Vaccine Management at a Glance

California COVID-19 Vaccination Program

This guide outlines requirements in CDC's COVID-19 Vaccination Program Provider Agreement and Vaccine Storage & Handling Toolkit. Refer to the EUA fact sheets or product inserts for vaccine-specific storage and handling and administration guidance. (See Vaccine Administration | Reporting Requirements at a Glance.)

Topic	Requirements & Guidance	Resource
Vaccine Management Checklist	*Organization must comply with CDC requirements for COVID-19 vaccine management (CDC Provider Agreement #7).* Manage your inventory carefully to maximize vaccinations, minimize wastage, and protect vaccine potency. Minimizing waste is important, but don't turn away potential recipients to avoid puncturing a vial at the end of the day. Vaccinate every eligible person who presents at a vaccination site—even if it means puncturing a multidose vial towards the end of the day. (See checklist and CDC wastage guidance.)	• Vaccine Management Checklist • Missed Vaccination Opportunities & Wastage
Vaccine Management Plan	How will you protect vaccines during a safety power shutoff or encroaching fire? Developing and implementing vaccine management plan is strongly encouraged. The plan documents how your staff should perform **routine** storage and handling tasks and respond to **vaccine-related emergencies**. Review and update it annually, or more frequently if changes occur, and include a review date and signature to validate it is current. Work with your provider to ensure all key practice staff complete the required training and log training completions in your practice's COVID-19 Vaccine Management Plan. Make available during site visits.	COVID-19 Vaccine Management Plan
Report Inventory to VaccineFinder	Sites must report inventory on hand to VaccineFinder **at least weekly on Fridays by close of business.** Adjust counts for shipments, transfers, or nonviable doses removed from inventory. Data help identify which communities have sufficient supply and how long vaccines sit on shelves. Data also help to measure how much vaccine is shipping to communities with health inequities.	Reporting Inventory to VaccineFinder

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Storage Units	*Organization must comply with CDC requirements for COVID-19 vaccine management. Those requirements include the following: Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 vaccine; (P.A. #7a)* **Ultra-cold freezers are not required.** CDC recommends purpose-built or pharmaceutical-grade units designed specifically for storage of biologics, including refrigerated and frozen vaccines; these units can be compact, under-the-counter style or large units. If not an option, commercial or household standalone units are also acceptable. If necessary, combination units may be used, but you must have a separate freezer unit if storing frozen COVID-19 vaccines. **Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.**	Vaccine Storage and Handling Toolkit & COVID-19 Addendum
Data Loggers	*Organization must comply with CDC requirements for COVID-19 vaccine management. Those requirements include the following: Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 vaccine; (P.A. #7a)* Storage units must be equipped with a digital data logger; devices with a buffered probe provide more accurate readings. CDC recommends devices with the following features: Current, minimum and maximum temperatures, detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®), alarm for out-of-range temperatures, reset button, accuracy within +/-.5°C accuracy (+/-1°F), and low-battery indicator. ***Ultra-cold devices:*** For accurate ultra-cold temperature monitoring, it is essential to use an air probe or a probe designed specifically for ultra-cold temperatures with the data logger. ***Backup devices:*** Providers must have at least one backup data logger in case a primary device breaks or malfunctions, and for transporting vaccines during vaccine redistribution and transfer or off-site clinics. ***Certificates of Calibration:*** Always use data loggers with a current and valid Certificate of Calibration testing. To determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, refer to CDC's Vaccine Storage and Handling Toolkit.	• Vaccine Storage and Handling Toolkit & COVID-19 Addendum • Data Logger Setup & Use

Topic	Requirements & Guidance	Resource
	Setup: Configure key settings for primary and backup digital data loggers, including device name, low and high temperature alarm limits, and a 30-minute logging interval.	
Recommended Temperatures	*Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 vaccine. (CDC Provider Agreement #7a.)* Complete CDC's product training for vaccines your location will order to ensure staff are trained on proper storage & handling.	• COVID Vaccine Product Guide • CDC's Vaccine Product Comparison Guide • Vaccine Storage and Handling Toolkit COVID-19 Addendum • EUA Fact Sheets by product
Orders & Distribution	Active and approved providers may request vaccines in myCAvax as vaccine orders (Standard or Small Order) and through Vaccine Marketplace to get doses quickly. Doses may be used for primary series, and additional and booster doses as authorized. Vaccines and ancillary kits are procured and distributed by the federal government at no cost. Location Coordinators receive emails for order status changes, order confirmations, and advance shipment notices. Vaccine Marketplace allows providers to **post inventory** (excess or short-dated that can't be used) to minimize wastage and **request doses**. Diluent and ancillary kits must be transported with vaccine. Contact COVID Call Center if you need help finding a match. California also offers a courier service that can transport vaccine across any distance, or for providers who are unable to transport/pickup vaccine for any reason. Contact COVID Call Center to arrange for vaccine transport.	• Ordering Vaccines • Ordering & Distribution Cadence
Critical Systems & Senders	It is extremely important that sites whitelist critical senders or they will not receive any communications about orders including advance shipment notices and quality/temperature information. Location Coordinators receive emails regarding order confirmations, advance shipment notices of vaccine and ancillary kits, and temperature monitoring alerts. Add critical senders to your contact list, or work with your IT staff to have these addresses included in your organization's email whitelist, to ensure emails are not filtered to Spam or Junk folders.	Critical Systems & Senders
Receiving & Storing Vaccine	*Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the*	• COVID Vaccine Product Guide

Topic	Requirements & Guidance	Resource
	manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 vaccine. (CDC Provider Agreement #7a.) **Never refuse vaccine shipments** to minimize waste. To receive vaccine shipments properly: • **Accept** all shipments. • **Verify** shipments & contents upon arrival for signs of damage, temperature excursions during transit, and discrepancies between packing slip, order and shipper contents. • **Store** vaccines properly in their original packaging. Label with beyond use date/time per manufacturer. Group vaccines in storage units and label (vaccine cartons, baskets, or shelf space) in large block letters to help ensure correct products are removed by patient population. • **Report** shipment incidents (if any) in myCAvax when discovered. Ancillary kits arrive within 24-48 hours of vaccines (see Ordering & Distribution Cadence). Inventory all kit supplies upon receipt to ensure quantities match vaccine doses received.	• Receiving & Storing Pfizer | Moderna | Janssen (J&J) • Receiving Redistributed Small Orders | video • COVID-19 Vaccine Product Information Guide for vaccines, kits, dimensions, and needle sizes • CDC's product lessons (staff training)
Report Shipment Incidents	*Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 vaccine. (CDC Provider Agreement #7a.)* Report shipment incidents for vaccine or kits (damage, temperature excursions in transit, & order discrepancies) in myCAvax under **Vaccine Inventory**—the same day shipment arrived. **Timing is critical. CPDH coordinates with shipper for replacement using your data. Please make sure data is accurate and complete.** Contact manufacturer or McKesson directly to resolve incidents and report resolution in your shipment incident reports. Report in myCAvax - **Vaccine Inventory**. Click **Shipment Incident**.	Reporting Shipment Incidents
Returning Shippers	Do not return spoiled, expired, or wasted vials to manufacturer or McKesson. • Pfizer 12Y+ gray cap, 5-11Y orange cap, and 6M-4Y maroon cap: watch video for return instructions* • For Moderna: Return shipper to your UPS delivery person.	• Receiving Pfizer Single-Use Shipper Video • Receiving & Storing Pfizer Vaccines

Topic	Requirements & Guidance	Resource
	• For Janssen: Dispose of cooler and packing materials; there is no return option available for refrigerated shippers. *** Pfizer pediatric shippers should be disposed of locally and should NOT be returned.** Single-use shippers will include a Logger Return Kit embedded in the lid of the shipper. Please remove the logger from the thermal shipper and follow instructions to return the logger to Pfizer.	• Receiving & Storing Moderna Vaccine • Receiving & Storing Janssen Vaccine
Temperature Monitoring	*Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance in CDC's Vaccine Storage and Handling Toolkit. (P.A. #7b)* Temperature monitoring is a critical step to protect vaccine viability. Vaccines must be stored under recommended storage temperatures. Vaccines must be stored under storage temperatures defined by product in EUA Fact Sheets for HCPs and CDC's Toolkit COVID-19 Addendum. Monitor and record your data logger's readings on your temperature logs for refrigerated, frozen, or ultra-cold vaccines, or use this COVID-19 Temperature Log. Take these steps to prepare for your initial vaccine shipment: • Post refrigerated and frozen temperature logs on corresponding storage units. • Ensure staff are trained to operate your data loggers and download the temperature data file in the event of an excursion; refer to device's product guide. • Some devices must be cleared (MIN/MAX temperatures and alarm symbol) after each recording to ensure staff don't record previous readings again (see image); check your device's product guide. • Train staff not to ignore alarm alerts; if temperature alarms go off repeatedly, do not disconnect the alarm until it has been confirmed as a false alarm. • Supervisors should plan to review logs to ensure staff understand how to record temperatures, record twice daily, and respond to all out-of-range temperatures. Record storage unit temperatures twice daily, at the beginning and end of the day. Record: • Minimum/maximum temperatures • Date and time • Name of person who recorded temperatures • Any actions taken if out-of-range temperatures are detected ***For satellite, temporary and off-site clinics:*** Monitor transport container temperatures using a data logger. Record temperatures hourly and check data loggers whenever containers are opened. (See Hourly Temperature Log.)	• How to Record Temperatures • COVID-19 Temperature Log • Hourly Temperature Log

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Reporting Temperature Excursions	*Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions. (P.A. #7c)* Any temperature outside recommended ranges is considered a temperature excursion and may impact vaccine viability. A temperature excursion triggers a visual or audible alarm or alert depending on the data logger. Staff will need to confirm when the excursion occurred and its duration. There may be multiple temperature excursions overnight. Depending on your device, there may be a temperature data file that must be downloaded to get the data manufacturers will need to determine whether vaccines can be administered or must be discarded. The manufacturer's determination is only as accurate as the data you provide. • Clear the alarm symbol to ensure staff don't respond to previous alerts. • Label exposed vaccines DO NOT USE so vaccines are not administered. • Alert the Vaccine Coordinator on duty or your supervisor. • Download the temperature data file (if any) and locate the excursion details. • Complete the Temperature Excursion Worksheet to gather data manufacturers will need to determine viability, then contact the manufacturer. • Report temperature excursions daily (if any) in myCAvax including resolution. • Do not administer vaccines until the manufacturer resolution is determined. Report in myCAvax - **Vaccine Inventory**. Click **Excursion**.	• Reporting Temperature Excursions • Report Temperature Excursion Worksheet **For quick answers:** • Janssen Stability Online Tool • Moderna Temperature Excursion Online Tool • Pfizer MI Digital Assistant (scroll down) • Pfizer 12Y+ gray cap: med info • Pfizer 12Y+ purple cap: med info • Pfizer 5-11Y orange cap: med info • Pfizer 6M-4Y maroon cap: TBD
Expiration Dates	*Organization must monitor and comply with COVID-19 vaccine expiration dates. (P.A. #7d)* Do not prepare or administer vaccines without first checking the expiration date. Do not prepare or administer vaccine past the manufacturer expiration date or use-by date. Discard vaccine after the earlier of the expiration or beyond-use (use-by) date. COVID-19 vaccine expiration dates may be extended. Strictly comply with the manufacturer guidance. When the current expiration date gets close, contact the manufacturer before discarding vaccine see if expiration dates have been extended. Use CDC's expiration date tracking tool to record extended expiration dates. Document the current date, the vaccine lot number, and the new expiration date. Do not discard vaccine without ensuring the expiration date has passed.	• CDC's Vaccine Expiration Date Tracking Tool • Expiration Date Tracker **Quick Lookups:** • Janssen expiry checker • Moderna expiry checker • Pfizer 12Y+ gray cap fact sheet • Pfizer 12Y+ purple cap fact sheet • Pfizer 5-11Y orange cap fact sheet

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	• *Pfizer-BioNTech (purple cap retired 12/23/21):* Check expiration date printed on the vial. Check Pfizer EUA Fact Sheets for expiry extensions. • *Pfizer 12Y+ (gray cap), 5-11Y (orange cap), 6M-4Y (maroon cap):* Regardless of storage condition, the vaccine should not be used after 12 months from the date of manufacture printed on the vial and cartons. • *Moderna:* Scan QR code on vial or carton, or look up expiration dates online. • *Janssen:* Scan QR code on outer carton, look up online, or call 800-565-4008.	• Pfizer 6M-4Y maroon cap fact sheet
Beyond Use Dates (BUD)	*Organization must monitor and comply with COVID-19 vaccine expiration dates. (P.A. #7d)* Do not prepare or administer vaccines without first checking the expiration date. Do not prepare or administer vaccine past the manufacturer expiration date or use-by date. Discard vaccine after the earlier of the expiration or beyond-use (use-by) date. Vaccines may have a shortened beyond use date (BUD) as specified in the EUA Fact Sheet for HCPs and documented in CDC's Toolkit COVID-19 Addendum. The BUD replaces the manufacturer's expiration date. If the vaccine has no beyond use date, use the expiration date. Label vaccines (date, time and staff initials) and track carefully to ensure vaccines aren't used past the beyond use date. Dispose of vaccines after the BUD in pharmaceutical waste or Sharps containers. Complete CDC's product training for vaccines your location will order to ensure staff are trained on storage and handling including beyond use dates and labels. ***Before Puncture*** Manufacturer-shortened expiration dates may apply if storing unpunctured vials under conditions other than coldest recommended temperatures. Use BUD labels so vaccines aren't used past reduced beyond use dates. (See easy-to-read chart.) Complete BUD labels and apply to cartons if transferring Pfizer gray cap, orange cap or maroon cap to refrigerator; Pfizer 12Y+ purple cap (retired 12/23/21) vials to refrigerator or freezer; or Moderna vials to the refrigerator. ***After Puncture*** Multidose vials have a reduced beyond use date after the first puncture. Use BUD labels, or alternate method, after thawing or mixing with diluent to prevent administration beyond the BUD date/time. Dispose of vaccine after the BUD date/time. (See easy-to-read chart.)	• COVID Vaccine Product Guide • CDC's Vaccine Product Comparison Guide • Vaccine Storage and Handling Toolkit COVID-19 Addendum • Beyond use date in vial or syringe for COVID-19 Vaccines • Pfizer 12Y+ (gray cap) BUD Label • Pfizer 12Y+ (purple cap) BUD Label • Pfizer 5-11Y (orange cap) • Pfizer 6M-4Y (maroon cap) BUD Label • Moderna 18Y+ BUD Tracking Label (Refrigerator) • Moderna 6M-5Y (dark blue cap) BUD Label

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Nonviable Vaccine	*Organization must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction (P.A. #8).* *Organization must comply with all federal instructions and timelines for disposing of COVID-19 Vaccine and adjuvant, including unused doses (P.A. #9).* Providers must account for nonviable vaccine as part of routine inventory management. Providers must report nonviable vaccine in myCAvax before disposal. **Spoiled:** Vaccines are considered spoiled if manufacturers determine vaccines were exposed to out-of-range temperatures and may not be used. (Consistent and accurate temperature monitoring should minimize spoiled vaccines.) **Expired:** Vaccines are considered expired if beyond the manufacturer expiration date or beyond use date as identified in product EUA fact sheet or product insert. (Careful vaccine management helps to minimize expired vaccines.) **Wasted:** Vaccines are considered wasted if drawn but not administered, left in open vials but doses not administered, lost or unaccounted, or if you are unable to draw a dose. (Careful vaccine management and administration should minimize wasted doses.) ***Disposal.*** Do not return nonviable COVID-19 vaccines. Please Do NOT leave vaccine in returned shippers. Pfizer, Moderna, and Janssen vaccines may be disposed of in a pharmaceutical waste container, or a comingled pharmaceutical/Sharps waste container. (Read more.) Report in myCAvax - **Vaccine Inventory**. Click **Wastage**.	Report Doses Spoiled, Expired, or Wasted
Vaccine Wastage	Minimizing waste is important, but don't turn away potential recipients to avoid puncturing a vial at the end of the day. • Vaccinate every eligible person who presents at a vaccination site—even if it means puncturing a multidose vial towards the end of the day. • Consider establishing and promoting standing vaccination days or half-days. • Vaccinate family members or friends who accompany patients to medical visits, even if they are not established patients at the vaccinating practice. • Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.	• Missed Vaccination Opportunities & Wastage • Guidance for Satellite, Temporary, and Off-Site Clinics

Topic	Requirements & Guidance	Resource
	• Fill no-show appointments with walk-ins or waitlist of nearby eligible residents; consider overbooking if data is available to support it.	
Preparation	See EUA Fact Sheets for HCPs or COVID-19 Addendum for product-specific guidance. Complete CDC's product training for preparation and administration details. Never miss a vaccination opportunity! Vaccinate every eligible person who presents at a vaccination site. CDC recommends this guidance to minimize wasted vaccine. • Prepare vaccines immediately prior to administration; in high-throughput settings, it may be necessary to pre-draw vaccine to support a fast-paced workflow. • Vaccine should be pre-drawn in quantities that can be administered prior to the beyond-use date/time. • Pre-drawn syringes must be shielded from direct sunlight at all times. • Providers must ensure maximum room-temperature time is observed. • In outdoor settings, pay close attention to workflow pace so vaccines can be moved to room temperature for protection if needed, and quantity of pre-drawn syringes adjusted accordingly.	• Vaccine Administration Checklist • Preventing Vaccine Administration Errors • COVID-19 Addendum • EUA Fact Sheets for HCPs • Missed Vaccination Opportunities & Wastage
Transport	*Organization must comply with CDC requirements for COVID-19 vaccine management. Those requirements include the following: Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 vaccine; (P.A. #7a)* Vaccine should be delivered directly to the facility where it will be administered to maintain the vaccine cold chain. However, there may be circumstances where COVID-19 vaccine needs to be transported. In these instances, appropriate precautions should be taken to ensure the cold chain is maintained. Vaccines must be transported following product-specific guidelines in CDC's Vaccine Storage & Handling Toolkit & COVID-19 Addendum. • Transport containers must be equipped with data loggers. • Document all transport events using the COVID-19 Vaccine Transport Log. • Report temperature excursions during transport in myCAvax; do not report as shipment incidents because vaccines weren't shipped. • Total transport time for transport alone (or transport plus clinic workday if vaccines are stored in transport containers) should be a maximum of 8 hours; consider using the Vaccine Transport Time Tracker.	• Vaccine Storage & Handling Toolkit COVID-19 Addendum • Transporting Vaccine • COVID-19 Vaccine Transport Log • Transport Time Tracker

Topic	Requirements & Guidance	Resource
	• Label vaccines with updated beyond use dates (if applicable).	
Vaccine Redistribution	Redistribution is the *routine* transport of vaccines to clinic locations responsible for their administration; the receiving location takes ownership of vaccines and must be an approved COVID-19 vaccination provider. For example, for large organizations whose vaccines are shipped to a central depot and require redistribution to vaccination locations. In these instances, providers must apply and receive authorization. Applications may be submitted in myCAvax during enrollment. Report events in myCAvax - **Vaccine Inventory** within 24 hours. Click **Transfer/Redistribution**.	• Redistribution Agreement: Before You Apply • CDC Vaccine Redistribution Agreement Redistributing Vaccines
Vaccine Transfers	Transfers are the transport of vaccines in response to an emergency or other unplanned event (e.g., excess supply or imminent expiration of doses). In these instances, the receiving location takes ownership of transferred vaccines and must be an enrolled and approved COVID-19 vaccination provider. Report events in myCAvax - **Vaccine Inventory** within 24 hours. Click **Transfer/Redistribution**.	Transferring Vaccines
Vaccine Repositioning	Repositioning is the transport of doses to another setting for administration when unused doses will be returned to the original facility at the end of the day. Satellite, temporary and off-site clinics are authorized to transport vaccines without prior authorization because ownership is not changing hands. However, these situations require enhanced storage and handling practices. The repositioning entity will report their doses administered and on hand at the end of the clinic day. Because ownership is not changing hands, providers do not report events to CDPH.	Repositioning Guidance for Satellite, Temporary and Off-Site Clinics
Record Keeping	*Organization must preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law. (P.A. #7e)* Providers must maintain all electronic and paper COVID-19-related records for a minimum of 3 years and make records available for review upon request. Such records include the following: • COVID-19 vaccine or ancillary product packing slips • transport logs • temperature logs • certificates of calibration testing (for data loggers)	

Topic	Requirements & Guidance	Resource
	• billing records • vaccine administration records (including medical records of administration) • vaccine ordering records and packing slips • any other COVID-19-related records	