

1. If the DDL can measure min/max temperatures, check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature

1. If the DDL does not read min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the freezer temperature under the appropriate day of the month.



If the temperature is out of range, TAKE ACTION!

1. Do **NOT** discard the vaccine.
2. Label the vaccine **"Do Not Use."**
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (frozen or refrigerated) to store the vaccine as quickly as possible.

Month _____ PIN Number _____

Facility Name _____

OPTION 1	Day of the month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Time															
Staff initials																
Min/max temperatures																
<p>Temperatures above -76°F and below -112°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.</p>																

S&H- Pfizer COVID-19 Vaccine

If using thermal shipper for storage, it should only be opened twice a day for a maximum of **3 minutes** to maintain temperature.

Trays

- When removing a tray that has less than 195 vials from frozen storage (< -60°C), the tray may be at room temperature (< 25°C) for up to **5 minutes** for transfer between ultra low temperature environments or to remove vials for thawing or use.
- After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.
- **Do not open the trays or remove vials until you are ready for thawing or use.**

Vials

- Once an individual vial is removed from the vial tray at room temperature, it has begun thawing. **It should not be returned to frozen storage.** It should be thawed for use.
- Vials should be stored upright and protected from light.



Vaccine S&H Best Practices

- Vials are glass and should be handled with care.
- Vials should be protected from light and when possible kept in the original packaging.
- Vials should always remain upright.
- Providers should develop and maintain clearly written and detailed storage and handling Standard Operating Procedures (SOP).
- Vaccines may need to be mixed with a diluent prior to administration. Always follow the manufacturer's guidance for use of the diluent.
- Store vaccines and diluents in original packaging.
- Rotate vaccines and diluents so that vaccine that expires first are in the front and will be used first.

Redistribution

Whenever possible, vaccine should be shipped to the location where it will be administered to prevent breaks in the cold chain.

Vaccine may need to be redistributed due to the following reasons:

- Larger organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations.
- Vaccines need to be redistributed to prevent wastage.
- Vaccine needs to be transported for clinics.

All sites/facilities receiving vaccine, even if redistributed from another location, **MUST** complete the Massachusetts COVID-19 Vaccine Program (MCVP) agreement.

Transferring Inventory

Prior to physically transporting inventory, sites must:

- Ensure that the receiving site has a completed MCVP agreement.
- Contact the Vaccine Unit to virtually transfer vaccines so that inventories continue to be accurate.
 - Eventually sites will be able to initiate transfers directly in the MIIS.
- Have an SOP and a plan to ensure that the cold chain isn't broken.

Transport

- Vaccines must be transported in a stable storage unit and monitored with a DDL.
- The time for transport alone or transport plus the clinic workday should be a maximum of 8 hours.
- Transport equal amounts of vaccines, diluents, and ancillary supplies.
- Upon arrival, vaccines should immediately be stored in appropriate units with a DDL.
- A partially used vial cannot be transferred from one provider to another.
- Transport will vary depending on vaccine, for more information consult manufacturer.

Transport – Pfizer Vaccine

Pfizer vaccine should be stored at ultra-cold temperatures, but there is stability to store vaccine at 2°C to 8°C.

When transporting Pfizer Vaccine:

- 1. Only full and unopened trays (195) should be redistributed at freezer temperatures.** If transporting a full tray of 975 doses, providers may transport at ultra cold temperatures in the original Pfizer shipper with dry ice.
2. If transporting vials outside of the tray, providers can only transfer at 2°C to 8°C.
 - Pfizer COVID-19 vaccine begins to thaw once it is taken out of the tray.



Transport – Moderna Vaccine

Moderna vaccine must be transferred frozen. It cannot be transferred at 2°C to 8°C.

Inventory Management

Massachusetts Immunization Information System (MIIS)

- Registration with the MIIS is required to receive COVID-19 vaccine.
- The MIIS is also integral to inventory management.
- Sites should be onboarded with the MIIS to ensure that vaccine administration data is reported to the MIIS. For assistance, please contact the MIIS Registry Help Desk at MIIShelpdesk@MassMail.State.MA.US.
- As immunization data is reported to the registry, your inventory will automatically be adjusted.

COVID-19 Expiration Dates

- EUA vaccine labels may not include expiration dates.
- CDC will post a COVID-19 Vaccine Expiration Date Tracking Tool on its website once vaccine available.
 - This link is currently not available.
- Expiration dates may change as additional stability data become available.

Beyond Use Date (BUD)

Some vaccines have a BUD, which is based on storage information in the package insert. Examples of vaccines with BUDs include:

- Reconstituted vaccines have a limited period of use once the vaccine is mixed with a diluent.
- Multidose vials might have a specified period of use once they have been entered with a needle.
- Manufacturer-shortened expiration dates may apply when vaccines are exposed to inappropriate storage units.

In the COVID-19 vaccine ancillary kits, CDC has provided vaccine labels to help keep track of BUDs for COVID-19 vaccine.

Reporting Inventory – Vaccine Finder and MIIS

Vaccine Finder

- One of the requirements to receive COVID-19 Vaccine is to update COVID-19 vaccine inventory every 24 hours.
- MDPH Immunization Division will take responsibility of this requirement for providers.
 - Providers will not need to directly report vaccine inventory to Vaccine Finder

MIIS

To ensure that the MIIS has the most accurate data:

- Ensure that your site is onboarded with the MIIS and can submit vaccine administration data directly to the registry.
- Complete COVID-19 Vaccine reconciliations in the MIIS Vaccines Module.

Temperature Excursion

- Any temperature outside of the recommended temperature ranges are considered a temperature excursion.
- If a temperature excursion occurs, providers must contact vaccine manufacturer to ensure viability.
- Providers should document all temperature excursions, including:
 - Date/Time of Excursion
 - Problem and Details
 - Who was contacted about temperature excursion
 - Resolution
- Providers must keep this information on hand for 3 years.

Vaccine Management Troubleshooting Log

This log should be used to document any Vaccine Management problems, including but not limited to the problems described below. Make sure keep detailed notes of all problems and resolutions. This log should be kept on file for three years in accordance with MDPH Immunization Division policy.

Practice Name _____ PIN _____

Date and time	Problem	Details	Date/time of call to Vaccine Unit	Resolution	Initials and date
	<input type="checkbox"/> Storage Unit Malfunction <input type="checkbox"/> Power Outage <input type="checkbox"/> Ordering Problem <input type="checkbox"/> Shipment/Delivery Problem <input type="checkbox"/> Vaccine Storage Problem <input type="checkbox"/> Other: _____				
	<input type="checkbox"/> Storage Unit Malfunction <input type="checkbox"/> Power Outage <input type="checkbox"/> Ordering Problem <input type="checkbox"/> Shipment/Delivery Problem <input type="checkbox"/> Vaccine Storage Problem <input type="checkbox"/> Other: _____				
	<input type="checkbox"/> Storage Unit Malfunction <input type="checkbox"/> Power Outage <input type="checkbox"/> Ordering Problem <input type="checkbox"/> Shipment/Delivery Problem <input type="checkbox"/> Vaccine Storage Problem <input type="checkbox"/> Other: _____				
	<input type="checkbox"/> Storage Unit Malfunction <input type="checkbox"/> Power Outage <input type="checkbox"/> Ordering Problem <input type="checkbox"/> Shipment/Delivery Problem <input type="checkbox"/> Vaccine Storage Problem <input type="checkbox"/> Other: _____				



Temperature
Excursion
Documentation

Example of Temperature
Troubleshooting Record

If your refrigerator or freezer is out of range, or if vaccine has been left out of refrigeration, immediately contact the MDPH Vaccine Management Unit at 617-983-6828 to determine if any vaccines have been damaged

Wastage and Spoilage

At this time, CDC has not given guidance about how COVID-19 vaccine that has been wasted/spoiled will be handled.

The 'Vaccines' module in the MIIS is currently used to process storage/handling issues and return spoiled our wasted routine. We expect that this will be the method to return vaccines.

- Spoiled vaccine is non-viable vaccine in its original container (vial or syringe). This includes expired vaccine or vaccine spoiled due to temperature excursions, transport conditions, or emergency situations such as a power failure.
- Wasted vaccine is non-viable vaccine that is not in its original container. This includes vaccine in an open vial, drawn into a syringe, or compromised because its container was dropped or broken.

Every effort should be made to prevent spoiled or wasted vaccine.

Resources

Please continue to monitor these webpages as more information becomes available and information may change.

MDPH COVID-19 Vaccine Webpage

<https://www.mass.gov/covid-19-vaccine-in-massachusetts>

MDPH Vaccine Management Website

<https://www.mass.gov/resource/vaccine-management>

CDC Storage and Handling Toolkit

<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

Pfizer Website

<https://www.cvdvaccine-us.com/resources>

There will be a QR code on the shipment that will lead to a public facing website.

CDC Info by Vaccine (Pfizer)

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



Thank You

Vaccine Management Unit: DPH-Vaccine-Management@massmail.state.ma.us