

# Vaccine Management Plan

## California COVID-19 Vaccination Program



Maintain a vaccine management plan for routine and emergency situations to protect vaccines and minimize loss due to negligence. The Vaccine Coordinator and Backup are responsible for implementing the plan.

**Instructions:** Complete this form and make sure key practice staff sign and acknowledge the signature log whenever your plan is revised. Ensure that all content is up to date. Keep the plan near storage units and available for review by CDC or program staff during site visits.

### Section 1: Important Contacts

Office/Practice Name		COVID-19 PIN			
Address					
Role	Name	Title	Phone #	Alt Phone #	E-mail
Provider of Record					
Organization Coordinator					
Location Coordinator (Vaccine Coordinator)					
Backup Location Coordinator					
Immunization Champion (optional)					
Receives vaccines					
Stores vaccines					
Handles shipping issues					
Monitors storage unit temperatures					

### Emergency & Support Contacts

Service	Name	Phone #	Alt Phone #	E-mail
COVID Call Center		(833) 502-1245		
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair				
Point of Contact for Vaccine Transport				
Dry Ice Company (if storing Pfizer in thermal shippers)				

## Section 2: Equipment Documentation

Vaccine Storage Units: Locations & Maintenance

Maintenance/Repair Company:  Phone:

Unit Type	Unit/Location ID	Brand	Model	Dates / Types of Service
Refrigerator				
Refrigerator				
Refrigerator				
Freezer				
Freezer				
Freezer				
ULT Freezer				
ULT Freezer				
ULT Freezer				

Location of Completed Temperature Logs:

## Section 2: Equipment Documentation, Cont.

### Digital Data Loggers

Data Logger Model/Serial Number	ULT Device?	Primary?	Backup?	Calibration Expiration Date	Alarm Setting Low	Alarm Setting High

### Digital Data Loggers Notifications

Auto-Alert Notifications Sent to Staff Contact		Text/ E-mail	
Auto-Alert Notifications Sent to Staff Contact		Text/ E-mail	
Auto-Alert Notifications Sent to Staff Contact		Text/ E-mail	

**For Devices with Auto-Alerts:** Outline or attach the practice’s protocol for responding to temperature excursions after the practice is closed. Consider implementing a phone tree. Ensure staff safety is addressed (e.g., for alerts after dark).

## Section 2: Equipment Documentation, Cont.

### Data Logger Maintenance

IT/Support Provided by		Contact		Phone	
Calibration Company/Laboratory		Contact		Phone	
Calibration Company/Laboratory		Contact		Phone	
Location of Certificates of Calibration					
Location of Backup Digital Data Logger					

### Pfizer Vaccine Temperature Monitoring

Pfizer tracks thermal shippers and monitors temperatures during transit using a Controlant Reusable Logger. Device is embedded in the foam lid and may not be removed. No temperature data displays on the device. After delivery, temperature monitoring data is no longer visible to Pfizer.

#### Reminders:

- Check the shipment status on the Controlant device to determine if vaccines can be stored.
  - If the "shipment status" LED is NOT BLINKING, vaccines may be stored and used.
  - If the "shipment status" LED is BLINKING/SHOWING RED, the device is functioning properly but has recorded an out-of-range temperature; look for emailed Quality Disposition Report, which will confirm if product can be used and actions required.
- *If storing vaccines in storage units:* [Deactivate the monitoring service and opt out.](#)
  - Pressing the stop button on the temperature monitoring device does not opt out of the remote temperature monitoring; you will receive an email from [onsitemonitoring@controlant.com](mailto:onsitemonitoring@controlant.com).
- *If storing vaccines in thermal shippers:* Dry ice must be replenished within 24 hours of receipt of vaccine and every 5 days thereafter.
  - Controlant automatically emails the Point of Contact for the vaccine order.
  - [Add up to 4 contacts](#) to receive daily emails and/or text alerts on the temperature status of the container.
  - If your contacts are not receiving the daily emails, watch [troubleshooting video](#) to troubleshoot your monitoring issues.
  - Review daily emails on the status of the container
  - Save the final email (full summary of status reports) for three years.
- Return thermal shippers and Controlant device as soon as vaccine is no longer being stored in them (within 30 days) using the included shipping label and instructions.
- 24/7 support hot line: 1-855-442-6687 or 1-701-540-4039, or [support@controlant.com](mailto:support@controlant.com)

## Section 3: Roles & Responsibilities

### PROVIDER OF RECORD

- Oversees key practice staff to ensure COVID-19 Vaccination Program requirements for [Vaccine Management](#), [Administration](#) and [Reporting](#) are met.
- Completes [required program training](#).
- Ensures key practice staff (receive, handle, manage, or administer vaccine) complete [required program training](#).
- Ensures key practice staff (receive, handle, manage, or administer vaccine) complete [CDC's COVID-19 lessons](#) for each vaccine product administered.
- Ensures vaccinators and staff preparing vaccines are familiar with manufacturer guidance in [EUA Fact Sheets for HCPs](#) for vaccine products administered.
- Ensures vaccinators are familiar with protocols and supplies to [prepare for anaphylaxis](#).
- Ensures vaccinators are familiar with [COVID-19 clinic guidance and recommendations](#).
- Ensures practice's storage units and temperature monitoring devices meet program requirements.
- Designates one staff as the Backup Vaccine Coordinator responsible for vaccine management when the primary Vaccine Coordinator unavailable.
- Authorizes and reports staffing changes regarding the Vaccine Coordinator, Backup Vaccine Coordinator and Provider of Record to the COVID Call Center.
- Ensures that vaccine management staff are knowledgeable of requirements for temperature monitoring and vaccine storage and are trained on use of the practice's data loggers.
- Updates and revises vaccine management plan at least annually and when necessary.
- Reviews program requirements and vaccine management plan & emergency protocols with staff at least annually and when necessary.
- Participates in compliance site visits.
- Keeps all COVID-19 electronic and paper documentation for three years.

### VACCINE COORDINATOR

- Completes required training lessons.
- Meets responsibilities described in the [Vaccine Coordinator job aid](#).
- Oversees the practice's vaccine management plan for routine and emergency situations.
- Monitors storage unit temperatures.
- Maintains COVID-19-related documentation in an accessible location.

### BACKUP VACCINE COORDINATOR

- Completes required training lessons.
- Meets responsibilities described in the [Vaccine Coordinator job aid](#) when the primary Vaccine Coordinator is not available.

### IMMUNIZATION CHAMPION

Consider assigning the role of Immunization Champion to focus on ensuring providers and staff are knowledgeable about IZ schedules, vaccine products and dosages, and on improving coverage levels.

## Section 4: Plan for Routine Situations

Refer to CDC's [Vaccine Storage & Handling Toolkit](#) to comply with COVID-19 Vaccination Program requirements.

### INITIAL EQUIPMENT SETUP

- Use vaccine storage units and digital data loggers that meet program requirements.
- Configure all storage units and digital data loggers to meet program requirements.
- Post on vaccine storage unit doors, or nearby in an accessible location. (Need [COVID-19 temp logs?](#))
- Do not store vaccines in storage units until temperatures are stable within recommended temperatures for 3–5 days.
- **For providers designated solely as mass vaccinators:** Only use purpose-built, transport units for transport & storage.

## DAILY TASKS

### Temperature Monitoring

- Read CURRENT, MIN, and MAX refrigerator & freezer temperatures twice a day, when the clinic opens and before it closes—even though using digital data loggers.
- Document temperatures on your temperature logs.

### Reporting

- Record vaccination data in My Turn daily, which [reports doses administered to CAIR](#).
- [Report inventory to VaccineFinder daily](#)—even on non-business days—once you receive shipments.
- [Report doses spoiled, expired, or wasted](#) in myCAvax and dispose of following guidance provided.
- [Report shipment incidents](#) in myCAvax for vaccine product or kits (including product viability, damage or packing slip discrepancies) the same day the shipment arrived at the office as documented by the carrier.
- [Report temperature excursions](#) in myCAvax and take immediate action to protect vaccines.
- Report [redistribution](#) or [transfer](#) events in myCAvax.
- Refer to [Reporting at a Glance](#) for related resources.

## WEEKLY TASKS

- Submit your location's Vaccination Capacity report in myCAvax each Monday by 4 pm.

## BI-WEEKLY TASKS

### Review and Certify Temperature Data

- Supervisor: Certify and sign that temperatures were recorded twice daily and corrective actions were taken.
- Download and review data files at the end of every two-week reporting period to look for missed excursions or temperature trends that might indicate performance issues with vaccine storage units.

## MONTHLY TASKS

### Vaccine Inventory

- Conduct a careful and accurate vaccine inventory.
- Check expiration dates and rotate stock to place vaccines that will expire soonest in front of those with later dates.
- [Transfer vaccines](#) likely to expire before use to your local health department or other COVID-19 providers.

## ANNUAL TASKS

- Review and update the practice's vaccine management plan.
- Review with key practice staff the vaccine management plan's section on preparing for and responding to vaccine-related emergencies and conduct regular vaccine transport drills to maintain competency.
- Calibrate primary and backup temperature monitoring devices annually (or every other year if the manufacturer's recommendation is for a longer period) following program requirements. Calibrate primary and backup devices on different schedules to ensure all storage units storing COVID-19 vaccines are equipped with data loggers at all times. File certificates of calibration in a readily accessible area, keep them for three years.

## TO MINIMIZE LOSS

- Respond to planned or sudden vaccine-related emergencies following the practice's vaccine management plan.
- Confirm clinic delivery days and hours to ensure staff are available to receive vaccine deliveries.

## PER PROVIDER SCHEDULE

### Vaccine Deliveries

- Vaccine shipments must be received and inspected immediately upon arrival.
- Receive & store vaccines according to manufacturer guidance. (See job aids for [Pfizer](#) | [Moderna](#) | [Janssen](#).)
- [Report shipment incidents](#) for vaccine product or kits (including product viability, damage or packing slip discrepancies) the same day the shipment arrived at the office as documented by the carrier.
- [Redistribute vaccines](#) (if authorized) to other enrolled, COVID-19 vaccination providers per [CDC agreement](#).

## Section 4: Plan for Routine Situations, Cont.

### PER PROVIDER SCHEDULE (cont.)

#### Routine Maintenance

- Establish a regular routine for cleaning vaccine storage units and defrosting manual-defrost freezers.
- Replace batteries in temperature monitoring devices every six months.

### VACCINE PREPARATION

- Check expiration and beyond-use dates before preparing or administering vaccines.
- Prepare vaccines per manufacturer instructions: [Pfizer Preparation](#) & [Mixing](#) | [Moderna](#) | [Janssen](#)
- Refer to [Vaccine Administration at a Glance](#) for related resources.

### AT EACH IMMUNIZATION VISIT

- Comply with all guidance for prioritization of COVID-19 vaccine doses.
- Do not ask for citizenship or photo ID in order to receive COVID-19 vaccine.
- Distribute [EUA Fact Sheet for Recipients](#) before administration.
- Prepare & administer vaccines and observe recipient per [EUA Fact Sheet for HCPs](#).
- Record vaccine administration data in My Turn daily.
- Set up protocols and procure necessary supplies to [prepare for anaphylaxis](#).
- Report any adverse events to [VAERS](#).
- Schedule 2<sup>nd</sup> appointment (if applicable).
- Provide Vaccination Record Card; encourage recipient to photograph it.
- Encourage registration for v-safe for appointment reminders (recommended).

### SATELLITE, TEMPORARY, AND OFF-SITE CLINICS

- [Repositioning Guidance for Satellite, Temporary, and Off-Site Clinics](#) (CDPH)
- [Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#)
- [Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#)
- [Considerations for Planning Curbside/Drive-Through Vaccination Clinics](#) | [Accessibility Fact Sheet](#) | [Checklist](#)
- [Vaccinating Homebound Persons With COVID-19 Vaccine](#)

### AS NEEDED

#### Changes in Staff and Training

- Anyone storing, handling, administering, or managing COVID-19 vaccines must complete the required lessons.
- Any clinician who administers COVID-19 vaccines must be knowledgeable of and familiar with all ACIP-recommended immunizations, including schedules, indications, dosages, and new products.
- Train staff authorized to accept packages to notify the Vaccine Coordinator when COVID-19 vaccines are delivered.
- Update the practice's vaccine management plan to reflect any changes in key practice staff.

#### Device Replacement

- Purchase a new data logger if existing device or probe malfunctions, is damaged, or if device provides repeated, inaccurate temperature readings. (Exception for probes replaced by the device manufacturer or calibration company.)
- When purchasing new data loggers: New devices must be able to generate a summary report of recorded temperature data since the device was last reset; summary reports must include minimum and maximum temperatures, total time out of range (if any), and alarm settings. Devices that only generate CSV data files or Excel spreadsheets are not acceptable.

## Section 5: Worksheet for Emergency Vaccine Management

The following sections include space for information and necessary actions to take in the event of an emergency, such as unit malfunction, mechanical failure, power outage, natural disaster, or human error.

In an emergency, contact the following people in the order listed:

Role/Responsibility	First & Last Name	Phone #	Alt Phone #	E-mail Address
1.				
2.				
3.				
4.				

Does the clinic have a generator? If so, where is it?

If your clinic does not have a generator, and/or your vaccine storage unit fails, it might be necessary to transport vaccines to an alternate storage location (e.g., a local hospital or another COVID-19 provider). Identify an alternate location(s) that has vaccine storage units and temperature monitoring devices that meet program requirements.

Alternate Vaccine Storage	Address & City	Phone #	Alt Phone #	E-mail Address

**Location of Emergency Packing Supplies:**

**Facility Floor Plan:** Attach a simple floor diagram identifying the location of key items needed during an emergency: circuit breakers, flashlights, spare batteries, keys to secured cabinets, backup digital data logger, vaccine storage units, coolers, etc.



## Section 6: Plan for Emergencies

**Do not risk staff safety during emergencies.** Use common sense when attempting to protect vaccines. Use the following guidance for safeguarding vaccines in the event of planned or unplanned power interruptions (e.g., power outages, weather-related circumstances, fires, building maintenance/repairs, etc.).

### CHECKLIST: BEFORE AN EMERGENCY

Proper preparation for emergencies is essential for protecting the viability of vaccines. Use the following checklist to help ensure practices are ready for planned or unexpected situations that might affect vaccine viability.

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Step	Description
1.	Maintain current emergency contact information for key practice staff in the vaccine management plan.
2.	Maintain current contact information for alternate vaccine storage location(s), including the facility name, address, and telephone number in the vaccine management plan.
3.	Be familiar with backup power sources for commercial- and pharmacy-grade units.
4.	Know the location of the backup data logger used for vaccine transport.
5.	Stock vaccine packing and transport supplies, including a hard-sided cooler, frozen gel packs, and bubble wrap.
6.	Keep copies of the <a href="#">COVID-19 Transport Log</a> and floor plans (when available) for easy access during a vaccine-related emergency.
7.	Review annually the steps key practice staff must take to protect vaccines during short- or long-term outages.
8.	<b>Vaccine Transport Drill:</b> Practice packing the transport cooler using packing supplies and materials that simulate vaccine boxes. Do NOT practice with actual vaccines.

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## Section 6: Plan for Emergencies, Cont.

### DURING AN EMERGENCY

Due to the risk to vaccines of improper packing and transporting, follow these step-by-step instructions during an emergency to determine whether vaccines should be transported or sheltered in place.

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Step	Description
1.	Do not open the unit.
2.	Place a “DO NOT OPEN” sign on vaccine storage unit(s) and leave door(s) shut to conserve cold air mass.
3.	Notify the emergency contacts identified on the vaccine management plan’s “Worksheet for Emergency Vaccine Management.”
4.	Note the time the outage started and storage unit temperatures (CURRENT, MIN and MAX).
5.	Assess to determine the cause of the power failure and estimate the time it will take to restore power.
6.	Take appropriate action.  <b>In the event of appliance failure:</b> Place vaccines in any approved backup storage unit with a compliant data logger, or transport vaccines to the designated alternate storage facility.  <b>For power outages after hours:</b> <a href="#">Report any temperature excursion</a> the next morning and take appropriate action.  <b>For planned outages expected to be short-term (approximately fewer than 4 hours)*:</b> Monitor storage unit temperature and <a href="#">report any excursions</a> once power has been restored.  <b>For planned/unplanned outages expected to be longer than approximately 4 hours,* or for any outage that extends beyond the current business day:</b> Transport vaccines to the designated alternate storage facility. If transport or relocation is not feasible (e.g., alternate location is not available or travel conditions are unsafe), keep vaccine storage units closed and notify the COVID Call Center as soon as possible.
7.	Once power has been restored, follow the steps listed in “After an Emergency.”

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\* **Note:** Practices using purpose-built (pharmacy-, biologic-, and laboratory-grade) and commercial-grade storage units may need to transport vaccines to an alternate location sooner than **2 hours** as temperatures in these units tend to increase faster during power failures.

## Section 6: Plan for Emergencies, Cont.

### AFTER AN EMERGENCY

Follow these step-by-step instructions after vaccine-related emergencies in compliance with VFC Program requirements and best practices.

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Step	Description
1.	Verify storage units are functioning properly.
2.	If vaccine storage units are outside the required temperatures ranges, record the time that power was restored and storage unit temperatures (CURRENT, MIN and MAX) on the temperature log.
3.	Once vaccine storage unit temperatures have stabilized, notify the emergency contacts identified on the vaccine management plan's "Worksheet for Emergency Vaccine Management."
4.	If vaccines were transported due to an emergency situation: <ul style="list-style-type: none"><li>A. Follow the same transportation procedures and transfer vaccine back to its original storage unit.</li><li>B. If vaccines were kept at the proper temperature during the power outage, notify supervisor that the vaccines may be used.</li></ul>
5.	If vaccines were maintained at required temperatures: <ul style="list-style-type: none"><li>A. Remove the "DO NOT OPEN" sign from storage unit(s).</li><li>B. Notify supervisor that vaccines may be used.</li></ul>
6.	If vaccines were exposed to out-of-range temperatures: <ul style="list-style-type: none"><li>A. Label affected vaccines "Do Not Use."</li><li>B. <a href="#">Report any temperature excursion.</a></li></ul>

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## Section 8: Annual Signature Log

Print name, sign, and date one signature block each year and when you update practice-specific information. By signing, staff acknowledge they have reviewed and are familiar with all the information in the document.

Updates & Comments					
Provider of Record		Signature		Date	
Vaccine Coordinator		Signature		Date	
Backup Vaccine Coordinator		Signature		Date	
Staff Who Updates VMP		Signature		Date	
Additional Staff		Signature		Date	
Updates & Comments					
Provider of Record		Signature		Date	
Vaccine Coordinator		Signature		Date	
Backup Vaccine Coordinator		Signature		Date	
Staff Who Updates VMP		Signature		Date	
Additional Staff		Signature		Date	
Updates & Comments					
Provider of Record		Signature		Date	
Vaccine Coordinator		Signature		Date	
Backup Vaccine Coordinator		Signature		Date	
Staff Who Updates VMP		Signature		Date	
Additional Staff		Signature		Date	
Updates & Comments					
Provider of Record		Signature		Date	
Vaccine Coordinator		Signature		Date	
Backup Vaccine Coordinator		Signature		Date	
Staff Who Updates VMP		Signature		Date	
Additional Staff		Signature		Date	