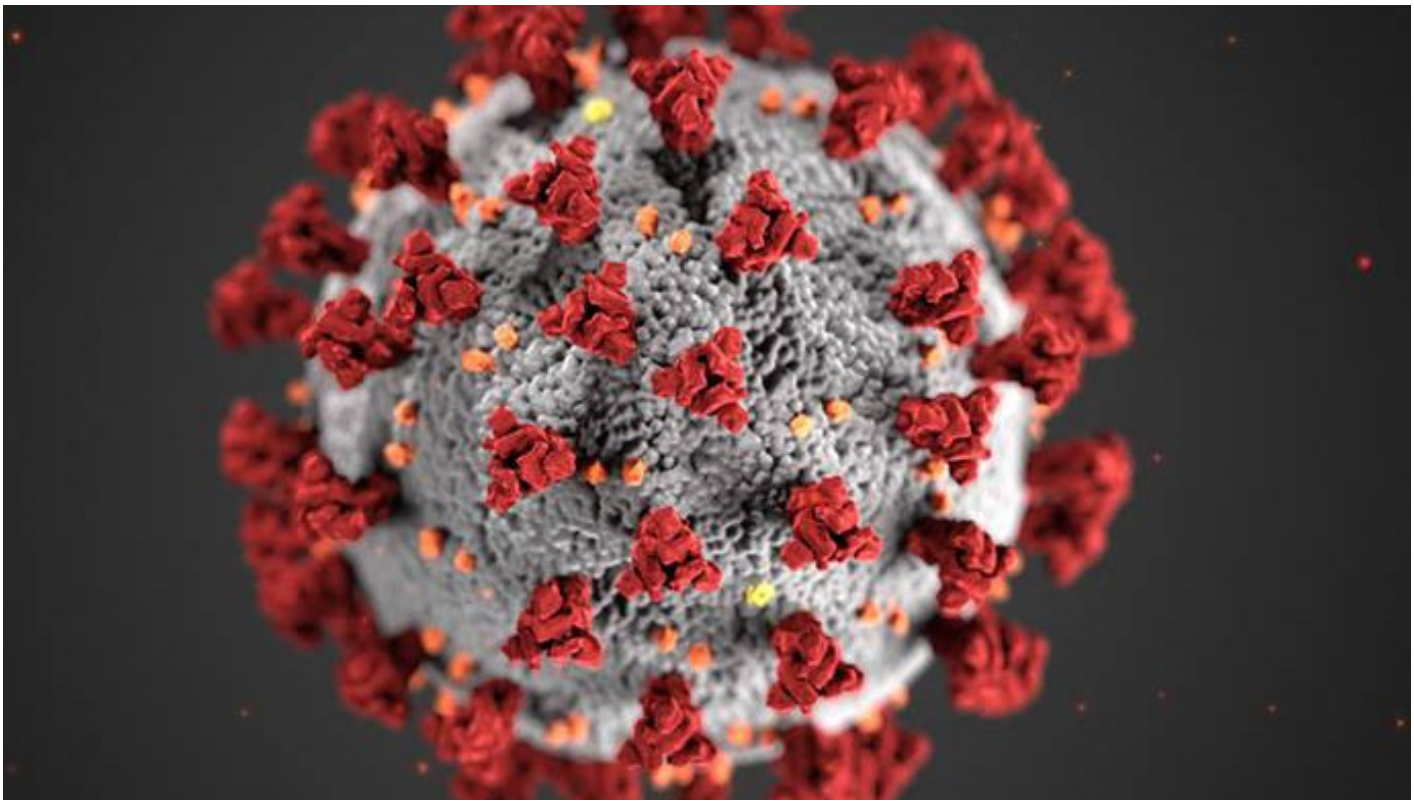
COVID-19 Vaccine Management Guide



Provider information

Organization name:	COVID-19 ID:	ALERT IIS number:

Key staff

Responsible provider:
Primary COVID-19 Vaccine Coordinator:
Back-up COVID-19 Vaccine Coordinator:

Oregon Health Authority

oregon immunization program

ALERT IMMUNIZATION INFORMATION SYSTEM
A PROGRAM OF OREGON FAMILYNET

Contents

Statement of purpose and applicability

In signing the COVID-19 vaccine provider agreement, providers commit to taking care of vaccines in accordance with the CDC's storage and handling toolkit. This guide is intended to communicate all the requirements that are applicable to providers based on the provider agreement and Oregon state rules. This guide has been incorporated into Oregon Administrative Rules.

Section 1: Overview

Summary of the available vaccines

The primary series of COVID-19 vaccines requires two doses of the vaccine separated by a period of time that is particular to the specific vaccine.

These vaccines all have a two-dose primary series for most recipients:

- Pfizer Gray Cap primary series (monovalent) for ages 12+ / sometimes labeled with the brand name "Comirnaty" – no diluent
- Pfizer Orange Cap primary series and booster (monovalent) for ages 5-11 – diluent required
- Pfizer Maroon Cap primary series (monovalent) for ages 6 months through 4 years – diluent required, 3 dose primary series for all recipients
- Pfizer Gray Cap bivalent booster for ages 12+ - no diluent
- Moderna primary series for ages 12+ (monovalent, red cap, light blue border)
- Moderna primary series for ages 6-11(monovalent, blue cap, purple border) labeled "booster doses only" but now authorized only as primary series for ages 6-11.
- Moderna primary series for ages 6 months through 5 years (blue cap, pink border label)
- Moderna bivalent booster (full dose for ages 18+) (blue cap, gray border)

- Novavax is a two-dose primary series authorized for recipients ages 12+. Recipients may receive a booster of one of the mRNA bivalent boosters

Providers should schedule an individual for their next dose before they leave their first dose appointment.

Some moderately or severely immunocompromised persons may receive additional doses as part of the primary series. The additional doses should be monovalent vaccines and must be the same vaccine brand as the first dose.

Johnson & Johnson is a single dose vaccine for the primary series for age 18+. J&J is disfavored and only recommended for individuals who will not or cannot receive one of the other authorized vaccines.

Many recipients ages 5 and older are recommended for a booster doses: second boosters are no longer authorized. (See Section 10: Vaccine Preparation and Administration for details on booster doses).

All Purple Cap Pfizer (for ages 12+) has expired and should be disposed of (see the "Spoiled, Wasted and Expired COVID-19 Vaccines" section below for instructions).

Gray Cap Pfizer, monovalent primary series version, is also fully approved under a Biologics License Application (BLA) for the primary series of individuals ages 12+ under the brand name Comirnaty®.

The Pfizer Gray Cap monovalent primary series and Comirnaty products are identical and either labeling can be administered to anyone authorized or approved for a vaccination under either BLA or EUA. The Pfizer EUA Fact Sheets for Recipients and Caregivers for both purple cap (now all expired) and gray cap/Comirnaty (12+ no dilution) products will cover both the *authorized* use of this vaccine (under the name Pfizer-BioNTech) and the *fully approved* use of this vaccine (under the name Comirnaty).

Moderna primary series for 12+ is licensed (fully approved) under the brand name Spikevax for ages 18 and older. Spikevax and Moderna primary series 12+ are the chemically the same product with different labeling.

Providers enrolled in the COVID-19 Vaccine Program must:

- Vaccinate using precautions against the spread of COVID-19. The CDC offers guidance here.
- Designate a primary and back-up vaccine coordinator who will be responsible for ensuring all vaccines are stored and handled correctly. If these change providers will need to resubmit their enrollment application here with updates.
- Train all staff members who receive vaccine deliveries and all those who handle and administer vaccines in vaccine-related practices and procedures. At minimum, two staff members must have completed all required ALERT IIS and Storage and Handling trainings.
- When key staff change (responsible provider, primary COVID-19 vaccine coordinator, back-up COVID-19 vaccine coordinator) resubmit your enrollment form with the updated info. If you need help contact Oregon Immunization Program right away to VFC.help@state.or.us.
- Keep all records related to COVID-19 vaccines for a minimum of three years (including temperature records and vaccine storage troubleshooting records). This is the Oregon Immunization Program requirement, other laws or governing bodies may require some records be kept longer.
- Provide current Vaccine Information Statement (VIS) or Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers in the patient's primary language prior to administering vaccine at every immunization visit.

- For published EUA Fact sheets and translations, visit the FDA COVID-19 Vaccines webpage and select the vaccine you are working with under the "COVID-19 Vaccines Authorized for Emergency Use" heading.
- EUA Fact Sheets are not interchangeable between COVID-19 vaccine products. Vaccinators must give the most current EUA Fact Sheet for the specific COVID-19 vaccine product that is given to a patient.
- Vaccinators must give EUA Fact Sheets to patients for every dose of their COVID-19 vaccine.

- Read listserv messages (Oregon Immunization Partner Updates) and visit the COVID-19 Vaccine Provider Training webpage to keep up with program developments. Ensure at least two staff maintain a subscription to the Oregon Immunization Program Listserv (Oregon Immunization Partner Updates). This listserv is the primary way that requirements and updates are communicated to Oregon providers. To sign up, email VFC.help@state.or.us. Providers are responsible for the information delivered through listserv messages.
- Maintain records in accordance with applicable laws listed in the National Childhood Vaccine Injury Act.
- Do not charge for the cost of any COVID-19 vaccine.
- Do not directly bill recipients an administration fee for a COVID-19 vaccine or accept donations for the service.
- Give individuals a COVID-19 vaccination record card after each vaccination.
- Ensure that vaccines are appropriately stored and managed at all times.
- Report all immunizations to ALERT Immunization Information System (IIS) with a valid vaccine eligibility code "S" (Special Projects) within 24 hours of administration. If "S" (Special projects) is not available in your EHR, choose "O" (Other). (OAR 333-049-0050).
- Use the ALERT IIS Inventory and Ordering modules to manage your COVID-19 vaccine stocks.
- Comply with all standards for vaccine management as outlined in this guide, including:
  - Have a written plan for vaccine management (i.e., this document, once completed).
  - Use storage equipment and thermometers (digital data loggers) that meet the requirements outlined in this document.
  - Document minimum and maximum temperatures daily and review digital data logger data weekly.
  - Notify the COVID-19 vaccine manufacturer when COVID-19 vaccine has been stored outside of the appropriate temperature range to ensure vaccine viability. Provide the Oregon Immunization Program with temperature logs when requested.
  - Document all transfers of COVID-19 vaccine in ALERT IIS. (OAR 333-047-1000)
- Recertify with the Immunization Program when required.
- Vaccinate in accordance with the Emergency Use Authorizations and product-specific protocols found in the Emergency Use Authorization Fact Sheets for Health Care Providers Those can be found for all authorized COVID-19 vaccines on the FDA website and manufacturer websites.

- Comply with OHA's COVID-19 Vaccination Site Non-Discrimination, ADA and Language Access Guidance in medical treatment. If possible, provide the individual who is receiving the vaccine, or their legally authorized health care representative, the option of consultation with a traditional health worker or other trusted community representative. The Oregon Health Authority (OHA) has a traditional health worker registry if a provider is interested in finding a traditional health worker to be available for consultations during vaccinations.

  OHA has the following tools for providers related to language access:

  - Preferred Language Cards
  - Limited English Proficiency website
  - Services such as Language Link contract to provide language access services for health care

- Know the do's and don'ts involved in providing a legally responsible COVID-19 vaccine program
- Participate in Quality Assurance Site Visits

The following task list may help keep up with requirements:

Daily tasks	Take minimum and maximum temperatures once a day at the start of the day.
	Document all immunizations in Patient Record.
	Ensure COVID-19 vaccine inventory is up to date in ALERT IIS. Providers that cannot send inventory into ALERT IIS daily through an EHR must manually update COVID-19 vaccine inventory in ALERT IIS every day.
Weekly	Download and review digital temperature data.
	Do a COVID-19 vaccine inventory count.
	Adjust COVID-19 vaccine inventory in ALERT IIS to match physical inventory.
	Troubleshoot any data quality issues you discover due to inventory count.
Every two years	Calibrate digital data loggers (or more often per manufacturer instruction).
As needed	Complete Required Trainings. (Click and scroll down to stocked COVID vaccines)
	Place vaccine orders after correcting ALERT IIS inventory.
	Complete vaccine redistribution documentation in ALERT IIS. Redistributed doses must be transferred in ALERT IIS.
	Update Emergency Use Authorization Fact Sheet for Recipients and Caregivers or Vaccine Information Statements (VISs) for each COVID-19 vaccine
	Submit temperature logs to Oregon Immunization Program upon request.
	Respond to temperature excursions and document them in your vaccine storage

	troubleshooting record. Contact the COVID vaccine manufacturer and report the outcome to Oregon Immunization Program: VFC.help@state.or.us.
	Update provider shipping hours in ALERT IIS.
	Report changes of key staff to Oregon Immunization Program.
	Participate in COVID-19 Quality Assurance Site Visit upon request.

Section 2: Employee training

Because of the evolving situation with new vaccines and new trainings, the Oregon COVID-19 Training for Vaccine Providers webpage will be continually updated with all required and recommended COVID-19 vaccine provider trainings.

Section 3: Ordering, coding, billing and documentation

Vaccine ordering

Instructions for ordering vaccine can be found on the COVID-19 Training for Vaccine Providers page. They are included under the heading, “Recommended ALERT IIS trainings”.

Vaccine coding

COVID-19 vaccines should always be recorded in ALERT IIS as eligibility code “S” or “Special Projects.” If code “S” is not available in the EHR, use code “O” for “Other Projects.”

Billing

Billing for vaccine and administration fees				
Number of doses in Series	Vaccine eligibility	Can you charge for the vaccine?	Administration fee	Individual cannot be billed
1	Special projects	No	Yes — $40.00 For vaccines given 3/14/21 or earlier: Yes — $28.39	Required
2	Special projects	No	Yes — $40.00 For vaccines given 3/14/21 or earlier: Yes — $16.94/1st injection Yes — $28.39/2nd injection	Required

Administration fees for third doses for immunocompromised individuals and booster doses can be billed the same $40 fee. Coding information can be found at the Centers for Medicare and Medicaid Services website.

COVID-19 vaccines are provided to enrolled providers free of charge. Providers may charge the specified administration fee. For uninsured and underinsured patients, the vaccine provider can seek reimbursement for an administration fee from the HRSA Provider Relief Fund. However, HRSA is now longer accepting claims due to lack of funds. **Providers may not seek reimbursement directly from patients. Administration fee limits apply to Medicare and HRSA billing only.**

- For some in-home vaccinations of recipients covered by Medicare, an additional (approximately) $35 reimbursement per home visited per day may be billed. Only immunizations occurring on June 8, 2021 and later are eligible for this additional in-home patient payment. Effective on August 24, 2021, Medicare will pay the additional payment amount (approximately $35 per dose administered), for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare patients receive a COVID-19 vaccine dose on the same day at the same group living location

Providers billing for this reimbursement will need to know the full eligibility rules. See the Centers for Medicare and Medicaid Services website and explanatory infographic to learn more.

Documenting vaccine administration

All vaccine administration records must contain the following data elements:

- Address of clinic/organization where vaccine was administered
- Name, manufacturer AND lot number of vaccine administered
- Date of administration
- Name and title of the individual administering the vaccine

OHA strongly recommends vaccine administration records contain:

- VIS or EUA Fact Sheet for Recipients and Caregivers publication date
- Date VIS or EUA Fact Sheet for Recipients and Caregivers was provided to individual

Up to date EUA fact sheets are available on FDA's website for each vaccine.

Documenting adverse events

Vaccinators must report all clinically significant adverse events that occur after the administration of vaccines to the Vaccine Adverse Event Reporting System (VAERS), even if they are not sure whether the vaccine caused the adverse event. VAERS accepts all reports, including reports of vaccination errors. See the Vaccine Safety section below for details.

V-safe

Vaccinators should provide an information sheet to an individual being vaccinated at every vaccination visit on how to enroll in v-safe, which is a free, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. The system also provides telephone follow-up to anyone who reports medically significant adverse events. Health checks by text message and email will come daily for the first week following vaccination and will arrive weekly for the next six weeks after that. **Note:** V-safe also provides second dose reminders. A parent or Guardian must enroll a child 15 or younger into v-safe.

Informed consent

Oregon has a policy to ensure that vaccine recipients understand the risks and benefits of the COVID-19 vaccine. Providers must follow Oregon's Informed Consent Policy. People 15 years old and older have the right to consent to medical treatment in Oregon.

Section 4: Inventory management

Managing your inventory

Provider organizations are required to:

- Enter COVID-19 vaccine stock into ALERT IIS prior to administering doses.
- Report all doses to ALERT IIS with eligibility code "S" (Special Projects) within 24 hours of vaccine administration.
- Reconcile Inventory Weekly (see section below)
- Collect all information required to be reported into ALERT IIS, including race and ethnicity information, from individuals being vaccinated.
- Report administration information into ALERT IIS in accordance with the Oregon Administrative Rules Chapter 333, Divisions 47 and 49. Additional information about reporting requirements and training can be found on the COVID-19 Vaccine Provider Training webpage.
- Count vaccines in the refrigerator and freezer and compare numbers to your ALERT IIS inventory weekly. You must submit a reconciled inventory count in ALERT IIS to place an order.
- Keep current on product-specific storage and handling trainings. Training links will be posted on the COVID-19 Training for Vaccine Providers webpage and major updates will come in listserv emails.

Reconciling your inventory

Provider organizations are required to count their physical inventory of COVID-19 and update ALERT IIS every week and submit reconciled COVID-19 inventory count once a week, at minimum.. For ultra-cold vaccines, do not hand count as that will melt the vaccine but make the best count possible.

- Print inventory count list from ALERT IIS.
- Compare quantity shown in ALERT IIS with physical inventory by lot number and make note of any differences.
- Troubleshoot inventory issues. Identify preventable errors such as incorrect lot numbers or inventory not entered into ALERT IIS. Refer to the ad hoc report (second report in the link) for inventory management training: http://bit.ly/ReportsTraining
- Make any corrections that are needed to your ALERT IIS inventory.
- Submit reconciled COVID-19 inventory count once a week, at minimum. The process for this

is outlined in the COVID inventory guide.

- Develop a plan for avoiding preventable errors and train staff. Adjustments must be made in ALERT IIS to account for those losses.

Spoiled, wasted, and expired COVID-19 vaccines

Spoiled, wasted or expired COVID-19 vaccines may not be returned. Dispose of these with medical waste or sharps container. CDC asks the clinics also destroy packaging to suppress the likelihood of vaccine counterfeiting.

Account for spoiled, wasted and expired doses in ALERT IIS as follows:

- Spoiled doses are accounted for as “spoilage reported by provider” except when one of the following is more appropriate:
    - Failure to store properly upon receipt (e.g., vaccine spoiled before making it into the storage unit),
    - Refrigeration failure reported by provider
- Doses that are drawn up and refused are accounted for using the code “other, not usable-reported by provider”.
- Expired doses will be flagged as Expired in ALERT IIS automatically. This will only be effective if providers have updated the expiration date for vaccines that come with a placeholder expiration date.
- If unable to extract the full number of doses from multidose vials of COVID-19 vaccine, the deficient number of doses should be reported to ALERT IIS as “other, not usable-reported by provider.”
- If the vaccine goes past the “Beyond Use Date”, that is, runs out of time in the fridge or freezer but has not been punctured, choose “spoilage reported by provider.” If it has been punctured, then it should be called “other, not usable by provider.”
- Report all spoiled/wasted/expired doses using the following Smartsheet link: Wasted/Spoiled/Expired Vaccine Dashboard - Smartsheet.com
- All administered doses must be the full volume indicated in the EUA Fact Sheet for COVID-19 vaccine providers. Never pool partial doses to make up a full dose. Instead, discard leftover partial doses and, if appropriate report as “other, not usable by provider”.

Section 5: Storage and handling equipment

Refrigerator and freezer requirements

Provider organizations are required to use vaccine storage units to store COVID-19 vaccine that meets the following requirements:

- Units must be able to maintain required vaccine storage temperatures:
    - Refrigerator: 2° to 8° Celsius (36° to 46° Fahrenheit)
    - Standard freezer: Set to -20° Celsius

NO storage of Orange Cap, Maroon Cap Gray Cap / Comirnaty presentations of Pfizer cannot in this range.

Moderna (all presentations): Acceptable range is - 50° to -15° Celsius or -58° to +5° Fahrenheit

- Ultra-cold freezer: -90° to -60° Celsius (-130° to -76° Fahrenheit)

- Units must be large enough to store the year's largest routine vaccine inventory and added COVID-19 vaccines, while maintaining proper temperatures.
- Units must contain a centrally located digital data logger rated for the temperature range required.
- Digital data loggers for refrigerators and standard temperature freezers must have a buffered probe.
    - Digital data loggers for ultra-low freezers will use unbuffered probes specifically made for ultra-cold. Traditional glycol-buffered probes freeze at ultra-low temperatures.
- Digital data loggers must be rated for the temperature range of the fridge or freezer units they serve.
- Units must be dedicated to the storage of vaccines (and other pharmaceuticals only as necessary). Food and beverages must NOT be stored in a vaccine unit. This practice results in frequent door opening and temperature destabilization.
- NEVER USE dorm-style refrigerators for vaccine storage under any circumstances.
- Store vaccine in original box to prevent exposure to light.

Refrigerator and freezer set-up

- Plug storage units into ordinary outlets. (Do not plug storage units into outlets controlled by a wall switch; outlets that have built-in circuit switches; extension cords; or surge protectors).
- Place "Do Not Unplug" stickers near the outlet and on storage equipment circuit breakers.
- New storage units may not be used until 72 hours of temperatures have been recorded in the proper range.
- When you move storage units to a new location, monitor temperatures for 48 hours before you store vaccines in the unit.
- Place water bottles throughout units—against walls, in the back, on the floor and in the doors—to help stabilize temperatures. This is not recommended for all purpose-built vaccine fridges and freezers. Do not add water bottles to ultra-cold freezers.

Refrigerator and freezer recommendations

OHA recommends but does not require that providers:

- Use pharmacy or biologic-grade storage units specifically designed for vaccine storage.
- Use stand-alone refrigerators and stand-alone freezer units only (household units may not be allowed in the future).
- Install plug guards or locks on outlets.

- Store vaccine in mesh or perforated trays that allow air circulation. For ultra-cold freezers, store vaccine in trays that came inside of thermal shippers.

Thermometer requirements

COVID-19 providers are required to maintain one calibrated digital data logger for every vaccine storage unit. These loggers must:

- Be tested for calibration at least once every 36 months or per manufacturer specifications. Certificates of calibration must include:
  - ✓ Model number
  - ✓ Serial number
  - ✓ Calibration date
  - ✓ Documentation that the instrument passed testing
  - ✓ Testing of ultra-cold temp loggers in the ultra-cold temperature range
- Have a buffered temperature probe (e.g., glycol, glass beads or similar) for vaccine kept at refrigerated or standard freezer temperatures. Ultra-cold temperature data loggers will use air probes or probes designed specifically for ultra-cold temperatures.
- Be able to display a minimum and maximum temperature since the logger was last checked.

Thermometer recommendations

In addition to the above requirements, we strongly recommend data loggers have:

- An alarm for out-of-range temperatures
- An accuracy of +/-0.5°C (+/-1°F)
- A low-battery indicator
- Memory storage for at least 4,000 readings
- A logging interval set to once every 15 minutes
- Been stored in the refrigerator so that they are pre-chilled and ready to use

For more information regarding refrigerators, freezers and thermometers, check out our guides at http://bit.ly/VFCProviderResources.

Section 6: Receiving vaccine

Refrigerated and Standard Freezer Temp Vaccines

To ensure receipt of vaccine:

- Staff must be on-site to receive state-supplied vaccine at least one day a week other than Monday, and for at least four consecutive hours on that day.
  - Deliveries will only be made during the hours and days you designate in ALERT IIS.

- Do not reject COVID-19 vaccine shipments.

Accept delivery and open your vaccine shipment immediately. Issues with shipments must be reported the same day the shipment is received. (see “Shipping-related contacts” below).

Check the temperature indicators in the shipping container to ensure vaccine remained in the recommended temperature range during shipment. See “Shipping Related Contacts” below for who to contact if the temperature indicators show that vaccines may have been exposed to out-of-range temperatures in shipment.

Check vaccine brands, expiration dates, lot numbers and quantities to be sure your delivery matches the packing slip and the ALERT IIS order transfer.

- If orders are filled in more than one shipment, packing lists will reflect what is in each box rather than what is in the complete order.

- Place the vaccine into your refrigerator or freezer. Rotate vaccine stock to ensure that vaccines that will expire or reach their beyond use date first are used first.
- Accept the vaccine order transfer in ALERT IIS to add the order to your inventory.
- Store ancillary kits which come with vaccine. See Ancillary Kits section below.
- Moderna (all products) can be stored for up to 30 days (but not to exceed the expiration date) at refrigerated temperatures and All current Pfizer products may be stored up to 10 weeks (but not to exceed the expiration date) in a refrigerator and transported at those temperatures without time limit.
  - When thawed, these vaccines should be handled with care and protected from shocks, drops, vibration, etc.
  - Use Moderna Beyond Use Date tracking materials to track dates for refrigerated Moderna vaccine.
  - Use Pfizer Beyond Use Date materials to track dates for refrigerated Pfizer vaccine.
  - Thawed COVID-19 vaccines cannot be re-frozen.
- The shipping containers used for Orange Cap, Maroon Cap and Gray Cap Pfizer / Comirnaty are single use and not returnable, but the data logger that ships with them must be returned. A return mailer is included in the shipper. Direct-ship Pfizer shipments contain a return label and packaging for the Controlant temperature monitoring device.
- Moderna shipping containers must be returned unless shipper indicates it is disposable. For Moderna, return mailing labels are on the inner flaps of the container which can be refolded as the outer flaps for the return shipment.
- Orange Cap Pfizer, Maroon Cap Pfizer, and Gray Cap Pfizer / Comirnaty (the Do-Not-Dilute Pfizer formula for ages 12+) may be stored in the refrigerator for up to 10 weeks (not to exceed the expiration date). There is no limit on transport time for these vaccines. They cannot be stored in a standard freezer. They must be in an ultracold freezer or a refrigerator. Once thawed they cannot be re-frozen and must be used *the earlier* of expiration date or the beyond use date (10 weeks from stepping down to fridge temperatures).

Ultra-cold Pfizer vaccine

Open your vaccine shipment as soon as you receive it. Before opening the thermal shipper that the vaccine arrives in, make sure you understand the handling instructions (from required trainings) and be ready to act fast.

- OHA recommends having a second staff member track time and assist whenever a staff member inspects the vaccines in the thermal shipper or recharges it with dry ice.
- **Dry ice should not be handled in enclosed spaces with poor ventilation. Protect exposed skin from dry ice and use eye protection. Find tips in this dry ice safety sheet.**
- When handling vaccine vials individually, wear exam gloves and have a secondary container ready for the vials.
- Orange Cap, Maroon Cap and Gray Cap Pfizer / Comirnaty come in a single-use thermal shipper that is not returned, **but the temperature monitoring device is returned using shipping materials enclosed in the non-returnable thermal shipper.**
- Ultra-cold vaccine is sensitive and should not be shaken at any time, including during reconstitution with diluent (gently invert it 10 times both before and after dilution).
- Do not attempt to take a complete inventory of ultra-cold vaccines upon arrival. Check the vaccine trays for damage. If damage is found, contact Pfizer Customer Service 1 (800) 666-7248 or CVGovernment@pfizer.com immediately after re-securing vaccine in ultra-low freezer or thermal shipper that has been replenished with dry ice.
- If orders are filled in more than one shipment, packing lists will reflect what is in each box rather than what is in the complete order.
- Comirnaty-labeled Gray Cap Pfizer arrives with printed expiration dates. These apply for so long as the vaccine is stored in ultracold conditions.
- Gray Cap Pfizer (non-Comirnaty labeling), Orange Cap Pfizer (ages 5 through 11) and Maroon Cap Pfizer (ages 6 months through 4 years) come with manufacture dates printed on them. Expiration dates are calculated from the manufacture date. (see Expiration Dates section below)
- Once Pfizer ultra-cold vaccines are thawed, they are subject to a Beyond Use Date (BUD) of:
    - 10 weeks after the start of thaw for Maroon Cap Pfizer, Orange Cap Pfizer and Gray Cap Pfizer (monovalent primary series and bivalent booster versions).
- Vials of vaccine that are removed from vaccine trays outside of an ultra-low temperature environment must be treated as thawed vaccine and refrigerated and used within 10 weeks for Maroon Cap, Orange Cap and Gray Cap Pfizer.
- Details about vaccine viability timelines will be the subject of upcoming trainings about specific vaccines. The CDC expiration date tracker may be helpful for keeping up with these dates.

Ancillary kits

Vaccines come with supplies to support the shipping quantity of vaccine. The contents of those supply kits are listed in the Product Information Guide.

Providers who are redistributing vaccine will have to distribute ancillary kit supplies in proportion to vaccine that is redistributed. An Ancillary Kit Configuration Tool to calculate how many needles, syringes, etc should be redistributed with vaccine can be found under “Vaccine Administration” on the COVID-19 Provider Training webpage.

- These contain injection needles, mixing needles (if appropriate), syringes, alcohol pads, vaccination cards, needle information cards and face masks and face shields for vaccinators.
    - Quantities and needle sizes vary between vaccines. Kits are built to support each of the shipping quantities. The contents of those supply kits are listed in the Product Information Guide.
    - Providers who are redistributing vaccine will have to distribute ancillary kit supplies in proportion to vaccine that is redistributed.
    - An Ancillary Kit Configuration Tool to calculate how many needles, syringes, etc. should be redistributed with vaccine can be found under “Vaccine Administration” on the COVID-19 Provider Training webpage.

Sometimes ancillary supplies will be missing items or defective. If you have defective ancillary supplies, please take the steps below as they are appropriate to your situation:

1. Report deficiencies to McKesson directly; the customer service desk is charged with responding to problems and identifying trends. McKesson Customer Service Phone: 833-272-6634 Email: SNSSupport@McKesson.com

2. Report deficiencies to the Oregon Immunization Program to help identify trends in problem equipment. VFC.Help@state.or.us

3. If a deficiency leads to an error or injury during vaccine administration, include the event in the report to VAERS.

4. Because syringes and needles are classified as medical devices, providers are encouraged to report any deficiencies by completing US Food and Drug Administration (FDA) form 3500: Per the FDA guidelines: If the case report involves more than one (1) faulty medical device, please prepare a complete copy of Form FDA 3500 that identifies one device and attach an additional copy of Form FDA 3500, with only Section E filled in, for each additional device

Shipping-related contacts – Report issues on day of delivery

I need help with…	Contact…
Pfizer vaccine shipment has a problem	Pfizer Customer Service Phone: 800-666-7248 Email: cvgovernment@pfizer.com

Pfizer ancillary kit has a problem	McKesson Customer Service Phone: 833-272-6634 Email: SNSSupport@McKesson.com
Moderna vaccine shipment has a problem	**Vaccine viability – temperature excursions during shipment for McKesson Specialty Distributed COVID Vaccine** 1. Supports calls/emails from provider/admin sites and awardee or federal/pharmacy ordering points of contact. 2. Questions/concerns about vaccine viability issues during shipment must be reported on the **same day as delivery.** **Phone:** 833-272-6635 Monday — Friday, 8 a.m.— 8 p.m. ET **Email:** COVIDVaccineSupport@McKesson.com (only send email if after hours)
Novavax or Johnson & Johnson vaccine shipment has a problem	McKesson Customer Service Phone: 833-343-2703 Email: COVIDVaccineSupport@McKesson.com
Moderna, Novavax or Johnson & Johnson ancillary kit has a problem	McKesson Customer Service Phone: 833-343-2703 Email: COVIDVaccineSupport@McKesson.com

Section 7: Storing vaccines

Light

Wherever you are storing COVID-19 vaccine, store it inside its box or tray to protect the vaccine from light.

Expiration Dates

For all vaccine ensure correct expiration date or Beyond Use Date.

Expiration dates may not always be printed on COVID-19 (a *placeholder* date in 2036 or 2069 may be printed on the vial and box – it is not the expiration date) vaccines and may also be updated based on ongoing vaccine stability studies. Expiration Dates should be adjusted in ALERT IIS to the current, accurate expiration date.

- Pfizer Orange Cap (ages 5 through 11) Pfizer Gray Cap, both monovalent primary series and bivalent booster versions (for ages 12+) and Maroon Cap Pfizer (ages 6 months through 4 years) come with a printed manufacture date, not an expiration date. The expiration date is 12 months later **inclusive of the manufacture month**. So a vial labeled with a manufacture date of 10-2021 would expire 09/31/22.
- The Comirnaty version of Gray Cap Pfizer is printed with an expiration date rather than a

manufacture date. No extensions to those dates have been announced.

- Pfizer Maroon Cap (for small children ages 6 months through 4 years) comes with a printed manufacture date.
- Pfizer now has a webpage for finding current expiration dates: Pfizer webpage
- Moderna expiration dates can be found on the Moderna webpage. Some but not all Moderna lot numbers received an expiration date extensile. The Moderna webpage will have all updated dates.
- Novavax expiration dates can be found using the Novavax webpage
- Johnson & Johnson expiration dates can be found on the Janssen webpage.
- Providers can also sign up for a database of lot numbers and expiration dates. To request access to this report, visit CDC's Vaccine Lot Number and Expiration Date webpage and complete the registration form.
- Once vaccines are under a Beyond Use Date time limit, expiration dates no longer apply, only the beyond use date matters. Exception: where the expiration date is sooner than the beyond use date.
- For all expiration date extensions:
  - Check the most recent EUA Factsheet or Manufacture webpage for the most up to date expiration date.
  - The extension of expiration dates applies only to doses which have been stored within recommended storage conditions (original storage environment).
  - Doses of Moderna and Pfizer stored at refrigerator temperatures (2°C to 8°C) at any time do not receive an extension and are valid only until their beyond use date. If the original expiration date was sooner than the beyond use date, however, an expiration date extension will allow storage of the vaccine through the full Beyond Use Date time.
  - Beyond Use Dates never add time to an expiration date.
  - Update expiration dates (but not beyond use dates) in ALERT IIS. To update the vaccine expiration date in ALERT IIS from the placeholder date it comes with to the true expiration date, follow the steps in section 1.2 of the Guide to Managing COVID-19 Vaccine in ALERT IIS.

Beyond use dates

When a vaccine is moved out of its original storage temperature (for all Pfizer – moved out of ultracold storage and for all Moderna – moved out of the standard freezer) the expiration date may lose importance. When vaccine 'steps down' to a different storage environment, there is new clock ticking: the Beyond Use Date (or BUD). That is the date on which the vaccine will spoil even if the expiration date has not yet been reached.

- For all Pfizer vaccines, the date would be 10 weeks after it is moved from ultracold temps to the refrigerator.

- For all Moderna products, that date would be 30 days after it moves from the standard freezer to the refrigerator.
- Novavax and J&J are only stored at refrigerated temperatures, so a beyond use date does not apply
- Once punctured, all of the vaccines will quickly spoil. See brand information for all times.

Beyond Use Dates never add time to a vaccine's life, they only take time away. In other words, when *either* the Beyond Use Date *or* the Expiration Date is reached, whichever comes first, vaccine should be treated as spoiled or expired (See the Spoiled, Wasted, Expired COVID-19 Vaccine section). To know which comes first, you will need to have updated the expiration dates.

Labels and guidance are available at the CDC website for Pfizer and Moderna.

Pfizer Vaccine handling timelines:

- Full and closed vaccine trays can be at room temperature for a maximum of 5 minutes before returning to ultra-cold storage).
- Open or partial vaccine trays may be at room temperature for a maximum of 3 minutes before being returned to ultra-cold storage.

  Once vaccine trays are returned to ultra-cold storage, staff should wait at least 2 hours before accessing them again.
- Single vials may be handled at room temperature – with buffer-like rubber gloves between the skin and the vial - for a maximum of 1 minute before being returned to ultra-cold storage.
- Full cartons of Pfizer may be at room temperature for up to 5 minutes between the shipper and on-site storage. Partially full cartons are allowed only the single vial handling time.
- For Pfizer shippers, remove the temperature monitoring device and return it in the enclosed shipping box.

After securing vaccines in storage units, store the ancillary kits which come with vaccines. These contain injection needles, mixing needles (if appropriate), syringes, alcohol pads, vaccination cards, needle information cards and face masks and face shields for vaccinators. Quantities and needle sizes vary between vaccines. Ancillary kits will come with quantities of supplies to support the number of doses shipped.

Controlant Device: The built-in Controlant temperature monitoring device will continue to monitor temperatures in the thermal shipper (for all Pfizer products). Whether or not a provider is using the thermal shipper for storage, the site will **press "stop shipment" and hold it for 5 seconds** when it opens the shipper to unpack it or add dry ice. This must be done when the shipper is opened and within 24 hours of delivery. Pressing and holding "stop shipment" lets Pfizer know that the package has been delivered and triggers the temperature device to give a report about vaccine quality. It does not actually stop the device from taking temperature readings.

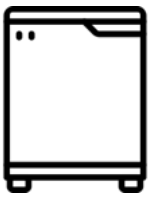
When the "stop shipment" button is pressed and held for 5 seconds the device will either blink green to show that the product may be used or it will blink red to tell the provider that the vaccine may have been affected by a temperature excursion. In either case, Controlant will send an email giving a quality report. Provider organizations must wait for the quality report before administering the

vaccines even if the Controlant Device Display indicated that vaccines were ok to use. Providers must respond to all emails from Controlant.

The Controlant temperature monitoring device that comes with it must be returned. The device functions as described above in this section. The non-returnable shipper will come with a shipping envelope to be used for returning the temperature monitoring device.

Special instructions for handling ultra-cold vaccine - Pfizer only

If storing Pfizer ultra-cold vaccine in an ultra-low freezer:



- Open thermal shipper immediately upon receiving it.
- Inspect outside of vaccine trays for damage.
- Secure vaccines in ultra-low freezer
    - within 5 minutes of opening thermal shipper (all Pfizer products).
- Press “stop shipment” or “stop” on the Controlant Temperature Monitoring Device and hold it down for 5 seconds. Check email for Quality Disposition Report which will mail within one hour – do not administer the vaccine until you receive the Quality Disposition Report, even if the Controlant device came with a display that indicated no excursions.

Pfizer vaccine may be stored in the refrigerator (2°to 8° Celsius/36° to 46° Fahrenheit) for up to 10 weeks or expiration date, whichever comes first. COVID-19 vaccine cannot be refrozen after it thaws.

If storing vaccine in standard freezer: Moderna

- **This range is allowed only for Moderna.**
- For **Moderna** (all presentations), store in standard freezer

  (-50 to -15°C / -58 to +5°F) until expiration
- For **Moderna** (all presentations), store in refrigerator (2 to 8°C / 36 to 46°F) for up to 30 days Do not refreeze thawed vaccine
- Inspect exterior of shipping trays for damage.
- Monitor temperatures using a digital data logger with a buffered probe.

If storing vaccine in refrigerator – all COVID-19 Vaccines

For all of the vaccines, the allowable refrigerator range is 2°C to 8°C / 36°F to 46°F). This range is allowed for the following amounts of time:

- **Novavax** up to its expiration date
- **J&J** up to its expiration date.
- **Pfizer products** for up to 10 weeks (or expiration date if earlier; do not re-freeze)

- **Moderna products** for up to 30 days (or expiration date if earlier; do not re-freeze)

Dispose of refrigerated vaccine at the earlier of the Beyond Use Date or Expiration Date.

Monitor temperatures using a digital data logger with a buffered probe.

Mark the boxes with beyond use date information: Pfizer and Moderna

Note: Do not place ultra-cold vaccine right next to other refrigerated vaccines when it is moved into the refrigerator.

Excursion-related contacts

I need help with…	Contact…
Temperature excursions within the clinics/site (see Section 6: Receiving vaccines, above, for shipping issues including excursions during shipping)	**For Pfizer** take action if any of the following occur. vaccine stored in: • An ultralow freezer, if temperatures become colder than -90°C (-130°F) or warmer than -60°C (-76°F); • in a refrigerator if temperatures become colder than 2 °C (36°F) or warmer than 8 °C (46°F). **Pfizer**: 1 (800) 666-7248 or cvgovernment@pfizer.com **For Moderna** Vaccines, take action if: • in standard freezer, temperatures become colder than -50°C (-58°F) or warmer than -15°C (+5°F) or • in refrigerator temperatures become colder than 2 °C (36°F) or warmer than 8 °C (46°F). **Moderna**: 1 (866) 663-3762 or excursions@modernatx.com **For Novavax** take action if vaccine temperatures become colder than 2°C (36°F) or warmer than 8°C (46°F): call Novavax 1-855-239-9174 **For Johnson & Johnson,** take action if vaccine temperatures become colder than 2°C (36°F) or warmer than 8°C (46°F), contact Johnson & Johnson Phone: 800-565-4008 (or) 1-908-455-9922 or JSCCOVIDTEMPEXCURSION@its.jnj.com

Section 8: Temperature monitoring

Temperature monitoring

- **Clinical staff check and record minimum and maximum temperatures at the start of each clinic day** using your digital data logger. Temperatures must remain in the following ranges:
  - Refrigerator: 2° to 8° Celsius (36° to 46° Fahrenheit)
  - Standard freezer (Moderna only): Set to -20° Celsius

    For all Moderna: -50 to -15° Celsius / -58 to +5° Fahrenheit
  - Ultra-cold freezer (Pfizer only): -90° to -60° Celsius / -130° to -76° Fahrenheit
- Record both the exact time the temperature is checked and the initials of the recorder in the temperature log.

  Note: Minimum and maximum temperatures recorded must be those reached since the last time temperatures were recorded on the daily temperature log. If your data logger has an automatic reset, you may have to review multiple measurement periods to capture all temperatures since you last reviewed them. Min/Max tip sheet available at: http://bit.ly/minmaxguide

  Temperature logs are available on our provider webpage and CDC includes them for the individual vaccines.
- **Download and review digital data logger every week,** preferably on Monday mornings or when returning to the clinic after a weekend or day of closure (data may be saved and reviewed on the cloud instead of downloaded).
- **Keep temperature monitoring documentation for three years.** This includes data from digital data loggers, daily temperature logs, data from alarm systems and vaccine storage troubleshooting records.
- **Test your alarm system** (if applicable) quarterly and document the results on your vaccine storage troubleshooting record (e.g., warming the thermometer or probe to intentionally trigger the alarm).

Responding to out-of-range temperatures

If temperatures are out of range a provider must:

- **Restrict use** of the refrigerator and/or freezer.
- **Place a "DO NOT USE-AWAITING GUIDANCE" sign** on the unit and notify your primary responsible staff.
- **Determine the cause and take action**. The table of Excursion Scenarios below provides examples of how you might handle different types of excursions.
- **Contact** the COVID-19 vaccine manufacturer for vaccine viability (See "Excursion Related Contacts" above). If you have questions after taking this step, contact the Oregon Immunization Program at 971-673-4832 or vfc.help@dhsoha.state.or.us.
- **Label** the affected boxes of vaccine with the duration of the excursion and the maximum or

minimum temperature reached. That way if later excursions occur it will be clear which vaccine experienced just the most recent and which also experienced any earlier ones.

- **Document** the incident. Include the following in your vaccine storage troubleshooting record (https://www.immunize.org/catg.d/p3041.pdf):
    - Length of excursion
    - Minimum and maximum temperatures
    - Steps taken to address the excursion
    - The outcome in your vaccine storage troubleshooting record.

Excursion scenarios – refrigerator and standard freezer

For all excursions involving COVID-19 vaccine:

- **Stop vaccinating with affected stock.**
- **Label "DO NOT USE-AWAITING GUIDANCE**".
- Contact the COVID-19 vaccine manufacturer for vaccine viability information.

To preserve vaccine **while contacting manufacturer**, do the following (as applicable):

If there is a slight temperature fluctuation due to an inventory count or the door being left ajar:

- Close the door. Recheck temperatures in 30 minutes to make sure they have returned to the recommended temperature range.

If there is a slight temperature excursion due to an unknown cause:

- Make a slight adjustment to the thermostat or follow your protocol. Recheck temperatures in 30 minutes.
- If temperatures have returned to normal range, continue to monitor temperatures closely until you are confident you have not over-adjusted and that your storage unit can maintain the appropriate temperature.
- If temperatures have not returned to normal range, move vaccine to a functioning unit.
- If there is a major excursion and your refrigerator or freezer appears to be malfunctioning:
    - Move vaccine to a functioning storage unit (see vaccine emergency plan, below).
    - Get the malfunctioning unit serviced. You may also want to contact the manufacturer of your vaccine storage equipment for guidance.

If you suspect the excursion is due to a malfunctioning thermometer (rather than a true excursion):

- Restrict use of the refrigerator and/or freezer. Place a "DO NOT USE" sign on the unit and notify your primary responsible staff.
- Place back-up thermometer in the storage unit to confirm the temperature reading.

If there is a power outage:

- Contact your power company to see how long the outage is expected to last.
- Do not move your vaccine if the power outage is expected to last less than four hours. Most storage units will maintain their temperatures during brief power outages as long as the door remains closed.

- If the power outage is expected to last longer than four hours, move the vaccine to your alternate storage facility (see vaccine emergency plan).

Excursion scenarios – ultra-low freezer

- Stop vaccinating with affected stock.
- Label “do not use” on Freezer door.
- Contact the COVID-19 vaccine manufacturer for viability information.
- Keep door to ultra-low freezer closed.
- Consider step down to fridge (irreversible).

Section 9: Redistribution and offsite clinics

Requirements for redistribution of all COVID-19 vaccines

- Transport with data logger (required)
- Pack according to this Vaccine Management Guide
- For offsite clinics: Set combined transport time and clinic workday amount to 8 hours or less.
- Transport equal amounts of vaccine, diluent and ancillary supplies
- Vaccine should be transported in the carton whenever possible.
- Store vaccines properly and immediately upon arrival at destination.
- Review transport temperatures and report any excursions to vaccine manufacturer (see “Excursion Related Contacts” above).
- Before transporting any vaccine to another location for use there, confer with the receiving institution to ensure that they can administer all of the redistributed vaccine before it expires.

To accelerate vaccine access:

- Hospitals and other sites that have received COVID-19 vaccine through the state may transfer excess doses to an LPHA or other *fully enrolled* COVID-19 vaccine provider registered with the state to receive vaccine, if the transferring hospital or other site is tracking the transfer in OHA’s ALERT IIS. This notice is the only advance permission that is required.
    - This permission is not a substitute for redistribution agreements, but rather, a clarification that one-off, occasional, unplanned transfers are acceptable if the transfer recipient is approved to receive COVID-19 vaccine and can properly store and handle the specific COVID-19 vaccine being transferred.
- Formal redistribution agreements are required for organizations with routine plans to receive COVID-19 vaccine at a main site and redistribute to smaller facilities.
- Redistribution of COVID-19 vaccine must meet all technical storage and handling requirements to ensure safe and effective vaccine.

Additional Pfizer redistribution requirements

- Only complete trays should be redistributed at ultra-cold temperatures.
- Thawed Pfizer products are not limited in the time they may be transported at refrigerator

temperatures but should be handled gently. Once thawed, COVID-19 vaccines cannot be refrozen.

Additional Moderna redistribution requirements

Moderna vaccines ship directly to sites in volumes of 100 doses per carton. Given the smaller shipment size compared to Pfizer vaccines, sites administering vaccine should receive a direct shipment if possible. However, because redistribution of vaccine may at times be required, consider the following general principles for Moderna vaccine redistribution:

- Once a vial of vaccine has been thawed, it may be stored refrigerated at 2 to 8°C (36 to 46°F) for up to 30 days. Mark with beyond use date: Moderna
- Once thawed, the vaccine cannot be re-frozen.
- When thawed, the vaccine should be handled with care and protected from shocks, drops, vibration, etc.
- If you must transport vaccine that has already been thawed, follow these general principles:
    - Care must be taken to ensure vaccine does not re-freeze during transport.
    - Vaccine must be protected as much as possible from drops, shocks, and vibration whether in the carton, vial, case or cooler.
    - If transport must be conducted at the vial level, the vial should be placed with dunnage (padding material like bubble wrap or similar padding) to minimize movement during transport.
    - The vaccine should always be transported in insulated containers qualified to maintain 2 to 8°C (36 to 46°F) for the duration of transport.
    - The transport containers must be secured when being transported to prevent unnecessary movement.
    - After completion of transport, vaccine should immediately be returned to appropriate storage conditions.
    - **Total transport time of thawed Moderna vaccines should not exceed 12 hours in total.**

Guidance for immunizing in home COVID-19 vaccine recipients

The CDC has special guidance for reaching in home recipients with vaccine.

Offsite and Point of Dispensing (POD) storage requirements – refrigerator and standard freezer

Providers holding offsite/Point of Dispensing (POD) clinics must meet the following storage and handling standards to ensure that the vaccine administered is safe and effective.

One person should be responsible for offsite clinic vaccine storage and handling including:

- Vaccine transport plans
- Portable storage unit operation
- Inventory management plan

- Offsite clinic temperature logs, which are available here: http://bit.ly/VFCProviderResources
- Offsite clinic emergency plan
- Training staff working at the clinic on proper vaccine storage and handling

Offsite and POD clinics should use ultra-cold vaccine only in its refrigerated state.

Main Clinic Storage

- Holds multiple weeks' worth of vaccine stock.
- Adheres to all storage and handling requirements in CDC Storage and Handling Toolkit: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

Vaccine Transport

- No more than one day's worth of vaccine transported along with equal amount of diluent, if applicable.
- Use of purpose-built vaccine transport containers strongly recommended.
- If a purpose-built container is unavailable, must be transported according to transport instructions in this guide.
- Include vaccine inventory count list.
- Monitor temps using a digital data logger.
- Document min/max on arrival and after return to main clinic.
- Unpack vaccines and move them to day storage immediately.

  Store only one day's worth of vaccine.

Day Storage

- Recommended: purpose-built vaccine transport container or portable powered storage unit.
- Units must be tested in advance to ensure ability to maintain required temps.
- Include water bottles to ensure stable temps.
- Monitor temps using a digital data logger.
- Take hourly temp readings and document min/max temps at end of day.
- Download and review the temp logs at the end of event.

Vaccination station

- No more than 10 doses or 1 hour's worth of vaccines should be stored at vaccination stations.
- Store vaccines in a small cooler (lunch pail or similar size).
- 1-2 conditioned water bottles in bottom.
- Insulating layer between water bottles and vaccine.

Out-of-range temps

- Immediately relocate the vaccine to stable back-up unit and label vaccines "DO NOT USE."
- Contact the COVID-19 vaccine manufacturer to determine vaccine viability.

Offsite and Point of Dispensing storage requirements – ultra-low freezer

We do not recommend transporting vaccine at ultra-cold temperatures. Pfizer vaccines can be kept for 10 weeks between 2° and 8°C. See CDC's Vaccine Storage and Handling Toolkit for detailed guidance. Key considerations:

- Use only refrigerated (2 to 8ºC) or standard freezer temperature (-15 to -25ºC) vaccine for offsite and POD vaccination clinics. Determine the total number of vials needed for that time period. Pack equal amount of diluent.
- Vaccines stored in the refrigerator should be used before additional vials are removed from frozen storage. Once thawed, the COVID-19 vaccine cannot be refrozen.
- Protect the vaccine from light. Place the vaccine in an opaque container when transporting.
- Document the beyond-use date (BUD) for these vials prior to transporting the vaccine.

Section 10: Vaccine preparation and administration

Vaccines must be prepared and administered according to exact specifications of the specific vaccine. Specifications can be found in the EUA Fact Sheet for Healthcare Providers available at the FDA and manufacturer websites. Great preparation and administration infographics can be found product by product at the CDC website. Select the vaccine you are working with under the "COVID-19 vaccines authorized for emergency use" heading.

Be sure you are selecting the right vaccine!

Primary series vaccine list

Age 6 months through 4 years:	Pfizer Maroon cap or Moderna (blue cap, magenta border) – monovalent
Age 5:	Pfizer Orange Cap monovalent or Moderna (blue cap, magenta border)
Age 6 through 11:	Pfizer Orange Cap monovalent; Moderna 6-11 monovalent (blue cap, purple border – labeled "Booster Doses Only")
Ages 12 through 17:	Pfizer Gray Cap/Comirnaty monovalent primary series version, Moderna for 12+ monovalent, primary series version (red cap with blue border); Novavax.
Ages 18+:	Pfizer Gray Cap/Comirnaty monovalent primary series version, Moderna for 12+ monovalent primary series version (red cap with blue border), Novavax, and J&J (if recipient otherwise won't receive a vaccine and is given specific notice about potential health outcomes)

Booster series vaccines list

Age 6 through 11:	Pfizer Orange Cap monovalent
Ages 12 through 17:	Pfizer Gray Cap bivalent booster version
Ages 18+:	Pfizer Gray Cap bivalent booster version, Moderna bivalent booster version (blue cap, gray stripe and border)

Some Pfizer Maroon Cap boxes are marked ages 2 through 4 and others are marked ages 6 months through 4 years. The vaccine is exactly the same in the two boxes and all of it is authorized by FDA for ages 6 months through 4 years of age.

Boxes of Moderna monovalent primary series (purple border and stripe) for 6- through 11-year-olds is mislabeled as "Booster Doses Only. The vaccine was made and the vials and boxes were printed before authorization for 6- through 11-year-olds. First, this presentation was authorized as a booster for age 18+, which is why the labels look how they do. But now this presentation cannot be given as a booster at all. The booster authorization for this presentation was revoked when the newer, bivalent booster doses for ages 18+ (Moderna) and 12+ (Pfizer) were authorized. Now, this presentation is only authorized a primary series for 6- through11-year-olds, but the printed labels still say "Booster Doses Only." To summarize, the Moderna vaccine with the purple border and stripe on the label is now only authorized as a primary series vaccine for 6- through 11 year olds.

Some Pfizer Gray Cap vaccine is labeled with the brand name "Comirnaty." Comirnaty is the same as the monovalent Gray Cap vaccine and should only be used for primary series doses.

Vaccine series information is well summarized at CDC's Interim Immunization Schedule and is described in full in the Interim Clinical Considerations for use of COVID-19 Vaccines

See Pfizer COVID-19 Vaccines at a glance and Moderna COVID-19 Vaccines at a glance.

See the CDC's COVID-19 Vaccine administration schedule at a glance.

Primary Series

COVID-19 vaccines require either a single dose or a multiple-dose series. All primary series doses should be monovalent vaccines.

- A recipient's doses in a multiple-dose series should be the same vaccine as the first dose.
- Pfizer Gray Cap (monovalent), Orange Cap (monovalent) – second dose in primary series follows 3 to 8 weeks (3 for immunocompromised individuals) after the first dose depending on the recipient's individual circumstances. For full details on the dosing schedule, see the CDC's Interim Clinical Considerations and Oregon's Model Immunization Protocols.
- Pfizer Maroon Cap (monovalent) – Pfizer Maroon Cap (ages 6 months through 4 years) is a 3-dose series. Dose 2 follows 3 to 8 weeks (3 for immunocompromised individuals) after dose 1. Dose 3 follows 8 weeks after dose 2.
- Moderna (all monovalent, primary series presentations), the second dose in primary series follows 4 to 8 weeks (4 weeks for immunocompromised individuals) after the first dose depending on the recipient's individual circumstance. For full details on the dosing schedule, see the CDC's Interim Clinical Considerations and Oregon's Model Immunization Protocols.
- Novavax is a 2-dose series; the second dose follows 3 to 8 weeks (4 weeks for immunocompromised individuals) after the first dose depending on the recipient's individual

circumstance. Additional doses for immunocompromised individuals are not authorized. For full details on the dosing schedule, see the CDC's Interim Clinical Considerations and Oregon's Model Immunization Protocols.

- Johnson & Johnson is a single-dose vaccine.
- If a recipient misses the second dose interval, they should receive the second dose as soon as possible. Second doses should not be administered early.
- Some immunocompromised persons may receive a 3rd dose of Pfizer or Moderna as part of their primary series. Because these doses are part of the primary series, they should be the original, monovalent formulation of the vaccine given for the other doses of the primary series, not the bivalent booster and not a different brand. The additional dose should follow the second dose of the same vaccine series by at least 28 days. Purple Cap Pfizer (now all expired) and Gray Cap / Comirnaty are interchangeable for completing a vaccine series. (See "Additional Doses for Immunocompromised Persons" below).
- Maroon Cap Pfizer is already a 3-dose primary series for all recipients. An additional primary dose for immunocompromised individuals is not authorized. The third does of Maroon Cap Pfizer follows 8 weeks after dose 2.
- Booster doses have been approved to follow all adult vaccines as well as for children ages 5 to 11. (See "Booster Doses" below). **Boosters have not yet been approved for anyone under 5**.

Post-puncture time

Once a vial has been punctured all doses must be administered or the remainder discarded within a fixed amount of time.

Pfizer Orange Cap, Maroon Cap	Store at 2 to 25°C (36 to 77°F) for up to 12 hours post-dilution (note some boxes were marked 6 hours prior to authorization however all Orange and Maroon Cap Pfizer may be stored up to 12 hours post puncture).
Pfizer Gray Cap monovalent or bivalent	Store at 2 to 25°C (36 to 77°F) for up to 12 hours post-dilution
Moderna (all):	Store at 2 to 25°C (36 to 77°F) for up to 12 hours post-puncture (discard after this time or after 20 punctures. Keep track of both time and number of punctures.
Novavax	Store at 2 to 25 °C (36 to 77 °F) for up to 6 hours post-puncture
J&J:	Store at 2 to 8 °C (36 to 46 °F) for up to 6 hours post-puncture or 9 to 25°C (47 to 77°F) for up to 2 hours post-puncture

Age of recipients

Pfizer: **Gray Cap Pfizer primary series, monovalent vaccine** has been authorized for primary series doses for children age 12 and older and adults.

Gray Cap Pfizer bivalent booster has been authorized as a booster for children age12 and older and all adults.

Orange Cap Pfizer monovalent is authorized for primary series and booster for children age 5 through 11 (booster can only follow Orange Cap primary series).

Maroon Cap Pfizer monovalent is authorized for children ages 6 months through 4 years

Moderna 12+ monovalent primary series: Original, monovalent primary series Moderna (red cap, light blue border) vaccine has been authorized as a primary series vaccine for recipients age 12 and older.

Moderna for ages 6-11, monovalent (blue cap, purple label border – labeled "Booster Doses Only") is authorized for the primary series for ages 6-11. It can be followed by a Pfizer bivalent booster.

Moderna for ages 6 months through 5 years, monovalent (blue cap and magenta label border) is authorized for children ages 6 months through 5 years.

Moderna 18+ bivalent booster (blue cap, gray label border) is authorized as a booster dose for recipients ages 18 and older.

Novavax: Novavax has been authorized as a primary series for recipients ages 12 and older

Johnson & Johnson: J&J vaccine has been authorized as a primary series for adults age 18 and older. It is disfavored.

Children 15 to 17 may consent to vaccine themselves. Younger children must have parental or guardian consent. Providers and staff are prohibited from requiring parental or guardian consent for a minor age 15 to 17 who is exercising their right to consent to treatment under ORS 109.640 (applicable to physicians, naturopathic physicians, dentists, physician assistants, nurse practitioners and optometrists).

Additional primary series doses for some immunocompromised persons

Immunocompromised people may not be protected after a regular primary vaccine series; an additional dose may protect them. An additional, monovalent primary series dose of Moderna or Pfizer is therefore recommended for moderate to severely immunocompromised individuals after an initial 2-dose series of those vaccines or after a single dose of J&J. The additional dose should be the same vaccine presentation as the other doses of the primary series. Immunocompromised Children under age 6 may who received Moderna may receive an additional dose of the Moderna vaccine for children 6 months through 5 years. Additional primary series doses have not been authorized for Pfizer recipients under age 5 as Maroon Cap Pfizer is a 3-dose series for all recipients. Additional doses have not yet been authorized for individuals receiving Novavax.

Moderate to severe immune compromise means receipt of immunosuppressive medications or treatments for solid organ transplantation or having been diagnosed with a condition or treated with medications that are considered to carry an equivalent level of immune compromise. These conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

Additional primary series doses of mRNA vaccine should be given at least 28 days after the second dose of the original mRNA vaccine series or 28 days after a single dose of J&J. These additional primary series doses are allowed for all ages using the appropriate vaccine for the age of the recipient. The additional vaccine dose should be the same monovalent vaccine product as the initial 2-dose primary vaccine series (though Gray Cap Pfizer and Purple Cap Pfizer may be used for different doses in the same series), ***except that*** after a primary dose of J&J the additional dose must be of monovalent Pfizer Gray Cap or monovalent Moderna for 12+. If the vaccine product given for the first two doses is not available, the other mRNA COVID-19 brand (Pfizer or Moderna) vaccine product may be administered instead. Recipients of Pfizer Maroon Cap vaccine are not authorized for an additional dose as it is a 3-dose primary series for all recipients.

Additional primary series doses for immunocompromised persons are not the same thing as "booster" doses. Booster doses are to boost immunity as it wanes following a vaccine dose or series. The third primary series dose, on the other hand, represents an extension of the primary series.

For full details on the dosing schedule for immunocompromised individuals, see the CDC's Interim Clinical Considerations and Oregon's Model Immunization Protocols.

Booster doses

What is a booster: Booster doses are doses given after the completion of a full primary vaccine series (including any additional primary series doses for moderately or severely immunocompromised) to boost immunity that may have waned over time.

For whom are boosters authorized: Booster doses are approved for all recipients ages 12 and older who have completed a primary series. Booster doses are authorized for recipients ages 5-11 who received Pfizer Orange Cap vaccine.

Booster doses are not authorized for anyone under 5 years of age, nor for people under 12 who received a primary series other than Pfizer Orange Cap.

What vaccine should be given as a booster: All booster doses administered to people ages 12 and older must be the bivalent booster. For age 12 through 17, only the Pfizer Gray Cap bivalent

booster is authorized, regardless of which brand of vaccine the recipient got for the primary series. Recipients 18 and older can get either the Pfizer Gray Cap bivalent booster or the Moderna bivalent booster (blue cap, gray stripe and border).

Recipients of Pfizer Orange Cap (ages 5-11) may receive a booster dose of Pfizer Orange Cap. The Pfizer Orange Cap booster is the only monovalent booster still authorized. It is the same product used for the primary series.

In the past, monovalent vaccines were authorized as booster doses for recipients ages 12 and older. People who received one or more monovalent booster dose are eligible for a bivalent booster.

When should the booster be given: Whether the primary series is 2 doses or 3 (for immunocompromised individuals), for ages 12 and older the bivalent booster should follow the last dose of the primary series (or last monovalent booster) by 2 months or more.

For ages 5-11, the Pfizer Orange Cap monovalent vaccine should be administered as a booster at least 5 months after completion of the Pfizer Orange Cap primary series.

How many boosters may be given: only one single bivalent booster is authorized for any individual.

Monovalent vaccines are no longer authorized as boosters for ages 12 and up. For this age group, only the bivalent boosters can be given as boosters, and only the older monovalent presentations can be given as primary series doses.

The CDC maintains a webpage dedicated to COVID boosters where you can find lots of information.

Giving the monovalent vaccine as a booster dose after a bivalent booster has been authorized for the recipient or giving bivalent booster to a vaccine recipient as a primary series dose is an administration error and should be reported to VAERS. (See VAERS information in Section 11 – Vaccine Safety – below).

Diluent

Only Orange Cap Pfizer and Maroon Cap Pfizer use a diluent. Diluent may come in different sizes, but only the specified amount should be drawn from the diluent vial. Then the diluent vial should be discarded no matter how much diluent remains. Due to sourcing issues, some diluent vials may be much larger than needed, what is left over should still be discarded.

Diluent volume is different for Orange Cap and Maroon Cap Pfizer:

- Pfizer Orange Cap: 1.3 mL
- Pfizer Maroon Cap: 2.2 mL
- Gray Cap Pfizer Mono- or bi-valent: DO NOT DILUTE, this vaccine does not require mixing
- Moderna (all): DO NOT DILUTE, this vaccine does not require mixing
- Novavax: DO NOT DILUTE, this vaccine does not require mixing
- J&J: DO NOT DILUTE, this vaccine does not require mixing

Ancillary supplies that come with vaccines that require dilution come with needles and syringes for drawing and mixing the diluent in addition to the needles and syringes for administering the vaccine.

Follow the manufacturer's guidance for storing the diluent.

Second-dose reminders

For COVID-19 vaccines that require a two-dose (or three-dose) series, all of the doses are critical. Providers and staff should take measures to ensure that patients return for all doses:

- Make appointments for the next dose at the time of the current dose.
- Give vaccine reminder cards that come in ancillary kits (required).
- Give patients information for signing up for v-safe.
- Use the ALERT IIS reminder/recall report to identify and contact patients.
- Use your Electronic Health Record to identify and contact patients.

For product-specific vaccine preparation materials, view the CDC website.

A person is "up to date" only after receiving a primary series and any recommended booster doses.

Selected Vaccination Resources

- CDC Video: Intramuscular (IM) injections video
- CDC Video: Comfort and restraining techniques for injections of younger children
- CDC Resource: Library of tipsheets on IM injections for all age groups
- Other CDC resources for COVID-19 Vaccines for Children and Teens

Section 11: Vaccine safety

Providers should know the information in the EUA Fact Sheet for Immunization Providers (See required trainings) and in the Model Immunization Protocols or Pharmacy Protocols for Immunization. In general, you should monitor patients for 15 minutes following vaccination. If patients have a history of immediate reactions to vaccines or other injectable therapies, or any history of anaphylaxis, monitor them for 30 minutes following vaccination.

The CDC has posted this pre-vaccination checklist. It also maintains a page on preparing for the potential management of anaphylaxis following a COVID-19 vaccine.

Providers should have the following medications and supplies at the vaccination site for assessing and managing anaphylaxis:

Should be available at all sites	If feasible, include at sites (not required)
1 multi-dose vial of epinephrine or 3 prefilled syringes or autoinjectors*	Pulse oximeter
Timing device to assess pulse	Oxygen
	Bronchodilator (e.g., albuterol)
	H1 antihistamine (e.g., diphenhydramine) †
	Blood pressure cuff
	Stethoscope
	H2 antihistamine (e.g., famotidine, cimetidine)
	Intravenous fluids
	Intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation [CPR] mask)

*Providers must be able to respond to early signs of anaphylaxis, with access to Emergency Medical Services able to respond immediately. For any cases of Anaphylaxis, EMS may need to respond with additional doses of epinephrine and will need to transport patient to the nearest medical center for further evaluation and management.

COVID-19 Vaccine providers are expected to supply Epi Pens or Epinephrine and assure this emergency equipment is available during administration of vaccine to children and adults. Providers must be prepared to administer epinephrine in doses appropriate to all recipients that they vaccinate.

Adverse events - VAERS

For COVID-19 vaccines, providers are also required to report the following specific adverse events (AEs) to VAERS:

- Vaccine administration errors (whether associated with an AE or not) (including giving the wrong vaccine presentation)
- Serious AEs (even if they are not sure if the vaccination caused the event)
- Multisystem inflammatory syndrome (MIS) in children or adults
- Cases of COVID-19 that result in hospitalization or death

Any additional specific AEs that require reporting or revised safety reporting requirements per FDA's conditions of authorized vaccine use under EUA will be posted on FDA's website and explained in the product-specific EUA Fact Sheet for Health Care Providers.

For administration errors, organizations or providers may submit a **single, aggregate** VAERS report describing the error, how it happened, and how many people were affected.

- You can leave blank the section on the VAERS form that asks for the patient's name and patient's history (questions 1-12).
- You can use Box 18 (Symptom Text) to describe what happened.

If, after the vaccination error, any vaccine recipients experience a health outcome, then an individual VAERS report must be filed for those recipients.

There are two ways to file a VAERS report:

- Online web form — https://vaers.hhs.gov/esub/index.jsp
  When using this online web form, reports must be completed in a single sitting and cannot be saved. This is the fastest method if you are able to complete it in a single session.
- Writable PDF form — https://vaers.hhs.gov/uploadFile/index.jsp
  A fillable PDF form can be downloaded and completed offline. Return to this webpage once complete and upload the form to finish the process. Use a computer where you can securely save documents containing protected health information.

Before starting your VAERS report make sure that you have the following information on hand:

- Individual's information (age, date of birth, sex)
- Vaccine information (brand name, dose number, lot number)
- Date, time and location administered
- Date and time when adverse event(s) started
- Symptoms and outcome of the adverse event(s)
- Medical tests and laboratory results (if applicable)
- Physician's contact information (if applicable)

Observation period

CDC recommends an observation period following vaccination with mRNA COVID-19 vaccines:

- Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy, people with a contraindication to another type of COVID-19 vaccine (such as Novavax or J&J), and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes.
- People with a history of a severe allergic reaction to a COVID-19 vaccine or one of its components should not receive that vaccine.
- All other persons should be observed for 15 minutes

CDC recommends an observation period following vaccination with J&J and Novavax:

- 30 minutes: Persons with a:
  - History of an immediate allergic reaction of any severity to a vaccine or injectable

therapy

- Contraindication to another covid vaccine
- History of anaphylaxis due to any cause

- People with a history of a severe allergic reaction to a COVID-19 vaccine or one of its components should not receive that vaccine.
- 15 minutes: All other persons

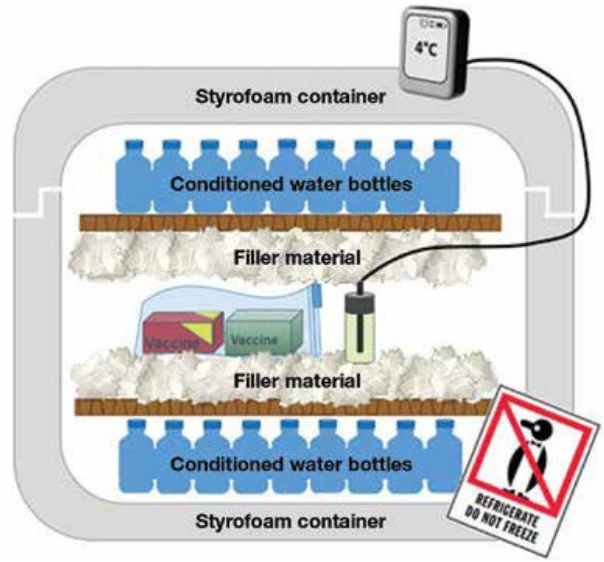
COVID-19 Emergency vaccine transport plan

Follow these instructions if you are redistributing COVID-19 vaccines or if you are executing your emergency plan due to refrigeration failure or power outage. See redistribution and offsite clinic section of this guide and the Transport and Redistribution FAQs. Instructions that apply to ordinary (not purpose-built) coolers are designated with an "*".

COVID-19 vaccine transport – fridge/standard freezer

Step 1: Gather materials	
Purpose-built transport cooler or qualified packout. As a last resort: hard-sided coolers or foam vaccine shipping containers	Insulating material
Conditioned frozen water bottles or phase change material cold packs for refrigerated vaccine; frozen water bottles for frozen vaccine. Don't combine frozen and refrigerated in single cooler.	Cardboard
Digital data logger	Current vaccine inventory – ALERT IIS printout
Step 2: Arrange delivery with accepting clinic	
Contact alternate storage facility with estimated time of arrival and approximate length of storage time.	
Step 3: Pack for transport	
If purpose-built transport cooler or qualified packout is not available, use a Styrofoam or hard-sided cooler that is at least 2 inches thick and designed for transporting vaccines.	
Pack purpose-built coolers and qualified packouts per manufacturer instructions. *For ordinary coolers, place a layer of conditioned frozen water bottles (for refrigerated vaccine) or fully frozen water bottles (for standard freezer temperature vaccine) in the bottom of the transport container. To condition frozen water bottles, run them under warm water for a few minutes until they begin to thaw and the ice spins freely inside the bottle. Use fully frozen water bottles for frozen vaccine. This means of transport is for relatively short times and short distances.	
*Cover water bottles with a layer of cardboard.	
*Cover the layer of cardboard with 1–2 inches of filler material (e.g., bubble wrap or crumpled paper), to ensure that vaccines do not touch water bottles and do not shift during transport.	
Place the vaccine in a plastic bag with a calibrated digital data logger (the display goes on the outside of the container) and place the bag on top of the filler material.	
*Place another layer, 1–2 inches, of filler material on top of vaccines and cover with another layer of cardboard.	
*Place another layer of conditioned frozen water bottles for refrigerated vaccine, or frozen water bottles for frozen vaccine on top of cardboard.	
Add vaccine inventory printout from ALERT IIS.	

Secure any gaps in the container with filler material and seal with packing tape.
Affix digital data logger display on the outside of the container, on top of the lid.
Affix “Rush!! Vaccine Perishable” and “Do Not Freeze” stickers to the transport container.



Step 4: Arrive at destination
Unpack and properly store vaccines.
Record minimum and maximum temperatures for the transport period.
Step 5: Document the event
When the vaccine is safely back at your office, document the transport in your vaccine storage troubleshooting record.
Contact the vaccine manufacturer if there were any out-of-range temperatures. Contact Oregon Immunization Program Help Desk with any questions: 971-673-4832.

- When external temperatures are below 20°F or above 85°F, only transport if necessary. Before doing so, contact the Oregon Immunization Program.
- Do NOT leave insulated container in an unconditioned location such as the trunk of a vehicle.
- Drive directly to the receiving site to minimize transport time.
- DO NOT use non-phase change gel cold packs ice to transport vaccine unless they are a component of a purpose-built cooler or qualified packout.
- Always use digital data loggers to monitor temperatures during transport.
- Frozen vaccine must be transported separately from refrigerated vaccine.

Ultra-low freezer failure

If an ultra-low freezer fails and temperatures drop below the recommended range, the vaccine will have to move to a standard freezer or refrigerator.

Key phone numbers and information

Write down storage unit details, key phone numbers and other instructions. Primary and back-up staff should keep a copy of this information along with building keys and alarm codes in case of emergency vaccine relocation or storage unit maintenance.

Vaccine storage equipment				
Unit type (e.g., freezer)	Location	Brand	Model #	Maintenance needs

Thermometers			
Primary or back-up	Brand	Model/serial #	Calibration due date

Important contact information	
Maintenance/repair company:	Phone number:
Power company:	Phone number:
Calibration company/laboratory:	Phone number:
Location of calibration certificates:	Location of back-up thermometers:

After-hours building access
Alarm codes and instructions:
Doors, locks and keys:
Light switches and flashlights:
Circuit breaker location and instructions:
Generator instructions:
Location of generator and fuel:
Routine maintenance and generator testing instructions:

Alternative storage site	
Facility name and contact person:	Phone number:
Address:	

Alternate storage site agreement- refrigerated and standard freezer temperature vaccine

_____ [Site A] and

_____ [Site B] have agreed that during a power outage or equipment failure, Site A may store its vaccine and other refrigerated pharmaceuticals in Site B's refrigerator and/or freezer with back-up generator.

Site A will contact Site B prior to transporting vaccine. This agreement is effective as of _____ and will remain until modified or terminated as agreed upon by both sites.

_____

Signature of Site A administrator or manager

_____

Signature of Site B administrator or manager

Your vaccine management guide must be updated annually, whenever key staff changes, or whenever requested by the Oregon Immunization Program. At that time, primary and back-up contacts as well as all staff who give vaccinations must review and sign the guide. All staff are responsible for ensuring that proper vaccine management is practiced as outlined in this guide. The most current version is always on the COVID-19 Training for Vaccine Providers webpage: https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Pages/COVIDTraining.aspx.

Date reviewed / /
Primary contact signature:
Back-up contact signature:
Additional staff signatures:

Oregon COVID-19
Vaccine Management Guide

You can get this document in other languages, large print, braille or a format you prefer. Contact the Oregon Health Authority Immunization Program at 971-673-0300. We accept all relay calls or you can dial 711.

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