

California Bridge Access Program

# Provider Operations Manual

*no-cost  
COVID-19 vaccines*

*thank  
you*

*for uninsured &  
underinsured adults*

**Program extended in September 2024!**



**BAP**

California  
Bridge Access  
Program

IMM-1469

## Welcome

Thank you for joining a partnership of federal, state and local health departments working to vaccinate all uninsured and underinsured adults against COVID-19.

Now that your enrollment application has been approved, there are additional steps to complete the onboarding process and ensure your practice is ready to receive vaccine and begin vaccinations.

This manual includes a startup guide that walks you through key requirements and setup considerations plus documentation of all key tasks.

Thanks again, and welcome!



## How to Use This Manual

This reference manual was designed to support a variety of learners and roles at different stages.

Maybe you took the training during enrollment, but now some time has passed and you're not sure where to begin.

Or maybe you're a new hire thrust into supporting an existing COVID-19 program you know nothing about.

Or maybe your provider location is introducing a new COVID-19 vaccine product and staff need training.

This manual provides training or a refresher and serves as an electronic reference on the job. It includes everything you need to know to implement the California Bridge Access Program in your practice.

## Who Will Benefit



FQHCs and Rural Health Centers  
Indian Health Service  
Tribal clinics  
Local Health Departments & clinics and other providers deemed eligible by LHDs



**Bookmark or check back frequently.**

This manual is updated frequently as more guidance is provided.

## Where Is the BAP Website?



**BAP**

California  
Bridge Access  
Program

<https://eziz.org/vfa-317/bap/>



## Special Note for Providers

You played a critical role in helping to end the COVID-19 pandemic.

For patients, you are one of the most trusted sources of information when it comes to vaccines. Patients may have questions and concerns about COVID-19 vaccines. You can help them understand the importance of vaccination, provide your strong recommendation, and build confidence in vaccines.

Strong vaccine confidence leads to more people getting vaccinated, which leads to fewer COVID-19 illnesses, hospitalizations, and deaths.

Thank you for the efforts you and your practice staff are making to keep California healthy.

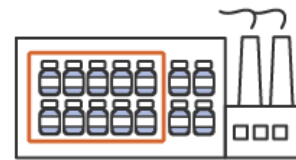


## About the Program

The California Bridge Access Program (CA BAP) provides no-cost COVID-19 vaccines to uninsured and underinsured adults (19 years and older) served by eligible and approved providers. Vaccine supply is limited. Insured patients—including patients covered by Medicare and Medi-Cal—are NOT eligible.



Centers for Disease Control and Prevention focuses on learning about COVID-19 disease—how it spreads and affects people – sharing with Americans and the rest of the world what they've learned



Vaccine manufacturers provide specific administration, storage & handling, and clinical guidance for their products.



California Department of Public Health shares guidance from manufacturers & CDC; partners with local health departments, providers, FQHCs, rural health centers, Indian Health Service, and other partners to ensure vaccines are allocated and distributed equitably.



Local health departments ensure vaccines are distributed equitably within their jurisdictions.



# Program Enrollment

Limited COVID-19 vaccines have been purchased by the U.S. federal government for providers enrolled in the California Bridge Access Program serving uninsured and underinsured adults. Providers enroll and sign the [Provider Participation Agreement](#) in myCAvax. Key points are highlighted below.

## Provider Agreement

- Locations must complete eligibility screening and documentation before each vaccination and report eligibility category 317 to CAIR for each recipient.
- Patients immunized with BAP-supplied vaccines may not be billed for the cost of the vaccine nor be charged an administration fee.
- Staff must store and handle COVID-19 vaccines according to [CDC's Vaccine Storage & Handling Toolkit](#) and COVID-19 Addendum to maintain the vaccine cold chain that protects vaccines.

## Vaccine Product Training

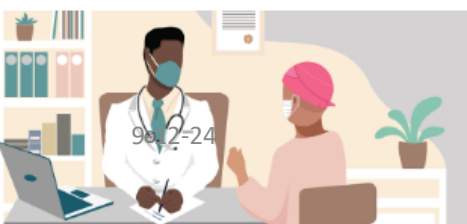
Vaccinators, clinicians, vaccine coordinators, and other staff who store, handle, or administer COVID-19 vaccine must complete the required [COVID-19 Vaccine Product Training](#) to ensure they are prepared to maintain vaccines under proper conditions.

## Vaccination Reporting

- Sites must enroll in the California Immunization Registry (CAIR), record vaccine administration information into your organization's medical record system within 24 hours of administration, and report that information to CAIR within 72 hours.
- As with other routine vaccines, the total number of patients immunized with COVID-19 vaccines and inventory on hand must be reported to CDPH on each vaccine order.
- Sites must display their vaccination location to the public on Vaccines.gov so eligible adults can find no-cost COVID-19 vaccines near them.

## Inventory Management

- Comply with CDPH Immunization Program guidance for dealing with temperature excursions.
- Monitor and comply with COVID-19 vaccine expiration dates including beyond-use dates.
- Report the number of doses that were unused, spoiled, expired, or wasted.
- Return nonviable vaccine to McKesson following CDPH guidance.



## Manual Objectives

1



Help you administer COVID-19 vaccines at your location

2



Provide self-paced training, resources, and essential contact information

3



Help locations remain compliant with program requirements that protect vaccines and recipients





# Click to Navigate

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9-12-24

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## Startup Guide



This section walks you through the initial preparations now that your enrollment application is approved. Once all steps are complete, your site should be ready to order vaccines.

Providers managing COVID-19 vaccinations, or other operations managers or supervisors, may wish to help incorporate COVID-19 vaccinations into practice protocols.

## Participants

Provider or operations manager/supervisor

Organization & Location Vaccine Coordinators



Follow the [Startup Worksheet](#) to complete your tasks



[Before We Start](#)

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## Before We Start

### Available Vaccines

COVID-19 vaccines are now considered routine vaccines and will be referred to as 2023-24 COVID-19 Vaccine moving forward. Providers will be notified when updated vaccine products for fall 2023 are authorized and approved.

- [2023-24 Spikevax \(Moderna COVID-19 Vaccine, mRNA\)](#)
- [2023-24 Novavax \(COVID-19 Vaccine, Adjuvanted\)](#)
- [2023-24 Comirnaty \(Pfizer-BioNTech COVID-19 Vaccine, mRNA\)](#)

See [COVID-19 Vaccine Product Guide](#) for summary chart of vaccine products and their recommended storage conditions.

### Platforms You'll Use

myCAvax	VaccineFinder	Local Registry (CAIR2, RIDE)	My Turn (Optional)
<p><b>Vaccine Management Platform</b></p> <p>Self-service platform that offers sites an all-in-one application for managing locations, ordering vaccine, and submitting reports for inventory management</p>	<p><b>Vaccine Tracking Platform</b></p> <p>BAP locations no longer need to be displayed on Vaccines.gov</p>	<p><b>Immunization Registry Platform</b></p> <p>A secure and confidential statewide information system that contains the immunization records for all California residents</p>	<p><b>Clinic Management Platform</b></p> <p>Offers providers an all-in-one application for clinic management, dose administration and reporting, public scheduling, and walk-ins for vaccine clinics</p>

#### Provider Call Center

For answers to all things COVID

(833) 502-1245

Hours: M-F 8AM-5PM

For myCAvax Help Desk inquiries: [myCAvax.HD@cdph.ca.gov](mailto:myCAvax.HD@cdph.ca.gov)

For My Turn Clinic Help Desk inquiries: [MyTurn.Clinic.HD@cdph.ca.gov](mailto:MyTurn.Clinic.HD@cdph.ca.gov)

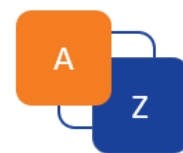
For all other inquiries: [providercallcenter@cdph.ca.gov](mailto:providercallcenter@cdph.ca.gov)



## Before We Start (Cont.)

### Glossary

We may reference these acronyms throughout this manual.



ACRONYM	MEANING
<b>BAP</b>	Bridge Access Program
<b>CAIR</b>	California Immunization Registry (CAIR2 and RIDE)
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CDPH</b>	California Department of Public Health
<b>CEO</b>	Chief Executive Officer
<b>CHC</b>	Community Health Center
<b>CMA</b>	California Medical Association
<b>CMO</b>	Chief Medical Officer
<b>DHCS</b>	California Department of Health Care Services
<b>EHR</b>	Electronic Health Record
<b>EMR</b>	Electronic Medical Record
<b>EZIZ</b>	California's VFC Program e-learning and resource website
<b>FQHC</b>	Federally Qualified Health Centers
<b>IHS</b>	Indian Health Service
<b>IIS</b>	Immunization Information Systems
<b>LHD/LHJ</b>	Local health department (or jurisdiction)
<b>myCAvax</b>	California's Vaccine Management System
<b>RIDE</b>	Regional Immunization Data Exchange (San Joaquin)

## Clinic Operations Setup

Some key requirements may need to be considered at the practice level to establish awareness with clinicians and key practice staff at the start. We'll walk through each of these steps in this section.



[Bookmark & Review BAP Provider Agreement](#)

[Confirm Coordinators Understand Their Roles & Responsibilities](#)

[Determine Which Vaccine Products Your Location Will Offer](#)

[Determine If Your Practice Will Implement Standing Orders](#)

[Prepare to Comply with Administration & Clinical Guidance](#)

[Review the BAP Billing & Reimbursement Policy](#)

[Determine How Your Practice Will Maintain COVID-19 Records](#)



## Bookmark & Review Provider Agreement



Provider organizations and locations participating in the California Bridge Access Program sign the [Provider Participation Agreement](#) in myCAvax during enrollment and agree to comply with all requirements.

### Program Requirements



The agreement covers all aspects of the vaccination program including:

- staff training on program and vaccine products administered
- eligibility screening and documentation to ensure only eligible adults are vaccinated with BAP-supplied vaccines
- billing and reimbursement policy
- reporting administration data to CAIR
- storage and handling of vaccine according to CDC's [Vaccine Storage & Handling Toolkit & COVID-19 Addendum](#)
- vaccine inventory management, ordering and reporting
- site visits
- fraud & abuse

**Fraud** is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

**Abuse** is defined as provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the program or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

### You might hear these terms

#### Section A. Provider Requirements and Legal Agreement

This section was signed by your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary).

#### Section B. Provider Profile Information

This section was completed for each vaccination location covered under the Organization listed in Section A and was signed by the location's Vaccine Coordinator.

## Bookmark & Review Provider Agreement (Cont.)

Inform practice staff of routine site visits. Site visits are a key opportunity for quality assurance monitoring and training of enrolled providers.

### Quality Assurance Visits

State or local public health staff are required to conduct certain provider oversight activities.

CA BAP providers must accommodate these staff and participate in quality assurance site visits and other educational opportunities associated with program requirements.



Items labeled with a key identify critical issues evaluated during quality assurance visits.

### Visit Goals

- assess provider adherence to program requirements and recommendations
- identify and address areas where providers are doing well and areas needing additional follow-up
- identify and address educational needs of COVID-19 vaccination providers to help them meet program requirements
- ensure vaccine recipients are receiving properly managed and viable vaccine



## Confirm Coordinators Understand Their Roles & Responsibilities

Staff filling these roles were identified during provider enrollment. Now that your application has been approved, ensure the assigned staff are comfortable with these roles and responsibilities. Roles may overlap and may be filled by the same person.



### Organization Vaccine Coordinator

This coordinator (identified on Section A) will

- ensure locations are prepared to conduct vaccine operations, staff are appropriately-trained, and facilities are prepared;
- may monitor all ongoing program communications; and
- may oversee program-related operations in affiliated locations.

**Email changes to this role to [providercallcenter@cdph.ca.gov](mailto:providercallcenter@cdph.ca.gov); copy your CEO or CMO.**



### Vaccine Coordinator & Backup

The onsite primary and backup Vaccine Coordinators (identified on Section B as Vaccine Coordinators) should be experts on your storage and handling protocols, and will

- complete and implement your vaccine management plan;
- receive and store vaccines, monitor storage unit temperatures, and manage vaccine inventory;
- monitor emails regarding vaccine orders, shipments, and temperature monitoring; and
- ensure the location's providers and key practice staff complete the required vaccine product training.

**Email changes to this role to [providercallcenter@cdph.ca.gov](mailto:providercallcenter@cdph.ca.gov); copy your Organization Vaccine Coordinator (or CEO or CMO).**



## Determine Which Vaccine Products Your Location Will Offer

The goal of the California Bridge Access Program is to vaccinate any adult aged 19 years and older who is uninsured or underinsured. All COVID-19 vaccines are ACIP-recommended for eligible populations and may be stored in routine refrigerators. Refer to FDA's [Fact Sheets for HCPs](#) for storage, administration, or clinical questions, or contact the Provider Call Center with questions.

### Available Products

Refer to the [COVID-19 Vaccine Product Guide](#) for a list of available vaccine products, storage and handling requirements, minimum order sizes, NDCs, billing codes, and more.

### Considerations:

- Which patient populations does your location serve?
- Which vaccine products are most requested by your patients?





## Determine If Your Practice Will Implement Standing Orders

The use of standing orders for vaccination facilitates the delivery of immunization services to patients in clinics, hospitals, and community settings. Standing orders have been shown to increase vaccination coverage rates.

### What is a standing order?

Standing orders authorize nurses, pharmacists, and other appropriately trained healthcare personnel to assess a patient's immunization status and administer without the need for clinician examination or direct order from the attending provider at the time of the interaction.

### Who recommends standing orders for vaccination?

CDC's Advisory Committee on Immunization Practices (ACIP) specifically recommends standing orders for influenza and pneumococcal vaccinations and several other vaccines (e.g., hepatitis B, varicella).

### Who is authorized to sign the standing orders?

In general, standing orders are approved by a medical director in a healthcare setting, a physician, or another authorized practitioner. State law or regulatory agency might authorize other healthcare professionals to sign standing orders.

### Templates for Standing Orders for Administering Vaccine:

Moderna [6M-4Y](#) | [5Y+](#)

Novavax [12Y+](#)

Pfizer-BioNTech [6M-4Y](#) | [5Y+](#)

Content quoted from [Using Standing Orders for Administering Vaccines: What You Should Know](#).

## Prepare to Comply with Administration & Clinical Guidance



All COVID-19 vaccines are ACIP-recommended. As vaccines are authorized, FDA publishes Fact Sheets for Healthcare Providers and Recipients & Caregivers; ACIP reviews submitted clinical data and makes its recommendations; and CDC reviews and may adopt recommendations. Finally, Western States Scientific Safety Review Workgroup issues its recommendations. Organizations must comply with all guidance.

### Program Requirements



- COVID-19 vaccines will be administered in compliance with the most recent immunization schedule, dosage, and contraindications established by the Advisory Committee on Immunization Practices (ACIP) and in compliance with all applicable requirements as set forth by the U.S. Food and Drug Administration (FDA), including but not limited to requirements in any Emergency Use Authorization (EUA) fact sheet that covers COVID-19 vaccine. (Provider Agreement #2)
- Before administering COVID-19 vaccine, an approved EUA fact sheet or vaccine information statement (VIS) will be provided as required to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Vaccine administration records will be maintained in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) <https://vaers.hhs.gov/>. (P.A. #4)



1. Strongly encourage vaccination for all eligible patients.
2. Prepare clinicians to comply with [ACIP Vaccine Recommendations](#) | [Adult Immunization Schedule](#) and CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines](#).
3. Prepare clinicians and vaccinators to comply with FDA's [EUA Fact Sheets for HCPs](#).
4. Determine how [Fact Sheets for Recipients & Caregivers](#) will be distributed in your location:  paper  electronic

## Review the Billing and Reimbursement Policy

BAP-supplied vaccines must be administered to any individual aged 19 years and older who is uninsured or underinsured. Insured patients, including patients covered by Medicare and Medi-Cal, are NOT eligible for COVID-19 vaccines provided through the Bridge Access Program. Never deny vaccination because recipients can't afford to pay.

### Program Requirements



- Patients immunized with BAP-supplied vaccines will not be billed for the cost of the vaccine nor be charged an administration fee. All systems will be checked to ensure patients are not charged and vaccine cost will not be billed. (Provider Agreement #3)



### Key Points

- Never charge for vaccine supplied at no cost by the Bridge Access Program.
- Never charge patients an administration fee for BAP-supplied vaccines.
- For CA BAP only, CDC considers “underinsured” to refer to a person who has health insurance, but the insurance does not include any vaccines; a person whose insurance covers only selected vaccines; a person whose insurance does not provide first-dollar coverage for vaccines.

## Determine How Your Practice Will Maintain COVID-19 Records

Providers are required to maintain all BAP-related patient and vaccine management documentation (both paper and electronic) for a minimum of three years and, upon request, make these records available for review.



### Program Requirements

- The patient's recorded BAP 317 eligibility status and all records related to the Bridge Access Program will be retained for three (3) years. If requested, patient records will be made available to CDPH. Records include, but are not limited to, vaccine administration documentation, billing records, and medical records that verify receipt of vaccine. Release of such records will be bound by federal and state privacy laws. (Provider Agreement #6)
- Preserve all records related to COVID-19 vaccine management (e.g., vaccine temperature logs, invoices, and packing slips) for a minimum of 3 years. (P.A. #8e)



### Sample paper or electronic records that must be maintained

- Vaccine ordering records
- COVID-19 vaccine product packing slips
- transfer and transport logs
- temperature logs and electronic data logger temperature data files
- certificates of calibration testing (for data loggers)
- billing records
- vaccine administration records (including medical records of vaccine administration)
- any other CA BAP-related records

## Systems Setup

Some key requirements may be fulfilled by use of applications that require initial setup. We'll walk through each of these steps in this section.



[About myCAvax](#)

[Display Location on Vaccines.gov](#)

[Confirm Readiness to Report Doses Administered](#)

[Onboard if using My Turn clinic management functionality](#)



## About myCAvax

myCAvax is a free application developed by California to support providers and local health departments participating in the State vaccination programs.

The logo for myCAvax, featuring the text "myCAvax" in white lowercase letters on a blue rectangular background.

### Vaccine Management Platform

Self-service platform that offers sites an all-in-one application for managing locations, ordering vaccine, and submitting reports for inventory management

### Who has a user account?

Your Organization Vaccine Coordinator and primary and backup Vaccine Coordinators at your locations are the system users. They were assigned user IDs and set up their passwords during enrollment.

Your Organization Vaccine Coordinator registered in myCAvax first and invited staff to register as Vaccine Coordinators at each affiliated provider location. Each location must have an onsite primary and backup Vaccine Coordinator.

### Next Steps

No further action is required to set up your Organization or Location in myCAvax.

## Display Location on Vaccines.gov

CA BAP locations no longer need to be displayed on Vaccines.gov.



## Confirm Readiness to Report Doses Administered

Sites must document vaccine administration in their medical record systems within 24 hours of administration and report doses administered to CAIR as soon as practicable and no later than 72 hours using either of two options. Locations must report the required data elements, including eligibility category of "317".

### Local Registry (CAIR2 or RIDE)

#### California Immunization Registry

A secure and confidential statewide information system that contains the immunization records for all California residents

#### Resources

- For more information, see [CAIR2 Data Exchange](#) or contact your [local Data Exchange Representative](#).

### Option 1: EHR connected to CAIR2/RIDE

#### Who has a user account?

A CAIR2 Org Code (IIS ID) will be assigned during enrollment for data exchange.

In addition, all sites are encouraged to enroll a staff member in the DX Quality Assurance (DX QA) user role; this role does not require formal training and allows staff to monitor data exchange transactions, lookup patients, and access reminder/recall and ad hoc patient reports.

#### To Ensure Quality Data

Make sure staff enter accurate and complete demographic and vaccination information:

- Report [these required data elements](#).
- [Report the race/ethnicity](#) of every patient immunized.
- Include email and/or cell phone information so patients can access their [digital vaccination records](#).
- Monitor data submissions through your EHR and CAIR2/RIDE reports to make sure data is submitted successfully.
- Contact your EHR vendor to resolve any issues.

Note: Providers already manually entering data into CAIR may continue to do so.





## Confirm Readiness to Report Doses Administered (Cont.)

Sites must document vaccine administration in their medical record systems within 24 hours of administration and report doses administered to CAIR as soon as practicable and no later than 72 hours using either of two options. Locations must report the required data elements, including eligibility category of “317”.

### Local Registry (CAIR2 or RIDE)

#### California Immunization Registry

A secure and confidential statewide information system that contains the immunization records for all California residents

#### Resources

[My Turn Onboarding](#)

### Option 2: Use My Turn

Sites may also use My Turn, which is integrated with CAIR out of the box, to report administration data.

#### Who has a user account?

User accounts and training needs will vary depending on the functionality your practice adopts. (See next page.)

#### Next Steps

[Complete digital enrollment](#) if you decide to use My Turn for submitting vaccine administration data instead of an EHR.

If you are in the process of onboarding and have questions, contact your assigned liaison.

## Onboard if Using My Turn Clinic Management Functionality

My Turn is a free application developed by California to offer the public one interface for eligibility screening and scheduling, and it has evolved to offer providers and local health department expanded clinic functionality. My Turn supports COVID-19 and flu.

### My Turn (Optional)

#### Clinic Management Platform

Offers an application for clinic management, public scheduling, walk-in registration for vaccine clinics, and/or submitting vaccine administration data to CAIR

#### Resources

[My Turn Digital Enrollment](#)

[My Turn Training Videos](#)

#### Who has a user account?

User accounts and training needs vary depending on the functionality your practice implements.

*Clinic Manager:* Uses My Turn Clinic to create and manage clinics, add vaccine inventory and supply, schedule hours of operation, add vaccine administrators, send SMS notifications to patients, view aggregate data, and view/export reports.

*Vaccine Administration/Assistant:* Uses My Turn Clinic to check in registered patients; add individual and bulk walk-in appointments; reschedule, cancel, or bulk update appointments; and edit a patient's vaccine record.

#### Next Steps

Locations can complete digital enrollment for My Turn. The Virtual Assistant can answer most questions or escalate to the Provider Call Center for assistance. See [My Turn](#) for more details.

## Vaccine Management Preparations

Vaccines must be stored properly from the time they are received until administration. Potency is reduced with overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored. This section walks you through proper setup and planning.



[Confirm Where You'll Store Vaccines](#)

[Set Up Storage Unit and Data Logger](#)

[Create Your Vaccine Management Plan](#)

[Stock Supplies for Vaccine-Related Emergencies](#)

[Designate Staff to Report and Return Nonviable Vaccine](#)





## Confirm Where You'll Store Vaccines

Manufacturers have announced that authorized COVID-19 vaccines for fall 2023 will have the same storage requirements as current products. Consider storing vaccines in your coldest environment to maximize the shelf life then move doses to refrigerated temperatures when ready to administer.



### Program Requirements

The location will comply with all requirements for COVID-19 vaccine management and reporting including the following:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert, Fact Sheet for Healthcare Providers Administering the Vaccine, and guidance in CDC's [Vaccine Storage and Handling Toolkit and COVID-19 Addendum](#);
- Monitor and record vaccine storage unit temperatures twice daily following guidance in CDC's [Vaccine Storage and Handling Toolkit and COVID-19 Addendum](#);
- Respond to and report temperature excursions following CDPH guidance. (Provider Agreement #8a-c)



Purpose-built or pharmaceutical-grade units are recommended

Commercial or household standalone units are acceptable

If necessary, combination units may be used but frozen vaccines must be stored in a standalone freezer

Temperatures must be monitored by data loggers to ensure vaccines are stored in recommended temperatures



Never store vaccines in freezer compartment of household-grade combination unit

Never store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit



## Set Up Storage Unit and Data Logger

Each site must have proper storage and monitoring equipment that is set up correctly. This equipment protects patients from inadvertently receiving compromised vaccine and protects your facility against costs of revaccinating patients and losing patient confidence in your practice. This requirement has several steps.

### Estimate storage needs for vaccines & ancillary kits.

For product or ancillary kit details including supplies and vial tray or outer carton dimensions, please refer to CDC's [COVID-19 Vaccine Product Information Guide](#), which is updated as new products are authorized.

### Protect your storage unit's power supply.

Even with appropriate equipment and temperature monitoring practices in place, power disruption can result in destruction of your entire vaccine supply.



Plug in only one storage unit per electrical outlet to avoid triggering a safety switch that turns power off

Use safety-lock plug or outlet cover to prevent unit from being unplugged

Post "DO NOT DISCONNECT" signs on outlets and circuit breakers for vaccine storage units

See [Preparing Storage Units](#) for details.



Avoid using

- Built-in circuit switches (may have red reset buttons) \*
- multioutlet power strips \*
- outlets that can be activated by a wall switch

\* If these must be used, make sure the power strip is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer. Contact the storage unit manufacturer for any additional questions or guidance regarding circuit switches, power strips, or surge protection.



## Set Up Storage Unit and Data Logger (Cont.)

### Organize & label shelf space or baskets.

Organize storage units so staff can locate the correct vaccine product to reduce errors caused by inadvertent administration of products with similar cap colors or vial labels or close in age indicators. See [Setting Up Storage Units](#) for details.

**Sample Refrigerator**

✓ Clearly label VFC, VFA, BAP, and private vaccines.

✓ Group vaccines (pediatric, adolescent, adult).

✓ Label shelf space or baskets to make vaccines easy to find.

✓ Position vaccines or baskets 2-3 inches away from walls, floor, and other baskets.

✓ Store vaccines in original packaging with earliest expiration date in front.

✓ Diluents may be stored next to refrigerated vaccines unless manufacturer states otherwise. Never store diluents in the freezer.

✓ If necessary, medications or biologics may be stored below vaccines and on a different shelf.

Usable space for vaccine is inside dashed lines.

✗ Do not block air vents.

✗ Do not stack baskets on top of each other.

✗ No vaccines in doors.

✗ No food or beverages.

**CDPH Contact:**

**Sample Chest Freezer**

**Refrigerator temperatures**

36.0°F 46.0°F

**Freezer temperatures**

-58.0°F 5.0°F



## Set Up Storage Unit and Data Logger (Cont.)

### Set up and install your data logger.

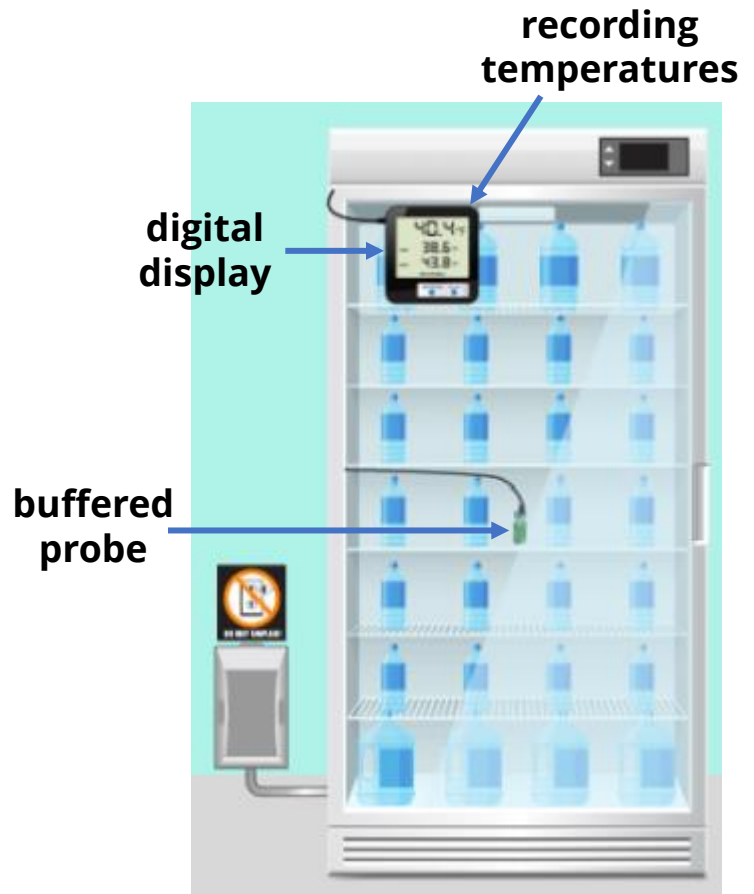
**CDC requires that COVID-19 vaccines be monitored with data loggers at all times.**

For accurate ultra-cold temperature monitoring, your data logger must use an air-probe or probe designed specifically for ultra-cold temperatures.

To ensure you are notified if temperatures drift outside recommended ranges, configure device alarm settings carefully (see [Data Logger Setup & Use](#)).

Always use devices with a current and valid [Certificate of Calibration Testing](#).

If feasible, keep an extra device on hand for vaccine transport or in case your primary device fails.



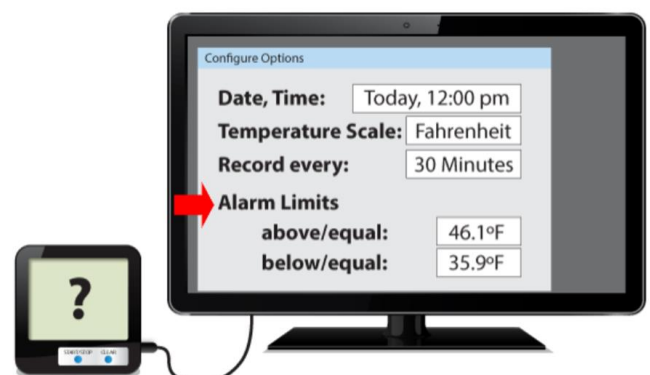
Place buffered probe in center of storage unit near vaccines and **secure vertically** to prevent leakage and inaccurate readings (see [proper probe placement](#)).

Place digital display where it can be easily read

Set to record every 30 minutes or less so you can respond promptly to alerts

Set HI & LO alarm limits to reflect recommended temperatures for COVID-19 vaccines you're storing

Be sure device is recording storage unit temperatures



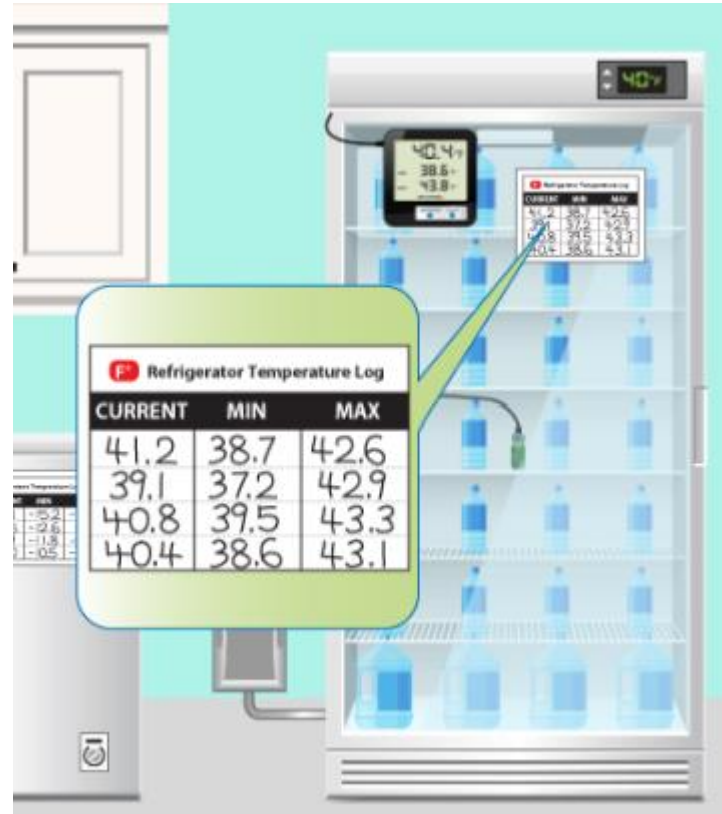


## Set Up Storage Unit and Data Logger (Cont.)

### Start recording storage unit temperatures.

Before using a unit for vaccine storage:

- Set storage unit temperatures to the recommended range for COVID-19 vaccines.
- [Monitor and record temperatures](#) twice daily for several days.
- Record your data logger's CURRENT, MIN, and MAX readings on your temperature log, or use this [COVID-19 temperature log](#).
- After two consecutive days of recorded temperatures within the recommended range for your COVID-19 products, your unit is stable and ready for use.
- Review instructions in the event [an alarm goes off](#) so you'll be prepared once vaccines arrive.



### Summary of storage unit setup tasks:

1. Estimate storage needs for vaccines.
2. [Prepare storage units](#) to protect your power supply.
3. [Set up storage units](#) and organize & label shelf space or baskets.
4. [Set up](#) your data logger; ensure staff know how to use it.
5. Start [recording storage unit temperatures](#); review instructions in the event [an alarm goes off](#).



## Create Your Vaccine Management Plan

How will you protect vaccines during a power safety shutoff or encroaching fire? Developing and implementing vaccine management plan is strongly encouraged. The plan documents your practice's standard operation procedures (SOPs) for routine storage and handling tasks and vaccine-related emergencies.


### Plan Template

Vaccine Coordinators are responsible for completing and implementing your location's vaccine management plan.

If you haven't documented your SOPs for routine and emergency situations in a management plan, use the [COVID-19 vaccine management plan template](#).

### Vaccine Management Plan

California COVID-19 Vaccination Program



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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)				

California COVID-19 Vaccination Program
IMM-1362 (5/6/21)



1. Plan to review the plan with key practice staff and update it annually, or more frequently if changes occur, and include a review date and signature to validate it is current.
2. Vaccine Coordinators should review their emergency SOPs to ensure they are prepared to implement the plan.



## Stock Supplies for Vaccine-Related Emergencies

Emergencies such as equipment failures, power outages, severe weather, or natural disasters usually happen without warning and may compromise your entire vaccine inventory. Your facility should have a sufficient supply of materials needed for vaccine transport of your largest annual inventory.

### Transport Container Options

Portable vaccine refrigerator or freezer units (preferred option)

Qualified container and packout \*

Soft-sided containers specifically engineered for vaccine transport

Hard-sided insulated containers or Styrofoam™ (**emergencies only**)

Manufacturer's original shipping container (**last resort only**)

### Coolant Options

Phase Change Materials (PCMs) to maintain proper temperatures

[Conditioned water bottle transport system](#) (**emergencies only**)

### Other Supplies

Data logger for each container

Insulating materials such as bubble wrap and corrugated cardboard

[COVID-19 Vaccine Transport Log](#)

[Transport Time Tracker](#)



Do not store food or beverage coolers in vaccine storage units (to prevent unnecessary opening/closing)

Never use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines

\* A type of container and supplies specifically designed for use when packing vaccines for transport. They are passive containers that do not require a power source and are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.

## Designate Staff to Report and Return Nonviable Vaccine



As with other routine vaccines, nonviable vaccines are returned to McKesson. This task typically is performed by Vaccine Coordinators at each provider location. Spoiled, expired, and wasted doses must be reported in myCAVax before return.



### Program Requirements

- Report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted following CDPH guidance. (Provider Agreement #8f)
- Return all nonviable vaccine to McKesson following CDPH guidance. (P.A. #8g)

For detailed instructions, please refer to [Reporting & Handling of Nonviable Doses](#).

## Staff Readiness

Introducing new vaccines into practice protocols involves many roles that must be properly trained for a smooth transition. This section overviews preparation and training for all key roles.



[Ensure Coordinators Are Set Up](#)

[Ensure Vaccine Coordinators Are Trained on Vaccines](#)

[Train Other Staff with Vaccine-Related Responsibilities](#)

[Determine Where You'll Track Training Completions](#)



## Ensure Coordinators Are Set Up



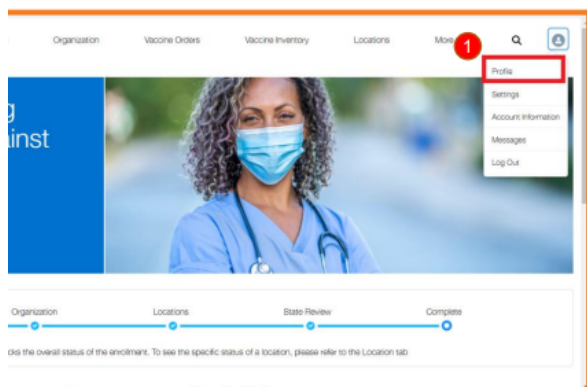
All communications for the California Bridge Access Program will be transmitted through email or phone. All Vaccine Coordinators should ensure that they have been correctly identified in the myCAVax system and that cell numbers and emails are accurate. Please note that accounts with no activity after 30 days are inactivated, and the user must contact the myCAVax Help Desk to reactivate the account.



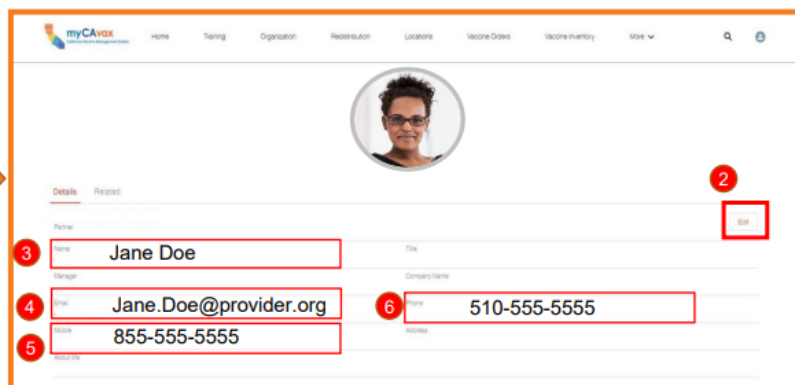
- To minimize vaccine shipment delays, login to myCAVax and confirm this information is accurate and complete:
  - location shipping address
  - phone numbers and emails (primary/backup Vaccine Coordinators)
  - Receiving days & hours (locations must offer full-day receiving hours, or minimally a four-hour window on a weekday other than Monday)

**Contact Provider Call Center to make any updates.**

myCAVax Home Page



myCAVax Profile Page



- Primary Vaccine Coordinators receive time-sensitive emails (order confirmation, advance shipments notices, and temperature monitoring alerts). To ensure these emails are not sent to Spam or Junk folders, add [these critical senders](#) to your contact list or have IT whitelist them.
- Determine if and how you will communicate Provider Call Center updates (clinical updates, delivery changes, new products, etc.) to clinicians & staff. Anyone may contact the Provider Call Center to be added to the email distribution list.
- If you will be responsible for displaying your location on Vaccines.gov, [follow these instructions](#) to enter public display location information.

## Ensure Vaccine Coordinators Are Trained on Vaccine Products



Vaccine Coordinators are responsible for implementing the location's vaccine management plan and must be well trained on the practice's storage and handling protocols for any COVID-19 products in your inventory.



1. Complete the required [COVID-19 Vaccine Product Training](#)—only for vaccines your site will administer—to ensure you are knowledgeable on storage and handling protocols.
  - Vaccine Coordinators receive an email to complete CDC's product training once enrollment is approved. **Sites will not be able to place their first order until training is complete.**
  - Providers listed on Section B will also be emailed a link to complete the required training.
2. Bookmark [COVID-19 Vaccine Product Guide](#) and review storage and handling, administration, and beyond-use (use-by) limits for products to be offered.
3. Review the list of [routine and recurring tasks](#) and their frequencies.
  - [Review receiving & storing instructions](#) for products your location will offer as well as the instructions for reporting shipment incidents.
4. Review the emergency protocols in your [COVID-19 Vaccine Management Plan](#).
5. Ramp up on myCAvax.
  - [Register](#) for Provider Office Hours for program and clinical updates.
  - For system job aids on myCAvax, visit Knowledge Center in myCAvax.

## Train Other Staff with Vaccine-Related Responsibilities



Vaccine effectiveness is a top priority. It is critical that healthcare professionals and personnel are familiar with the COVID-19 vaccine products in their facility's inventory. Training applies to anyone receiving, storing, handling, managing, or administering COVID-19 vaccines.

### Product Training

Guidance for vaccine storage, handling, preparation, and administration may differ for each vaccine product. Therefore, all healthcare staff members need training in COVID-19 vaccination—even if they are already administering routinely recommended vaccines.

Training must be ongoing as new COVID-19 vaccines become available and as recommendations evolve. See the next page for guidance and links to training.



## Train Other Staff with Vaccine-Related Responsibilities (Cont.)

A variety of healthcare professionals and personnel will be needed to implement your COVID-19 vaccination efforts. *Duties and roles may vary at your location.*

Role	Training	Resources
<b>Scheduling Desk, Check-In Staff, Vaccinators</b>	<ul style="list-style-type: none"> <li>• Age indications and number of primary doses</li> <li>• Verification of any previous COVID-19 vaccination (vaccine product and date given)</li> <li>• Timing and scheduling for next doses</li> <li>• Proper screening for allergies, medical history, vaccination history, and contraindications</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">My Turn Screening Form</a></li> <li>• <a href="#">ACIP Recommended Adult Immunization Schedule</a></li> </ul>
<b>Vaccinators</b>	<ul style="list-style-type: none"> <li>• Prepare and administer each vaccine product according to manufacturer <a href="#">EUA Fact Sheets</a></li> <li>• Identify beyond-use (use-by limits) for products (see <a href="#">vaccine product guide</a> for summary chart)</li> <li>• Don't use vaccines past earlier of expiration or beyond-use (use-by) limits</li> <li>• Dilute Pfizer pediatric formulations correctly</li> <li>• Demonstrate competency in administration including dose-withdrawal techniques</li> <li>• Locate correct injection site by patient profile</li> <li>• See <a href="#">Technical Training for New Vaccinators</a> for job aids and other resources</li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">COVID-19 Vaccine Product Guide</a></li> <li>• <a href="#">COVID-19 Vaccine Product Training</a></li> <li>• <a href="#">Vaccine Preparation</a></li> <li>• <a href="#">Vaccine Administration</a></li> <li>• <a href="#">Managing Expiration &amp; Beyond-Use Dates</a></li> </ul>
<b>Clinicians</b>	Review CDC's product training for products your location will administer; includes administration & clinical guidance	<a href="#">COVID-19 Vaccine Product Training</a>
<b>Medical Support Staff</b>	This role is not licensed to administer but may assist with vaccine preparation & cold chain mgmt.	<a href="#">COVID-19 Vaccine Product Training</a>
<b>Administrative Support Staff</b>	This role may assist with receiving, data reporting and distribution of required materials to recipients <ul style="list-style-type: none"> <li>• Ensure staff authorized to accept packages are trained to notify the Vaccine Coordinator when vaccines are delivered</li> </ul>	Vaccine Coordinator can train staff based on their responsibilities
<b>Billing</b>	Review BAP billing and reimbursement policies.	<a href="#">Billing &amp; Reimbursement</a>
<b>Supervisors</b>	Ensure staff who monitor storage unit temperatures are trained on temperature monitoring, use of the practice's data loggers, and required actions for out-of-range temperatures	<ul style="list-style-type: none"> <li>• <a href="#">How to Record Temperatures</a></li> <li>• <a href="#">Reporting Temperature Excursions</a></li> <li>• <a href="#">Data Logger Setup &amp; Use</a></li> </ul>





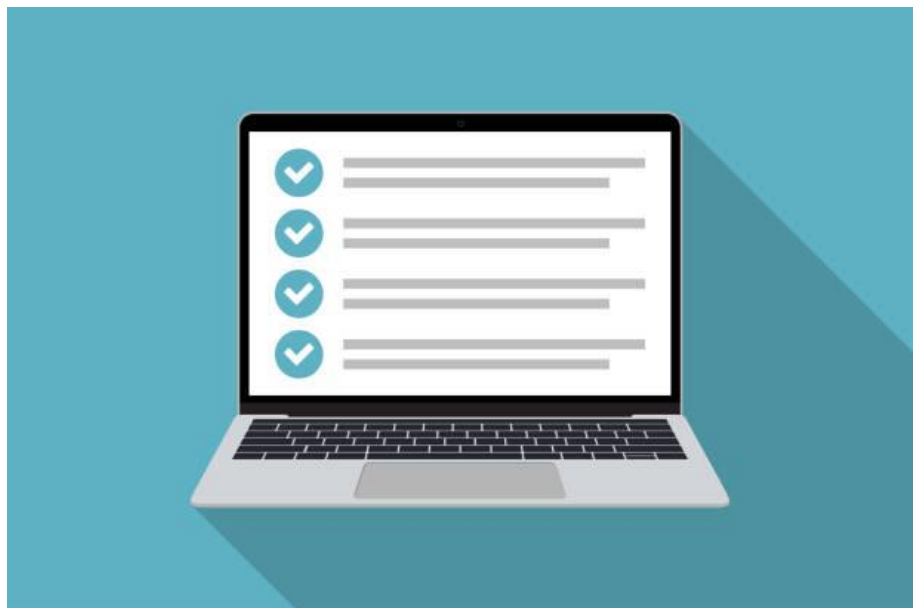
## Determine Where You'll Track Training Completions

Providers must track, maintain documentation of, and monitor the status of the training received by vaccination staff to ensure the training requirement is met and make documentation available during quality assurance visits.

### Plan Template

Training completions may be documented in any electronic or paper system:

- [COVID-19 Vaccine Management Plan](#)
- personnel form
- training database or log
- other system



## You're Done!

After completing training, the Vaccine Coordinators will maintain daily vaccine operations at the provider site. Before vaccines arrive, review the Startup Checklist to ensure your practice is ready.

## Next Steps

The rest of this manual walks you through the next steps to get you on your way!



**Order  
Vaccines**



**Receive &  
Store Vaccines**



**Routine Tasks &  
Reporting**



**Manage Vaccine  
Inventory**



**Patient Visit**



[Register](#) for **Provider Office Hours** and review [archived sessions](#)!

Bookmark EZIZ's [Bridge Access Program](#) to find additional job aids!



### **Provider Call Center**

For answers to all things COVID

(833) 502-1245

Hours: M-F 8AM-5PM

For myCAVax Help Desk inquiries: [myCAVax.HD@cdph.ca.gov](mailto:myCAVax.HD@cdph.ca.gov)

For My Turn Clinic Help Desk inquiries: [MyTurn.Clinic.HD@cdph.ca.gov](mailto:MyTurn.Clinic.HD@cdph.ca.gov)

For all other inquiries: [providercallcenter@cdph.ca.gov](mailto:providercallcenter@cdph.ca.gov)

# 1. Ordering Vaccines



Vaccine Coordinators may submit Standard Orders weekly for any COVID-19 vaccine products in myCAVax. Small Orders and Vaccine Marketplace are not supported for BAP-supplied vaccines.

## Audience

Vaccine Coordinators



[About Vaccine Orders](#)

[Vaccine Products](#)

[Submitting Vaccine Order Requests](#)

[Minimizing Shipment Delays](#)

[When to Expect Vaccines](#)



## About Vaccine Orders

Vaccines are procured and distributed by the federal government at no cost to BAP providers or recipients. Available vaccine products and configurations are dependent on vaccine supply and appear in myCAvax for ordering. Ancillary kits do NOT ship with vaccine.

### Program Requirements



- The total number of patients immunized with COVID-19 vaccines and current inventory on hand will be reported to the California Department of Public Health (CDPH) according to the BAP reporting guidelines. The patient's recorded BAP 317 eligibility status and all records related to the Bridge Access Program will be retained for three (3) years. If requested, patient records will be made available to CDPH. Records include, but are not limited to, vaccine administration documentation, billing records, and medical records that verify receipt of vaccine. Release of such records will be bound by federal and state privacy laws. (Provider Agreement #6)
- Order vaccines according to the BAP ordering guidance; providers who have not ordered vaccines in a period longer than 6 months may be terminated from the Bridge Access Program. (P.A. #7)

### Ordering Cadence

Locations may submit vaccine order requests in myCAvax weekly. Vaccines are delivered to the location's shipping address. Redistribution is not allowed. Refer to the [Weekly Ordering Cadence Calendar](#) for deadlines and delivery estimates.

### Reporting Doses Administered and Inventory

Providers are accountable for all BAP-supplied vaccines upon receipt and must be able to provide documentation to support their numbers. Providers must report vaccine accountability numbers with each vaccine order to receive new vaccines.

Plan to report *doses administered since previous order* (run CAIR registry reports to ensure accurate numbers are reported) and *doses on hand* (ensure nonviable doses are removed from inventory, reported as waste, and returned to McKesson) on each vaccine order.

## Vaccine Products

Moderna, Novavax, and Pfizer-BioNTech vaccines have been updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5; bivalent products are no longer authorized for use in the US.

Locations may order vaccine in myCAvax. Refer to CDPH's [COVID-19 Vaccine Product Guide](#) for a chart of available products, minimum order sizes, NDCs, CVX codes, storage and handling, preparation and administration, and use-by limits.

**Minimum Order Quantities:** Package size.

NCDs listed below are for the updated vaccine products that may be authorized and approved for fall 2023. Providers will be notified when products are authorized and approved.

Manufacturer	Order Intention (Pediatric, adult, or mixed)	NDC	CDC Description
Moderna Spikevax 12Y+	Mixed	80777-0102-01	12Y+, SDV, 10-pk
Novavax	Mixed	80631-0102-01	12Y+, MDV5, 2-pk
Pfizer-BioNTech Comirnaty 12Y+	Mixed	00069-2362-10	12Y+, SDV, 10-pk

# Submitting Vaccine Order Requests

Vaccine Coordinators may submit requests in myCAvax. Requests are reviewed and approved by your local health department, processed by CDPH, and fulfilled by CDC. Vaccines ship to the shipping address of the location on your order. Before submitting your request, keep these points in mind.

## When Submitting a Vaccine Order Request

1

Check inventory on hand first; order what's needed to last until the next ordering period.

2

As with other routine vaccines, plan to report *doses administered since previous order* (run CAIR registry reports to ensure accurate numbers are reported) and *doses on hand* (ensure nonviable doses are removed from inventory, reported as waste, and returned to McKesson)—only for products you intend to order.

3

Locations may submit vaccine order requests weekly per [BAP ordering cadence calendar](#). (Vaccines are delivered to each location's shipping address.)

4

Request doses in multiples according to carton size; multiple vaccine products may be selected on the same order.

5

Standard Orders are transmitted to and fulfilled by CDC and can't be canceled once transmitted.

6

Vaccine Coordinators receive emails regarding order confirmations and advance shipment notices of vaccine and kits; add [these senders](#) to your contact list or whitelist to ensure they aren't sent to Junk or Spam.



# Minimizing Shipment Delays

Take steps to prevent order approval delays or delivery mishaps.

## Key Points

Login to myCAvax and ensure the following information is accurate and complete for your location. Contact the Provider Call Center for assistance if needed.



- **receiving days and hours** (locations must offer full-day receiving hours to facilitate delivery, or minimally a four-hour window on a weekday other than Monday)
- **location's shipping address**
- **phone numbers and emails** (primary and backup Vaccine Coordinators)



Vaccines must never be left unattended. Ensure your receiving days and hours reflect times when staff are guaranteed to be present.

## When to Expect Vaccines

Because the Public Health Emergency has ended, COVID-19 vaccine distribution will no longer be expedited. Distribution will follow the cadence of other routine vaccines.

### Moderna and Novavax vaccines will be shipped by McKesson.

- COVID-19 vaccine orders will follow same shipping timelines for routine vaccines (shipping approximately within 3 days of order receipt at McKesson).
- Moderna (SPIKEVAX®) vaccine ships frozen between -50°C and -15°C (-58°F and 5°F).
- Novavax vaccine ships like other routine refrigerated vaccines at temperatures between 2° to 8°C (36° to 46°F).

### Pfizer vaccines will ship directly from Pfizer

- Will be shipped on dry ice on ultra low temperature conditions.
- CDC contract stipulates vaccines must be delivered within 15 days of order receipt by CDC.
- For vaccines with diluent (6m-4y) diluent will be shipped separately and will arrive at the same time of before vaccines arrive.

## Notifications

Primary Vaccine Coordinators (Point of Contact on the order) receive these emails:

- **Order status changes** (pending and rejected)
- **Order acknowledgement** (order was received by McKesson)
- **Advance shipment notices** (vaccine and ancillary kits) by McKesson and Pfizer
- **Pfizer temperature monitoring report** (in-transit temperatures in thermal shippers)



Add [these senders](#) to your contact list or have IT whitelist them to ensure emails aren't sent to Junk or Spam folders.





## 2. Receiving & Storing Vaccine Shipments



Upon delivery, locations assume responsibility for storing vaccines under recommended temperatures. Proper storage and handling protects vaccine viability, which is necessary to stimulate a healthy immune response after vaccination. This section covers receiving vaccine shipments and reporting shipment incidents.

### Audience

Vaccine Coordinators



[About Receiving Shipments](#)

[Moderna Spikevax Vaccine 12Y+ Fact Sheet](#)

[How to Receive Moderna Vaccine](#)

[Novavax Vaccine 12Y+ Fact Sheet](#)

[How to Receive Novavax Vaccine](#)

[Pfizer-BioNTech Comirnaty Vaccine 12Y+ Fact Sheet](#)

[How to Receive Pfizer-BioNTech Vaccine](#)

[Reporting Shipment Incidents](#)



## About Receiving Shipments

Vaccine shipments must be inspected immediately and vaccines stored properly upon arrival. See product-specific guidance on next pages. Staff who accept vaccine deliveries should be trained to immediately notify the primary or backup Vaccine Coordinator when vaccine shipments arrive.

### Program Requirements



The location will comply with all requirements for COVID-19 vaccine management and reporting including the following:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert, Fact Sheet for Healthcare Providers Administering the Vaccine, and guidance in CDC's Vaccine Storage and Handling Toolkit and COVID-19 Addendum. (Provider Agreement #8a)
- Respond to and report temperature excursions following CDPH guidance; (P.A. #8c)
- Preserve all records related to COVID-19 vaccine management (e.g., vaccine temperature logs, invoices, and packing slips) for a minimum of 3 years. (P.A. #8e)



### Key Tips

- Never refuse vaccine shipments; never leave a shipper unpacked and unattended. If vaccines and diluent get too warm, they cannot be used.
- Verify vaccine for signs of damage, discrepancies between packing slip and contents, and temperature excursions in transit for vaccines.
- Store vaccines in [proper storage units](#) monitored by [data loggers configured](#) for the recommended temperatures; place doses soon to expire in front.
- Apply CDC's vaccine-specific beyond-use date labels (**TBD**) to track use-by limits if storing vaccines under temperatures colder than primary recommended range.
- [Report any shipment incidents](#) in myCAvax when discovered.
- Providers are encouraged to recycle the cardboard components of shipping containers through their local recycling program.

# Moderna Spikevax Vaccine 12Y+ Fact Sheet

Approval of Spikevax (COVID-19 Vaccine, mRNA) to include the 2023-2024 formula, a change to a single dose for individuals 18Y+ and approval of a single dose for individuals 12-17Y. Updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5. Administer vaccine intramuscularly.

**Product Profile:** NDC 80777-0102-04

[Provider Letter](#) | [Package Insert](#)

## [COVID-19 Fact Sheet](#)

### COVID-19 Vaccine Adolescent/Adult (12Y+), 2023-2024 Formula

Vaccine Fact Sheet



Topic	Comirnaty	Spikevax	Novavax COVID-19 Vaccine
<b>Manufacturer</b>	Pfizer-BioNTech	Moderna	Novavax
<b>Product Info</b>	<a href="#">Prescribing Info</a>   <a href="#">Pfizer at a Glance</a>	<a href="#">Prescribing Info</a>   <a href="#">Moderna at a Glance</a>	<a href="#">Prescribing Info</a>   <a href="#">Novavax at a Glance</a>
<b>Protects Against</b>	Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
<b>Approved Ages</b>	12 years + (see <a href="#">age transition guidance</a> )	12 years + (see <a href="#">age transition guidance</a> )	12 years +
<b>Routine Schedule &amp; Intervals</b>	<p><b>Individuals 12 years and older:</b></p> <ul style="list-style-type: none"> <li>• <b>Unvaccinated:</b> 1 dose</li> <li>• <b>Previously vaccinated with any COVID-19 vaccine:</b> 1 dose at least 2 months after the last dose of COVID-19 vaccine</li> <li>• <b>Immunocompromised:</b> See <a href="#">CDC guidance</a></li> </ul>	<p><b>Individuals 12 years and older:</b></p> <ul style="list-style-type: none"> <li>• <b>Unvaccinated:</b> 1 dose</li> <li>• <b>Previously vaccinated with any COVID-19 vaccine:</b> 1 dose at least 2 months after the last dose of COVID-19 vaccine</li> </ul> <p><b>Immunocompromised:</b> See <a href="#">CDC guidance</a></p>	<p><b>Individuals 12 years and older:</b></p> <ul style="list-style-type: none"> <li>• <b>Unvaccinated:</b> 2 doses at least 3 weeks apart</li> <li>• <b>Previously vaccinated with any COVID-19 vaccine:</b> 1 dose at least 2 months after the last dose of COVID-19 vaccine</li> <li>• <b>Immunocompromised:</b> See <a href="#">CDC guidance</a></li> </ul>
<b>Administration</b>	Intramuscular (IM) injection	Intramuscular (IM) injection	Intramuscular (IM) injection
<b>Packaging</b>	Single-dose vials – 10 vials per box  <b>Prefilled syringes:</b> 10 single-dose, manufacturer-filled syringes (NCD 0069-2377-10)	Single-dose vial – 10 vials per box (pre-filled syringes available for private purchase)	5-dose vials – 2 vials per box (10 doses per box)

## How to Receive Moderna Vaccine

Never refuse vaccine shipments. Verify shipments & contents upon arrival. Store vaccines properly in original packaging. Report shipment incidents when discovered for resolution. Inventory kit supplies upon receipt to ensure quantities match doses.

### Instructions for All Moderna Vaccine Products

1

Examine the shipping container for signs of physical damage.

2

Open the box and remove TagAlert Temperature Monitor from box (placed in the inner box next to vaccine).

3

Press and hold the Start & Stop button until STOP icon appears in display.

4

Follow the Receiver Instructions on the card to determine if vaccines are okay to use.

#### Left arrow points to a green checkmark:

The vaccine is ready to use. Store the vaccine at proper temperatures immediately.

#### Right arrow points to a red X:

The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label DO NOT USE! Report the shipment incident.



**MCKESSON**

**ALERT: Do not Place on Dry Ice**

INSTRUCTIONS

- 1 Remove TagAlert Temperature Monitor from Box (placed in inner box next to vaccine)
- 2 Follow Receiver Instructions on the card:
  - Press and hold the Start & Stop button until the Stop icon appears
  - Read Indicator Status to determine if the appropriate temperature was maintained during transit.

Vaccine should be placed in appropriate storage as soon as possible upon receipt.

## How to Receive Moderna COVID-19 Vaccines (Cont.)

Never refuse vaccine shipments. Verify shipments & contents upon arrival. Store vaccines properly in original packaging. Report shipment incidents when discovered for resolution. Inventory kit supplies upon receipt to ensure quantities match doses.

### Instructions for All Moderna Vaccine Products (Cont.)

5

If vaccine is okay to use, unpack shipper.

6

Inspect vaccine carton for damage, confirm order quantities, and confirm there is no expired vaccine.

7

Store vials upright, in original packaging, and protected from light. Place vials with earlier expiration dates in front.

8

Apply [storage and beyond-use-date tracking labels](#): Use *storage labels* to help staff easily identify the correct product based on recipient's age; use *BUD tracking labels* to identify beyond-use-date limit for refrigerated storage.



**If storing vaccine in a freezer:** Store between -50°C and -15°C (-58°F and 5°F) until expiration.

**If transferring to refrigerator:** Store between 2°C and 8°C (36°F and 46°F) **for up to 30 days**; label with BUD of **30 days**.

9

[Report all shipment incidents](#) in myCAvax for vaccine product or kits (including temperature excursions in transit, damage, or order discrepancies) the same day the shipment arrived.

Providers are encouraged to recycle the cardboard components of shipping containers through their local recycling program.

# Novavax Vaccine 12Y+ Fact Sheet

Authorized under EUA for use in individuals 12 years of age and older and updated to include the spike protein from the SARS-CoV-2 Omicron variant lineage XBB.1.5 (2023-2024 formula). Administer vaccine intramuscularly.

**Product Profile:** NDC 80631-0102-01

[Fact Sheet for HCPs](#) | [Recipients](#)

[COVID-19 Fact Sheet](#)

## COVID-19 Vaccine Adolescent/Adult (12Y+), 2023-2024 Formula

Vaccine Fact Sheet



Topic	Comirnaty	Spikevax	Novavax COVID-19 Vaccine
<b>Manufacturer</b>	Pfizer-BioNTech	Moderna	Novavax
<b>Product Info</b>	<a href="#">Prescribing Info</a>   <a href="#">Pfizer at a Glance</a>	<a href="#">Prescribing Info</a>   <a href="#">Moderna at a Glance</a>	<a href="#">Prescribing Info</a>   <a href="#">Novavax at a Glance</a>
<b>Protects Against</b>	Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
<b>Approved Ages</b>	12 years + (see <a href="#">age transition guidance</a> )	12 years + (see <a href="#">age transition guidance</a> )	12 years +
<b>Routine Schedule &amp; Intervals</b>	<p><b>Individuals 12 years and older:</b></p> <ul style="list-style-type: none"> <li>• <b>Unvaccinated:</b> 1 dose</li> <li>• <b>Previously vaccinated with any COVID-19 vaccine:</b> 1 dose at least 2 months after the last dose of COVID-19 vaccine</li> <li>• <b>Immunocompromised:</b> See <a href="#">CDC guidance</a></li> </ul>	<p><b>Individuals 12 years and older:</b></p> <ul style="list-style-type: none"> <li>• <b>Unvaccinated:</b> 1 dose</li> <li>• <b>Previously vaccinated with any COVID-19 vaccine:</b> 1 dose at least 2 months after the last dose of COVID-19 vaccine</li> </ul> <p><b>Immunocompromised:</b> See <a href="#">CDC guidance</a></p>	<p><b>Individuals 12 years and older:</b></p> <ul style="list-style-type: none"> <li>• <b>Unvaccinated:</b> 2 doses at least 3 weeks apart</li> <li>• <b>Previously vaccinated with any COVID-19 vaccine:</b> 1 dose at least 2 months after the last dose of COVID-19 vaccine</li> <li>• <b>Immunocompromised:</b> See <a href="#">CDC guidance</a></li> </ul>
<b>Administration</b>	Intramuscular (IM) injection	Intramuscular (IM) injection	Intramuscular (IM) injection
<b>Packaging</b>	Single-dose vials – 10 vials per box  <b>Prefilled syringes:</b> 10 single-dose, manufacturer-filled syringes (NCD 0069-2377-10)	Single-dose vial – 10 vials per box (pre-filled syringes available for private purchase)	5-dose vials – 2 vials per box (10 doses per box)

# How to Receive Novavax Vaccine

Never refuse vaccine shipments. Verify shipments & contents upon arrival. Store vaccines properly in original packaging. Report shipment incidents when discovered for resolution. Inventory kit supplies upon receipt to ensure quantities match doses.

## Instructions

- 1 Examine the shipping container for signs of physical damage.
- 2 Open cooler and remove WarmMark monitor (may be located under frozen gel packs at top of the cooler).
- 3 Remove instruction card for temperature monitor and follow guidance on back. (If temperatures are too warm, report as a shipment incident.)
- 4 Inspect vaccine carton for damage, confirm order quantities, and confirm there is no expired vaccine. (Report any discrepancies or expired vaccine as a shipment incident.)
- 5 If vaccine is ready to use, transfer vial trays to your refrigerator, vials upright and in original packaging to protect from light.



**This product CANNOT be stored in a routine freezer.**

Store between 2°C and 8°C (36°F and 46°F).

Apply [storage and handling labels](#) to shelves or bins to prevent administration errors.

- 6 [Report all shipment incidents](#) in myCAvax for vaccine product or kits (including temperature excursions in transit, damage, or order discrepancies) the same day the shipment arrived.
- 7 Providers are encouraged to recycle the cardboard components of shipping containers through their local recycling program.

# Pfizer-BioNTech Comirnaty Vaccine 12Y+ Fact Sheet

Approval of Comirnaty (COVID-19 Vaccine, mRNA) to include 2023-2024 formula, and a change to a single dose for individuals 12Y+. Updated to include a monovalent (single) component that corresponds to Omicron variant XBB.1.5. Administer intramuscularly.

**Product Profile:** NDC 00069-2362-10  
NDC 00069-2377-01

[Provider Letter](#) | [Package Inserts](#)  
[COVID-19 Fact Sheet](#)

## COVID-19 Vaccine Adolescent/Adult (12Y+), 2023-2024 Formula

Vaccine Fact Sheet



Topic	Comirnaty	Spikevax	Novavax COVID-19 Vaccine
<b>Manufacturer</b>	Pfizer-BioNTech	Moderna	Novavax
<b>Product Info</b>	<a href="#">Prescribing Info</a>   <a href="#">Pfizer at a Glance</a>	<a href="#">Prescribing Info</a>   <a href="#">Moderna at a Glance</a>	<a href="#">Prescribing Info</a>   <a href="#">Novavax at a Glance</a>
<b>Protects Against</b>	Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
<b>Approved Ages</b>	12 years + (see <a href="#">age transition guidance</a> )	12 years + (see <a href="#">age transition guidance</a> )	12 years +
<b>Routine Schedule &amp; Intervals</b>	<p><b>Individuals 12 years and older:</b></p> <ul style="list-style-type: none"> <li>• <b>Unvaccinated:</b> 1 dose</li> <li>• <b>Previously vaccinated with any COVID-19 vaccine:</b> 1 dose at least 2 months after the last dose of COVID-19 vaccine</li> <li>• <b>Immunocompromised:</b> See <a href="#">CDC guidance</a></li> </ul>	<p><b>Individuals 12 years and older:</b></p> <ul style="list-style-type: none"> <li>• <b>Unvaccinated:</b> 1 dose</li> <li>• <b>Previously vaccinated with any COVID-19 vaccine:</b> 1 dose at least 2 months after the last dose of COVID-19 vaccine</li> </ul> <p><b>Immunocompromised:</b> See <a href="#">CDC guidance</a></p>	<p><b>Individuals 12 years and older:</b></p> <ul style="list-style-type: none"> <li>• <b>Unvaccinated:</b> 2 doses at least 3 weeks apart</li> <li>• <b>Previously vaccinated with any COVID-19 vaccine:</b> 1 dose at least 2 months after the last dose of COVID-19 vaccine</li> <li>• <b>Immunocompromised:</b> See <a href="#">CDC guidance</a></li> </ul>
<b>Administration</b>	Intramuscular (IM) injection	Intramuscular (IM) injection	Intramuscular (IM) injection
<b>Packaging</b>	Single-dose vials – 10 vials per box  <b>Prefilled syringes:</b> 10 single-dose, manufacturer-filled syringes (NCD 0069-2377-10)	Single-dose vial – 10 vials per box (pre-filled syringes available for private purchase)	5-dose vials – 2 vials per box (10 doses per box)



## How to Receive Pfizer-BioNTech Vaccine

Never refuse vaccine shipments. Verify shipments & contents upon arrival. Store vaccines properly in original packaging. Report shipment incidents when discovered for resolution. Inventory kit supplies upon receipt to ensure quantities match doses.

### Instructions for Maroon, Orange and Gray Caps

1

Examine the shipping container for signs of physical damage.

2

Open thermal shipper in a well-ventilated room.

3

**For pre-filled syringes:** Product does not ship with temperature monitor and is good for 84hrs from date on the sticker on the box.  
**For Vials:** Determine if product is okay to use by checking Controlant's shipment quality report (arrives within 1-3 hours) and follow the instructions below.

#### For Vials:



Hold STOP button  
**for 5 seconds**  
 to accept delivery



Shipment LED turns on  
**for 3 seconds,**  
 alarm status is empty

No excursion has been  
 noted, check the report



Alarm LED blinks **every 5 seconds**

Excursion may have taken  
 place, check report before  
 using product

**If connection status shows no signal,** move logger to an area with better cellular signal and press the stop button again.

**If battery status shows less than 10%,** plug logger into a USB port to charge at least 20 minutes before pushing the stop button again.

**If battery is dead,** contact Controlant at 1-855-442-668765 or support@controlant.com.

## How to Receive Pfizer-BioNTech COVID-19 Vaccines (Cont.)

Never refuse vaccine shipments. Verify shipments & contents upon arrival. Store vaccines properly in original packaging. Report shipment incidents when discovered for resolution. Inventory kit supplies upon receipt to ensure quantities match doses.

### Instructions for Maroon, Orange and Gray Caps

4

If vaccines are okay to use, unpack shipper following instructions for [single-use](#) or [medium thermal shippers](#). Wear safety goggles (or glasses with side shields) and waterproof, insulated gloves.

5

Inspect vaccine carton for damage, confirm order quantities, and confirm there is no expired vaccine.

6

Label product with expiry date printed on the shipper label before storing (vial date is the manufacture date).

7

Store vials upright, in original packaging, and protected from light. Place vials with earlier expiration dates in front.

8

Apply [storage labels](#) to help staff identify correct products & [BUD labels](#) to identify beyond-use-date limits for refrigerated storage.

**CANNOT be stored in a routine freezer.**

**If transferring to ULT freezer:** Store between -90°C to -60°C (-130°F to -76°F) **within 5 minutes**; do not open tray(s) or touch vials. Store and use up to expiration.

**If transferring to refrigerator:** Store between 2°C and 8°C (36°F and 46°F) **for up to 10 weeks**; label with BUD of **10 weeks**.



9

[Report all shipment incidents](#) in myCAvax for vaccine product or kits (including missing return labels, temperature excursions in transit, damage, or order discrepancies) the same day the shipment arrived.

**Important:** Providers are no longer required to return the shipping containers. Packing slips can be requested from Pfizer Customer Service if providers need more than the sticker on the box.

# Reporting Shipment Incidents



Vaccine Coordinators may report shipment incidents in myCAvax. Timing is critical. Report incidents for vaccine the same day shipments arrived. Please make sure data is accurate and complete.



## What's a Shipment Incident?

**Report any of these issues ASAP for resolution:**

- Broken, Torn, or Tampered with
- Not ordered/incorrect recipient
- Out-of-range temperature
- Package never arrived
- Previously opened
- Shipping contents discrepancies

## Step 1: Report the Shipment Incident in myCAvax

McKesson requires that shipment incidents be reported the day of receipt for resolution. Gather the information you'll need to report the shipment incident.

1. Note any discrepancies between the packing slip, vaccine order, and contents of the box.
2. Note the box's tracking number (if multiple boxes were received).
3. Navigate to Vaccine Inventory in myCAvax to report the Shipment Incident.
4. Scan and attach the packing slip for all incidents to your incident report.
5. **For Moderna/Novavax temperature excursions:** Attach a picture of the TagAlert monitor and its location in the shipper.



## Reporting Shipment Incidents (Cont.)



Vaccine Coordinators may report shipment incidents in myCAVax. Timing is critical. Report incidents for vaccine and kits the same day shipments arrived. Please make sure data is accurate and complete.

### Step 2: CDPH Internal Review and Outreach to Shippers



Providers are no longer required to contact McKesson or Pfizer for a resolution on their direct ship orders. CDPH will review shipment incidents reported in myCAVax and will contact the shipper on behalf of the provider. Refer to the Guidance/Resolution section of the report for updates.

Incidents must be reported as soon as delivery has been made and/or when an incident has been identified (missing orders/incorrect recipient) to ensure vaccine stability before use.

**Local ship orders:** These shipment Incidents must be resolved between the provider and the local health department; CDPH will not contact the LHD on providers behalf.

**Moderna & Novavax:** Vaccines ship from McKesson.

**Pfizer-BioNTech:** Pfizer vaccines ship directly from Pfizer.

Point of Contact	Incident	Contact Info
<b>McKesson Specialty</b>	Moderna and Novavax Shipments: Issues with Temperature Monitor (Out-of-Range Temperatures)	Must be reported <u>same day as delivery</u> .  (833) 272-6635 Mon-Fri, 8 a.m. - 8 p.m. ET <a href="mailto:COVIDVaccineSupport@McKesson.com">COVIDVaccineSupport@McKesson.com</a>
<b>Pfizer Customer Service</b>	Pfizer Comirnaty vaccine shipment issue	<a href="mailto:MRNAVaccines@pfizer.com">MRNAVaccines@pfizer.com</a>
<b>Provider Call Center</b>	Other Shipment issues	<i>Allow CDPH team at least 1 business day to contact the Shipper and receive a resolution for the incident.</i>  <a href="mailto:ProviderCallCenter@cdph.ca.gov">ProviderCallCenter@cdph.ca.gov</a> or 1-833-502-1245

## Reporting Shipment Incidents (Cont.)



Vaccine Coordinators may report shipment incidents in myCAvax. Timing is critical. Report incidents for vaccine and kits the same day shipments arrived. Please make sure data is accurate and complete.

### Step 3: Report Deficiencies for Syringes & Needles

Providers are encouraged to report deficiencies for syringes and needles to the US Food and Drug Administration (FDA) to help identify unknown risk for approved medical products.



The reporting process ensures enough information is gathered so trends in packaging and shipping problems can be identified. General instructions:

- Complete [FDA Form 3500](#) online. ([Instructions for Voluntary Reporting by Health Professionals](#))
- Provide photos, lot number, order number, date ordered, and date received when filing a report.
- 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.

**Important:** If a deficiency leads to an error or injury during vaccine administration, report the incident to [VAERS](#) (vaers.hhs.gov) and [VERP](#) (verp.ismp.org).

### 3. Routine Tasks & Reporting



Once vaccines arrive, there are key tasks you'll perform on a daily, weekly, or as-needed basis. Reporting requirements are recurring once vaccines arrive. Tasks covered in this section are linked to other resources for detailed coverage.

### Audience

Vaccine Coordinators (including Organization Vaccine Coordinators)



[Recurring Tasks and Frequency](#)



## Recurring Tasks & Frequency

Refer to this table as a cheat sheet for recurring tasks. Note that all listed reporting tasks are required for the COVID-19 vaccination program.

	Daily	Weekly	Notes
<a href="#"><u>Display location on Vaccines.gov</u></a>			one-time
<a href="#"><u>Order vaccines</u></a> (myCAvax)			weekly
<a href="#"><u>Receive and store vaccines</u></a> (follow product-specific guidance)			upon delivery
<a href="#"><u>Report shipment incidents</u></a> (myCAvax)	yes		ASAP for resolution
<a href="#"><u>Record storage unit temperatures</u></a> (record on your temperature log)	twice daily		beginning & end of day
<a href="#"><u>Report temperature excursions</u></a> (myCAvax)	yes		when discovered
<a href="#"><u>Report doses administered</u></a> (My Turn or your EHR)	yes		no later than 72 hrs.
<a href="#"><u>Report doses spoiled, expired, or wasted</u></a> (myCAvax)			before return
<a href="#"><u>Report transfers</u></a> (myCAvax)			within 24 hrs. of event
<a href="#"><u>Report adverse events to VAERS</u></a> (via phone or online)			each event
<a href="#"><u>Rotate vaccine and remove expired vaccine</u></a>		Yes	upon receipt
<a href="#"><u>Recalibrate data logger</u></a>			every two to three years
<a href="#"><u>Review your vaccine management plan and check supplies for emergency transport</u></a>			annually or if updated
<a href="#"><u>Introduce new vaccines in your practice</u></a>			as needed

## 4. Managing Vaccine Inventory



Efforts to vaccinate your patients fall short if your inventory is not managed to ensure vaccine potency and removal of expired vaccine. This section prepares you to protect the cold chain and to manage expiration dates to ensure expired vaccine is not inadvertently administered.

### Audience

Vaccine Coordinators



[Inventory Management Checklist](#)

[Monitoring Storage Unit Temperatures](#)

[Reporting Temperature Excursions](#)

[Managing Expiration & Beyond-Use Dates](#)

[About Wastage & Missed Vaccination Opportunities](#)

[Reporting & Handling of Nonviable Doses](#)

[Transporting Vaccine](#)

[Transferring Vaccine](#)





# Inventory Management Checklist

Efforts to raise immunization levels in provider populations fall short if vaccine inventory is not managed to ensure viability. Vaccine inventory management is an essential practice that can prevent inadvertent administration of expired vaccine and vaccine loss due to temperature excursions. Use this checklist to get started.

## Store Vaccine under Recommended Temperatures



- Don't reject shipments; report shipment incidents in myCAvax the same day for resolution.
- Store vaccines under [manufacturer-recommended temperatures](#); label cartons with beyond-use dates as recommended by vaccine manufacturers.
- Group adult vaccines together and label in large letters (cartons, baskets, or shelf space) to ensure correct products are removed for administration.
- Record storage unit temperatures twice daily on a temperature log with current, min and max readings, or use [COVID-19 log](#); report temperature excursions daily in myCAvax.

## Manage Expiration & Beyond-Use Dates

- Remove deauthorized products immediately to prevent administration errors.
- Rotate stock weekly (and when new shipments arrive) to ensure vaccines soon to expire are used first.
- As expiration dates draw near, check for extensions using [Novavax](#) and [Pfizer-BioNTech](#) expiry tools and contact Moderna; label product with updated dates to prevent errors.
- If unable to use before expiration, contact your local health department about transfers.
- Strictly comply with the manufacturer guidance on expiration dates.
- Remove spoiled or expired vaccine IMMEDIATELY to prevent administration errors.
- Do not use vaccine after the earlier of expiration or use-by date.

## Report Vaccine Wastage

- Report doses spoiled, expired, or wasted in myCAvax.
- For deauthorized vaccine products:* Report as "Waste" and use "Other" to add comment "deauthorized"; dispose of products following practice protocols (may be disposed of in a pharmaceutical waste container, or a comingled pharmaceutical/Sharps container).
- For nonviable 2023-24 COVID-19 vaccine:* Report as "Waste" and return to McKesson; label as "nonviable vaccine".

# Monitoring Storage Unit Temperatures

Record storage unit temperatures at the beginning and end of the clinic day. Accurate and consistent temperature monitoring is a critical task. If temperatures drift out of range in the afternoon but aren't discovered until the next day, your entire vaccine supply may be wasted.

## Program Requirements



The location will comply with all requirements for COVID-19 vaccine management and reporting including the following:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert, Fact Sheet for Healthcare Providers Administering the Vaccine, and guidance in CDC's [Vaccine Storage and Handling Toolkit and COVID-19 Addendum](#).
- Monitor and record vaccine storage unit temperatures twice daily following guidance in CDC's Vaccine Storage and Handling Toolkit and COVID-19 Addendum. (Provider Agreement #8a and b)

## Temperature Logs

Record data logger's current, MIN, and MAX readings twice daily on the [COVID-19 Temperature Log](#) or write in the "BAP" funding source on the [Universal Temperature Log](#). Post logs on refrigerators, freezers, and ULT freezers to prevent recording errors.

## Keys to Success

- Ensure staff are trained to record storage unit temperatures properly and [report temperature excursions](#) immediately.
- Ensure staff are trained to operate your data loggers and download any temperature data file in the event of an excursion; refer to your device's product guide.
- Some devices must be cleared (MIN/MAX and alarm symbol) after each recording to ensure staff don't record previous readings again; 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.



# Reporting Temperature Excursions

Vaccine Coordinators may report excursions in myCAvax. If temperatures drift out of recommended ranges, immediately label vaccines DO NOT USE and contact the manufacturer to determine if vaccines are okay to administer.

## Program Requirements



The location will comply with all requirements for COVID-19 vaccine management and reporting including the following:

- Respond to and report temperature excursions following CDPH guidance; (Provider Agreement #8c)
- Preserve all records related to COVID-19 vaccine management (e.g., vaccine temperature logs, invoices, and packing slips) for a minimum of 3 years. (P.A. #8e)

## What's a Temperature Excursion?

Any temperature outside manufacturer-recommended ranges is considered a temperature excursion and may spoil vaccines.



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 or over weekend.

## What's a Temperature Data File?

Your device may have a temperature data file that must be downloaded to get the data that manufacturers will need to determine whether vaccines may be administered. The manufacturer's determination is only as accurate as the data you provide.

9-12-24

### Sample Data File

	Limit	First Event	Events	Time	Pass/Fail
High	8.1°C	1/16/2018 2:34 PM	5	25 Mins	<b>FAIL</b>
Low	1.9°C	None	0		PASS

## Reporting Temperature Excursions (Cont.)

Vaccine Coordinators may report excursions in myCAvax. If temperatures drift out of recommended ranges, immediately label vaccines DO NOT USE and contact the manufacturer to determine if vaccines are okay to administer.

### Vaccine Stability Determination

Contact the vaccine manufacturer to determine if vaccines stored in storage units may be used after exposure to out-of-range temperatures.

Manufacturer	Contacts
Moderna	866-MOD-ERNA or 1-866-663-3762 excursions@modernatx.com <a href="#">Online</a>
Novavax	844-NOVAVAX 8:00AM-8:00PM ET <a href="#">Online</a>
Pfizer-BioNTech	(800) 438-1985 <a href="#">Online</a>



# How to Report Temperature Excursions

Vaccine Coordinators may report excursions in myCAvax. If an alarm goes off, take action immediately to determine if vaccines may be used then report the temperature excursion.



1

## Instructions

Clear MIN/MAX and any alarm symbol to ensure staff don't respond to previous alerts during the next recording.



2

Label exposed vaccines DO NOT USE and alert your Vaccine Coordinator or supervisor that vaccines may have been damaged.



3

Download your data logger's temperature data file and save to the folder created for your device. Save data files for 3 years.

4

Look for excursion details in the data file. Refer to device's product guide or video to learn how to identify temperatures outside the HI/LO alarm limits.



5

Report all temperature excursions in myCAvax.

- Note the Batch Excursion Number assigned by myCAvax.
- Contact vaccine manufacturers if directed and provide the excursions details.
- Record myCAvax Excursion # under Incident IDs on your temp log.

6

Do not administer vaccines without the manufacturer's determination. If vaccines are not okay to use, [report and return nonviable doses](#).

7

Make sure your data logger is recording storage unit temperatures.

## Managing Expiration & Beyond-Use Dates

Managing your vaccine inventory to ensure that vials soon to expire are used first helps to minimize vaccine wastage; removing expired vaccine immediately prevents inadvertent administration errors than may require patient revaccination.

### Program Requirements



The location will comply with all requirements for COVID-19 vaccine management and reporting including the following:

- Monitor and comply with COVID-19 vaccine expiration and beyond-use dates; never administer expired vaccine. (Provider Agreement #8d)



## Expiration Dates

**Never administer expired vaccine.** Expiration dates may be extended as more data come in. To determine expiration dates:

- Moderna: Contact Moderna at 866-663-3762
- Novavax: Online [expiry checker](#)
- Pfizer-BioNTech: Online [expiry checker](#)


## Beyond-Use (Use-By) Dates

Vaccines may have a shortened beyond-use date (BUD), which replaces the expiration date. **Always discard vaccine after the earlier of the expiration or beyond-use date.**

*Before First Puncture:* Manufacturer-shortened expiration dates may apply if storing unpunctured vials under conditions other than coldest recommended temperatures. Apply [CDC's vaccine-specific BUD tracking labels](#) so vaccines aren't used past these reduced limits.

*After Puncture:* Multidose vials have a use-by date limit after puncture. Label vial with puncture date/time so vaccine is not used after this time limit.

See [COVID-19 Vaccine Product Guide](#) for storage limits before and after puncture.

FORMULATION: 5 Through 11 Years of Age <b>Pfizer-BioNTech COVID-19 Vaccine</b>	
Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.	
Lot number(s):	<u>123456A</u>
Today's date:	<u>06 / 01 / 2021</u> Time: <u>2:30 PM</u>
<b>USE BY*</b>	
Date:	<u>08 / 10 / 2021</u> Time: <u>2:30 PM</u>
*As the 10 week deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.	
Name:	<u>Amy Nurse RN</u>
	

# How to Manage Expiration Dates

Follow these instructions to manage expiration and beyond-use dates.

## Instructions

1

Rotate vaccines weekly and whenever a new shipment arrives to ensure vaccines soon to expire are used first.

2

As expiration dates draw near, check for extensions using [Novavax](#) & [Pfizer-BioNTech](#) expiry tools and contact Moderna at 866-663-3762; label product with updated expiration dates to prevent errors.

3

If unable to use vaccines before expiration, contact your local health department about vaccine transfer.

4

Do not administer expired vaccine. Strictly comply with vaccine manufacturer guidance on expiration and beyond-use (use-by) date/time limits.

5

IMMEDIATELY remove vaccine after the earlier of the expiration or use-by date to prevent inadvertent administration errors.

6

[Report expired vaccine](#) in myCAvax then return vaccine to McKesson.



# About Wastage & Missed Vaccination Opportunities



## Never miss a vaccination opportunity because of fear of vaccine wastage!

Do your best to follow clinical and inventory management best practices to maximize vaccinations and minimize dose wastage where possible.

### Key Points

Multi-dose vials are a challenge for providers, and CDC is aware that the limitations of available presentations may result in more waste. Moderna and Pfizer-BioNTech 12Y+ vaccines are available as single-dose vials; Novavax is working to supply single-dose vials, but they may not be here by fall 2023.

### Never Miss a Vaccination Opportunity

Vaccinate every eligible person who presents at a vaccination site—even if it means puncturing a multi-dose vial at the end of the day—to [increase vaccination coverage by up to 20%](#).

#### Punctured vials must be used within:

##### 12 hours

- Moderna Bivalent 6Y+
- All Pfizer-BioNTech vaccines
- Novavax

### Tips to Reduce Wastage

- Coordinate the number of vials needed with the anticipated number of patients when preparing for daily clinics to reduce over-thawing of vaccine.
- Follow guidance in [CDC Toolkit](#) to reduce waste in vaccine storage, transport, handling, and administration.



## Reporting & Handling of Nonviable Doses

Vaccine Coordinators must report nonviable doses in myCAVax. Remove spoiled, expired, or wasted vaccines from storage unit immediately to prevent administration errors. Return all spoiled and expired vaccines to McKesson. Dispose of wasted vaccines following practice protocols.

### Program Requirements



The location will comply with all requirements for COVID-19 vaccine management and reporting including the following:

- Report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted following CDPH guidance. (Provider Agreement #8f)
- Return all nonviable vaccine to McKesson following CDPH guidance. (P.A. #8g)

### What to Do with Nonviable COVID-19 Vaccines

Report spoiled, expired, or wasted vaccine in myCAVax. Providers may return spoiled and expired vaccines to McKesson; dispose of wasted vaccine (and vials that have been opened or punctured) following practice protocols. See definitions of each on the next page.

**Wasted vaccines:** Dispose of all products following practice protocols (may be disposed of in pharmaceutical waste containers or comingled pharmaceutical/Sharps containers).

**Updated 2023-24 COVID-19 vaccines:** Return all spoiled/expired vaccines to McKesson; a return shipping label will be sent to attach to the shipping container. Clearly label the outside of the shipping container "Non-viable Vaccine enclosed" and return to this address:

MCKESSON SPECIALTY CAR VACCINE: VFC -OBV  
 8745 FOREST HILL IRENE  
 SUITE 105  
 OLIVE BRANCH, MS 38654

**For deauthorized COVID-19 vaccine products:** Report as "Waste" (use "Other" to add comment "deauthorized") before disposal.

## Reporting & Handling of Nonviable Doses (Cont.)

Vaccine Coordinators must report nonviable doses in myCAvax. Remove spoiled, expired, or wasted vaccines from storage unit immediately to prevent administration errors. Return all spoiled and expired vaccines to McKesson. Dispose of wasted vaccines following practice protocols.

### Spoiled Vaccine

Report doses as spoiled if manufacturers determine vaccines were exposed to out-of-range temperatures and may not be used. Vaccines could spoil as a result of these conditions:

- data logger indicates that storage unit temperatures are out of the recommended range
- storage unit temperatures were not monitored as required
- Vaccines were not stored properly upon receipt
- vaccines spoiled during transfer
- natural disaster, power outage, or mechanical failure



Consistent and accurate temperature monitoring minimizes spoilage.

### Expired Vaccine

Report doses expired if past the earlier of the expiration or beyond-use (use-by) date as identified in product EUA fact sheet.



Careful and consistent vaccine management minimizes expired vaccines.

### Wasted Vaccine

Report doses as wasted and dispose of as a result of these conditions:

- vaccine was deauthorized by FDA
- punctured multi-dose vials are past the use-by date/time limits
- unable to draw the maximum doses printed on the vial label because low dead-volume needles/syringes were not available; any remaining unused doses will be identified as waste (never pool vaccine from multiple vials to make a single dose)
- vaccines were drawn into the syringe but not administered
- vials are damaged (e.g., due to a drop causing damage to vial integrity or sterility)
- vaccines are lost or unaccounted, unable to draw a dose in vial (see below)

## Transporting Vaccine

Do not ship vaccines. Vaccines should not be routinely transported. If necessary, transport vaccines following guidelines in CDC's Vaccine Storage & Handling Toolkit using appropriate packing materials that provide the maximum protection. Refer to CDC's [emergency transport guidance](#) as needed.

### Program Requirements



The location will comply with all requirements for COVID-19 vaccine management and reporting including the following:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert, Fact Sheet for Healthcare Providers Administering the Vaccine, and guidance in CDC's [Vaccine Storage and Handling Toolkit and COVID-19 Addendum](#). (Provider Agreement #8a)
- Monitor and record vaccine storage unit temperatures twice daily following guidance in CDC's [Vaccine Storage and Handling Toolkit and COVID-19 Addendum](#). (P.A. #8b)
- Respond to and report temperature excursions following CDPH guidance. (P.A. #8c)
- Preserve all records related to COVID-19 vaccine management (e.g., vaccine temperature logs, invoices, and packing slips) for a minimum of 3 years. (P.A. #8e)

### Key Points

- Designate any trusted individual with a general understanding of vaccine storage and handling and transport protocols; designee need not be a licensed healthcare provider.
- Total transport time alone, or transport plus clinic workday, should not exceed 8 hours, or manufacturer's guidance if it is different.
- Transport equal amounts of vaccines, diluents, and ancillary supplies.
- Transporting punctured vials is not recommended; if necessary, transport time counts towards use-by limits; follow [U.S. Pharmacopeia COVID-19 Vaccine Toolkit](#) for guidance; do not transport punctured vials from one provider to another, or across state lines.
- Monitor temperatures using a data logger and report temperature excursions in transit.

## Transporting Vaccine (Cont.)

Do not ship vaccines. Vaccines should not be routinely transported. If necessary, transport vaccines following guidelines in CDC's Vaccine Storage & Handling Toolkit using appropriate packing materials that provide the maximum protection. Refer to CDC's [emergency transport guidance](#) as needed.

### Transport Equipment

Vaccines may be transported using a portable vaccine refrigerator and a data logger (or qualified containers and pack out). CDC does not recommend transporting ultra-frozen vaccine; if necessary, use a portable ULT freezer that can maintain a temperature of -80° C.



General Transport System Recommendations	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator, Freezer, or Ultra-cold Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
<a href="#">Conditioned Water Bottle Transport System</a>	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No*
Food/Beverage Coolers	No	No

\*The original shipping container for ultra-cold COVID-19 vaccine can be used for transport.

### Qualified Container & Pack-out

These products are specifically designed for use when packing vaccines for transport. For example, PCM (see below) refrigerated or frozen vaccine transport container. Soft-sided containers specifically engineered for vaccine transport are acceptable.

**IMPORTANT:** Hard-sided insulated container or Styrofoam™ may only be used in emergencies and in conjunction with the [Packing Vaccines for Transport during Emergencies](#) tool.

### Coolants for Transport

Phase change materials (PCMs) at 4°C to 5°C (39°F to 41°F) may be used to maintain proper temperatures. Follow manufacturer's instructions to reduce risk of out-of-range temperatures during transport. Do not use frozen gel packs or coolant packs from original shipments.

### Digital Data Loggers

Vaccine transport containers must be monitored using a data logger that meets specifications in CDC's [Vaccine Storage & Handling Toolkit](#) and has a current and valid Certificate of Calibration Testing. For ultra-low-temperature transport, use a device with an air-probe or a probe designed specifically for ultra-cold temperatures.

## Transporting Vaccine (Cont.)

Do not ship vaccines. Vaccines should not be routinely transported. If necessary, transport vaccines following guidelines in CDC's Vaccine Storage & Handling Toolkit using appropriate packing materials that provide the maximum protection. Refer to CDC's [emergency transport guidance](#) as needed.

### Beyond-Use/Expiration Dates by Transport Option

Vaccine Product	Transport Method	Destination Storage Unit	Storage & Handling Details for Unpunctured Vials
Moderna products	Frozen -50° to -15°C *	Freezer -50° to -15°C *	Frozen transport is preferred; store vaccine <b>till expiration</b> . To find expiration date, scan QR code on vial or carton, or look up expiration dates <a href="#">online</a> .
	Refrigerated (2°C–8°C)	Refrigerator (2°C–8°C)	May transport more than once for up to <b>12 hours total</b> ; label vaccines with BUD of up to <b>30 days</b> from date first transferred to refrigerated temperatures
Novavax	Refrigerated (2°C–8°C)	Refrigerator (2°C–8°C)	Store <b>till expiration</b> . To find expiration date, check <a href="#">online</a> .
Pfizer products	Refrigerated (2°C–8°C)	Refrigerator (2°C–8°C)	Store up to <b>10 weeks</b> . Vaccine may be transported more than once.
	ULT transporter ** -90°C and -60°C	ULT freezer -90°C and -60°C	Store <b>till expiration</b> ; should not be used after 12 months from date of manufacture printed on vials and cartons.

# How to Transport Vaccine

Refer to CDC's [Vaccine Storage & Handling Toolkit](#) for detailed guidance. Ideally, limit total transport and clinic time combined to a maximum of 8 hours or follow manufacturer guidance if it differs.

## Instructions

1

Determine how many vaccine vials will be transported.

2

Prepare to transport before removing vaccines from storage units.

- Complete as much of the [Vaccine Transport Log](#) as you can.
- Set up the data logger using the vendor user guide or video.

3

Remove vaccines from storage unit and pack for transport.

- Remove vials quickly but carefully.
- Complete the transport log including temperatures prior to transport. (Vaccine may have QR code to identify lot numbers and expiration dates.)
- Consider the [Vaccine Transport Time Tracker](#) if vaccines will be stored for off-site clinics.
- Ensure the data logger is set up and recording temperatures.
- Insert transport log into transport container before sealing.
- Drive (don't ship) vaccines to the destination location.

4

Transport equal amounts of vaccines, diluents, and ancillary supplies (e.g., record cards and PPE).

5

Upon arrival, store vaccines properly according to manufacturer recommendations.

- Confirm that vaccines were not exposed to out-of-range temperatures; [report any temperature excursions](#) immediately.
- Record temperatures upon arrival on your transport log.

# Transferring Vaccines

Transferring vaccines is not a routine event but a response to an emergency or other unplanned event (e.g., excess supply or imminent expiration of doses). Prior approval is not required. The receiving location takes ownership of transferred vaccines and must be an enrolled and approved COVID-19 vaccination provider.

## Key Points



- Sender assumes full responsibility for ensuring receiving provider location is covered by a Provider Participation Agreement and adheres to its requirements
- Coordinate with the receiving location to ensure they can store and use vaccine doses
- Sender must ensure validated cold-chain procedures are in place in accordance with the manufacturer's instructions and guidance in CDC's [Vaccine Storage & Handling Toolkit](#)
- Sender Vaccine Coordinator must report transfer events in myCAvax within 24 hours of vaccine delivery; report must indicate if vaccines were exposed to a temperature excursion in transit
- Only transfer vaccines once
- Do not transfer punctured multi-dose vials to another provider or across state lines
- Keep all documents for three years
- See [Guide to COVID-19 Vaccine Redistribution, Repositioning & Transfer](#) for transfer scenarios

# How to Transfer Vaccine

Follow these instructions to transfer vaccine to affiliated COVID-19 locations.

## Instructions

1

Contact your local health department's Immunization Coordinator to confirm receiving location(s) is an enrolled and approved CA BAP Provider. (First time only.)

2

Determine how many vaccine vials will be transferred.

3

Contact receiving location to confirm they can store and use the doses before expiration. Notify receiver they must accept the transfer in myCAvax.

4

Record beyond-use or expiration dates on [Vaccine Transport Log](#) so receiving location will know when doses must be properly disposed.

5

Follow transport protocols in your Vaccine Management Plan and [Transporting Vaccines](#).

6

Receiving location must properly store vaccine upon delivery.

- Apply beyond-use tracking labels (see [CDC Resources](#)) if applicable (see [BUD by Transport Option](#)) using dates provided on the transport log.
- [Report shipment incident](#) in myCAvax for any temperature excursion in transit.
- Vaccine Coordinator must report receipt of transferred vaccine in myCAvax (look for an email notification once sender reports the transfer event).

7

Sender contacts the receiving location to ensure doses were stored properly and that temperature excursions (if any) were reported.

- Sender Vaccine Coordinator must report the transfer event in myCAvax within 24 hours of the delivery.





## 5. Patient Visit



Proper administration protocols ensure recipients are well informed prior to administration and vaccines are administered to minimize administration errors.

### Audience

Vaccine Coordinators

Vaccinators



[Patient Visit Checklist](#)

[Eligibility Screening & Documentation](#)

[How to Screen & Document Eligibility](#)

[Vaccine Preparation](#)

[Vaccine Administration](#)

[Responding to Administration Errors](#)

[Billing & Reimbursement](#)



# Patient Visit Checklist

**Vaccinate every eligible adult!** Incorporate these steps into practice protocols to ensure recipients are informed of products administered and leave with proof of vaccination and next appointments scheduled.

## Patient Care

- Screen recipients (see [My Turn checklist](#)) for contraindications and precautions before administration.
- [Screen and document eligibility](#) for BAP-supplied vaccines: recipient is uninsured or underinsured and 19 years of age or older.
- Strongly recommend COVID-19 and other routine vaccines to address gaps in immunizations.
- If patient is anxious, try using these [tips to ease anxiety during vaccination](#).



## Administration

- [COVID-19 vaccines may be coadministered](#) for children, adolescents, and adults.
- Prepare and administer vaccines ([see checklist](#)) per [EUA Fact Sheets](#).
- Distribute [EUA Fact Sheet for Recipients](#) or [current COVID-19 VIS](#) (paper or electronic) **BEFORE** administration.
- Carefully read vial labels. DO NOT RELY ON CAP COLOR.
- Observe recipient for 15 minutes (30 minutes for history of allergic reactions or contraindications; monitor and [respond to potential anaphylaxis](#)).
- Report any moderate to severe adverse events to [VAERS](#).
- Distribute completed (or updated) vaccination record cards per practice protocols.
- Recommend California's [Digital Vaccination Record](#).
- Report administration data daily using My Turn or EHR/EMR connected to CAIR2/RIDE; request recipient mobile number and email required for digital vaccination record.
- [Report nonviable vaccine](#) and return to McKesson as with other routine vaccines.
- Do not bill patients for the cost of the vaccine nor charge an administration fee.

## Eligibility Screening & Documentation



Eligibility screening must be conducted prior to administration to ensure doses only go to eligible adults. Ensure protocols are in place so vaccinators know when to use 317-funded vaccines (e.g., Vaccines for Adults or CA BAP) versus private vaccines.

### Program Requirements



- COVID-19 vaccines will be administered to any individual aged 19 years and older who is uninsured or underinsured. Insured patients, including patients covered by Medicare and Medi-Cal, are NOT eligible for COVID-19 vaccines provided through the Bridge Access Program (hereafter referred to as BAP). Staff will consult the BAP [Eligibility Based on Insurance Status](#) table as needed to determine specific vaccine eligibility for patients. Eligibility screening will be conducted prior to the administration of vaccine doses. Verification of eligibility may be obtained verbally from the individual. All staff, including front office and billing staff, will be knowledgeable of BAP eligibility. (Provider Agreement #1)
- Within 24 hours of administering a dose of COVID-19 vaccine to a BAP-eligible patient, administration data will be recorded in the recipient's permanent medical record and submitted to the State's Immunization information System (CAIR2 or Healthy Futures/RIDE) no later than 72 hours; providers must ensure that the proper vaccine eligibility category "317" is documented in CAIR. (P.A. #5)
- The patient's recorded BAP 317 eligibility status and all records related to the Bridge Access Program will be retained for three (3) years. If requested, patient records will be made available to CDPH. Records include, but are not limited to, vaccine administration documentation, billing records, and medical records that verify receipt of vaccine. Release of such records will be bound by federal and state privacy laws. (P.A. #6)

### Key Points

- COVID-19 vaccines must be administered to any adults 19 years and older who are uninsured or underinsured\*.
- Insured patients, including patients covered by Medicare and Medi-Cal, are NOT eligible for COVID-19 vaccines provided through the California Bridge Access Program.
- Verification of eligibility may be obtained verbally from the individual.
- Administration data (including eligibility category 317) must be documented in CAIR.

\* For CA BAP only: CDC defines as "a person who has health insurance, but the insurance does not include any vaccines; a person whose insurance covers only selected vaccines; a person whose insurance does not provide first-dollar coverage for vaccines".



## Eligibility Screening & Documentation (Cont.)

Eligibility screening must be conducted prior to administration to ensure doses only go to eligible adults. Ensure protocols are in place so vaccinators know when to use 317-funded vaccines (e.g., Vaccines for Adults or CA BAP) versus private vaccines.

### What Staff Need to Know

All staff, including front office and billing staff, must be knowledgeable of CA BAP eligibility.

#### Front Office Staff

Ensure staff are familiar with the CA BAP [Eligibility Based on Insurance Status](#) as a quick reference guide. It clearly identifies who is eligible and who is not.

#### Billing Staff

Ensure staff know that patients immunized with BAP-supplied vaccines must not be billed for the cost of the vaccine nor be charged an administration fee.

Systems and practice protocols must be in place to ensure patients are not charged and vaccine cost will not be billed.

### Eligibility Based on Insurance Status

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#### Bridge Access Program

A limited supply of COVID-19 vaccine will be made available through the Bridge Access Program for uninsured and underinsured adults (19 years and older) to prevent loss of access when vaccines transition to the commercial market. Insured patients—including patients covered by Medicare and Medi-Cal—are **NOT** eligible for the COVID-19 vaccines provided through this program. This temporary program will sunset at the end of 2024.

**✓ Eligible for COVID-19 Vaccine through BAP (317 Funds)**

Patient health insurance status:

- Uninsured/No Insurance** (includes those who receive primary care through county safety net programs; these are NOT considered health insurance)
- Underinsured** (has health insurance, but the insurance does not include any vaccines; insurance covers only selected vaccines; insurance does not provide first-dollar coverage for vaccines.)
- Insurance NOT through Medi-Cal or Medicare** (only eligible for COVID-19 vaccines if **NOT** covered by patient's private insurance plan)<sup>1</sup>

**✗ Not Eligible for COVID-19 Vaccine through BAP (317 Funds)**

Patient health insurance status:

- Medi-Cal Fee-For-Service/Medi-Cal Managed Care** ([bit.ly/CAhealthplans](http://bit.ly/CAhealthplans))
- Medicare Part B (medical benefit) AND Part D (prescription drug benefit)**
- Medicare Part B Alone**
- Medicare Part D Alone**
- Insurance NOT through Medi-Cal or Medicare**<sup>1</sup>

1. Fully insured adults whose insurance covers the cost of the vaccine(s) are NOT eligible for COVID-19 vaccine—even if the insurance includes a high deductible or co-pay, the plan's deductible has not been met, or the insurance has cost sharing.



# How to Screen & Document Eligibility

Follow [these instructions](#) to screen and document CA BAP eligibility.

## Instructions

1

Screen prior to administration of any 317-funded vaccine (e.g., Vaccines for Adults and Bridge Access Program). Eligibility is self-reported, and verification of eligibility may be obtained verbally.

2

Document patient's eligibility, including screening date, whether eligible for VFA and/or BAP, and which criterion is met.

3

Use a compliant recordkeeping system to record your findings and maintain 317 eligibility records for three years. Use either

- CAIR and your EHR/EMR, or
- CAIR and the [317 Eligibility Screening Record for Adult Patients](#) (see below).

4

Communicate to the patient their eligibility.

### 317 (VFA & BAP) Eligibility Screening Record for Adult Patients

**At each immunization visit, determine if patients are eligible for COVID-19 vaccines (if participating in the Bridge Access Program) and/or other routinely recommended vaccines through 317 funds (e.g., VFA).**

**Patient Information**

Patient Name (Last, First, MI): \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Provider Name: \_\_\_\_\_

**Eligibility Criteria for 317-Funded Vaccines (e.g., VFA and BAP)**

✓ **Eligible for VFA and/or BAP (COVID) vaccines if at least 19 years of age and**

- Has no insurance, or
- Is underinsured (public or private health insurance does not cover all vaccines or covers vaccines with a fixed dollar limit which has been reached)

✓ **Eligible for certain VFA vaccines if at least 19 years of age and**

- Has Medicare **Part B**, but **NOT Part D**, patient is eligible for:
  - Hep A
  - Hep B (if considered low risk for Hep B)
  - HPV, MMR, Varicella, and Zoster
  - Td (if no wound exposure) and Tdap
- Has Medicare **Part D**, but **NOT Part B**, patient is eligible for:
  - Hep B, PCV20

**Document Patient's Eligibility**

**Write the screening date and check appropriate status.** (Note: verification of responses is not required. Keep this record for at least 3 years and make it available to state or federal officials upon request).

Screening Date	✓ Eligible for VFA and BAP (COVID) (No insurance)	✓ Eligible for VFA and BAP (COVID) (Underinsured)	✓ Eligible for some VFA vaccines (Medicare Part B or Part D only)	✗ Not Eligible for BAP (COVID) (Medicare Part B or Part D only)	✗ Not Eligible for VFA or BAP (COVID) (Both Medicare Part B & D or insurance pays for vaccines*)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Part B <input type="checkbox"/> Part D	<input type="checkbox"/> Part B <input type="checkbox"/> Part D	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Part B <input type="checkbox"/> Part D	<input type="checkbox"/> Part B <input type="checkbox"/> Part D	<input type="checkbox"/>
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\* Note: adults enrolled in Medi-Cal or Medi-Cal Managed Care are considered insured.  
 California Department of Public Health, Immunization Branch IMM-1226 (8/28/23)



# Vaccine Preparation

Proper preparation and administration help to ensure patients receive sufficient protection after vaccination and minimize revaccination efforts due to administration errors.

## Key Points

Follow [Vaccine Administration Checklist](#) to minimize administration errors and revaccination.

- Prepare dose immediately before administration if practical to minimize vaccine wastage and exposure to out-of-range temperatures.
- Read labels carefully. Vaccine vials may have similar cap colors.
- Check expiration dates of vaccines (and diluents, if applicable) before preparation; never administer vaccine past the earliest of the expiration or use-by date.
- Prepare vaccines in a clean, designated medication area away from any potentially contaminated items.
- If [coadministering with routine vaccines](#), consider establishing separate stations for mixing or drawing vaccine into syringes to avoid medication errors.
- Predrawn syringes should be labeled with name of vaccine, dosage (amount), exact beyond-use date/time, lot number, and initials of preparer.
- Prepare vaccines (e.g., thawing, mixing, drawing) according to manufacturer requirements and CDC guidance. (Refer to product package insert or [EUA Fact Sheets](#).)
- Double check vial to determine if vaccine needs to be reconstituted and confirm diluent amount. (See [COVID-19 Vaccine Product Guide](#) for a summary chart.)
- Always label punctured vials and syringes with the name of the vaccine and expiration or beyond-use date/time and discard once the beyond-use date/time has been reached.
- [Report and return](#) expired or residual vaccine in a multidose vial (dispose of diluent vial if applicable according to practice protocols) when there's not enough for a full dose. Never combine partial doses to make a full dose.

# Vaccine Administration



Vaccine must be administered in accordance with product-specific requirements and clinical guidance from CDC and the respective manufacturer.

## Program Requirements



- COVID-19 vaccines will be administered in compliance with the most recent immunization schedule, dosage, and contraindications established by the Advisory Committee on Immunization Practices (ACIP) and in compliance with all applicable requirements as set forth by the U.S. Food and Drug Administration (FDA), including but not limited to requirements in any Emergency Use Authorization (EUA) fact sheet that covers COVID-19 vaccine (Provider Agreement #2)
- Before administering COVID-19 vaccine, an approved EUA fact sheet or vaccine information statement (VIS) will be provided as required to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Vaccine administration records will be maintained in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) <https://vaers.hhs.gov/>. (P.A. #4)
- Within 24 hours of administering a dose of COVID-19 vaccine to a BAP-eligible patient, administration data will be recorded in the recipient's permanent medical record and submitted to the State's Immunization information System (CAIR2 or Healthy Futures/RIDE) no later than 72 hours; providers must ensure that the proper vaccine eligibility category "317" is documented in CAIR. (P.A. #5)

## Key Points

Follow [Vaccine Administration Checklist](#) to minimize administration errors and revaccination.

- Always check labels, dosage, and expiration or beyond-use dates (as noted in the EUA) before administering vaccine (see [COVID-19 Vaccine Product Guide](#) for summary chart).
- Always use proper hand hygiene between vaccine recipients.
- Use age, weight, gender, and location are used to determine needle selection. (See CDC [Needle Gauge and Length](#).)
- Verify vaccine recipient information (i.e., name and date of birth) so vaccine is administered to the correct recipient.

## Vaccine Administration (Cont.)

Vaccine must be administered in accordance with product-specific requirements and clinical guidance from CDC and the respective manufacturer. Refer to the [Vaccine Administration Checklist](#).

### Key Points (Cont.)

- ❑ Distribute [EUA Fact Sheet for Recipients](#) or [current COVID-19 VIS](#) (paper or electronic) **BEFORE** administration.
- Use [these tips](#) to help ease anxiety during vaccination.
- [Report and return](#) expired or residual vaccine in a multidose vial (or diluent vial if applicable) when there's not enough for a full dose. Never combine partial doses to make a full dose.
- Inform recipients of any administration errors and respond following [this guidance](#).



### Regarding Adverse Events

Providers should observe COVID-19 vaccine recipients following vaccination for a **minimum of 15 minutes** or **30 minutes** if the recipient has a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy or a history of anaphylaxis due to any cause.

CDC encourages all providers to keep the necessary supplies to treat anaphylaxis immediately available.

COVID-19 vaccination providers are required to report moderate and severe adverse events to [VAERS](#).







## Responding to Administration Errors

A vaccine administration error is any preventable event that may cause or lead to inappropriate medication use or patient harm. Administration errors can have many consequences, including inadequate immunological protection, possible injury to the patient, cost, inconvenience, and reduced confidence in the health care delivery system.

### Common Causes

**Training:** Insufficient staff training; changes in recommendations and eligible populations

**Protocols:** Lack of standardized protocols, nonstandard or error-prone abbreviations

**Performance:** Distraction, patient misidentification

**Packaging:** Easily misidentified products (common cap colors or label borders)

### Key Points

- Use the [Vaccine Administration Checklist](#) to train staff on proper protocols for COVID-19 vaccination.
- Ensure check-in staff and vaccinators are properly trained on ACIP's [Recommended Adult Immunization Schedule](#).
- Ensure vaccinators are properly [trained on any COVID-19 vaccine products](#) your location will administer—paying extra attention to dilution of Pfizer vaccines.
- [Organize storage units](#) and separate products with similar packaging or labels.
- If more than one vaccine is being administered, consider separating recipients by vaccine type in clearly designated waiting lines/areas, with separate administration stations for each vaccine type, to prevent medication errors.



## Responding to Administration Errors (Cont.)

A vaccine administration error is any preventable event that may cause or lead to inappropriate medication use or patient harm. Administration errors can have many consequences, including inadequate immunological protection, possible injury to the patient, cost, inconvenience, and reduced confidence in the health care delivery system.

### In the Event of Errors

Step	Action
1.	Inform the recipient of the vaccine administration error.
2.	Refer to <a href="#">CDC's Vaccine Administration Errors &amp; Deviations appendix</a> to determine whether revaccination may be recommended. Contact the manufacturer for any questions. <ul style="list-style-type: none"> <li>• Moderna: 1-866-MODERNA (1-866-663-3762)</li> <li>• Novavax: 844-NOVAVAX</li> <li>• Pfizer-BioNTech: 800-438-1985</li> </ul>
3.	Contact your <a href="#">local CAIR2/RIDE representative</a> to determine how the dose should be entered into the CAIR, both as an administered dose and to account for inventory.
4.	Report all COVID-19 vaccine administration errors <a href="#">to VAERS</a> —even those not associated with an adverse event. ( <a href="#">Reporting to VERP</a> is strongly encouraged to help prevent future errors or patient harm.)
5.	Determine how the error occurred and implement strategies (e.g., education/training) to prevent it from happening again.

## Billing & Reimbursement



Patients immunized with BAP-supplied vaccines must not be billed for the cost of the vaccine nor be charged an administration fee. Ensure billing staff are properly trained and systems and protocols are updated so patients are not charged, and vaccine cost is not billed.

### Program Requirements



- Patients immunized with BAP-supplied vaccines will not be billed for the cost of the vaccine nor be charged an administration fee. All systems will be checked to ensure patients are not charged and vaccine cost will not be billed. (Provider Agreement #3)



## 6. Infrequent Tasks



This section includes guidance for infrequent tasks.

### Audience

Vaccine Coordinators



[Introducing New Vaccines in Your Practice](#)

[Changing Staff or Contacts](#)

[Setting Up a New Storage Unit & Data Logger](#)



## Introducing New Vaccines in Your Practice

When new vaccines are introduced into your practice’s supply, ensure staff are properly trained on what’s new and reinforce storage and handling basics staff already know. Follow this guidance to introduce a new vaccine into your practice.

### Review Clinical and Safety Data

Clinicians should review package inserts or [EUA Fact Sheets](#) for any new Moderna, Novavax, and Pfizer-BioNTech vaccines and prepare vaccinators to administer new products.

### Complete Required Vaccine Product Training

Ensure staff who store, handle, administer or manage COVID-19 vaccines complete the [required product training](#) (or study the manufacturer’s EUA Fact Sheets) for each new vaccine as related to their role. (Refer them to the [COVID-19 Vaccine Product Guide](#) for summary chart of storage, handling, and administration details by product.)

Pfizer-BioNTech Vaccines	Location Coordinator	Vaccinator	Provider
<ul style="list-style-type: none"> <li>• Pfizer-BioNTech at a Glance (PDF)</li> <li>• Mixing Diluent &amp; Vaccine (PDF)</li> </ul>	✓	✓	✓

Moderna Vaccines	Location Coordinator	Vaccinator	Provider
<ul style="list-style-type: none"> <li>• Moderna at a Glance (PDF) &amp; video</li> </ul>	✓	✓	✓

Novavax Vaccine	Location Coordinator	Vaccinator	Provider
<ul style="list-style-type: none"> <li>• Novavax at a Glance (PDF)</li> </ul>	✓	✓	✓

### Review Immunization Schedule

COVID-19 vaccines are now considered routine vaccines. Train staff to use [ACIP’s Recommended Adult Immunization Schedule](#) or CDPH’s [COVID-19 Vaccine Timing Guide | Spanish](#).



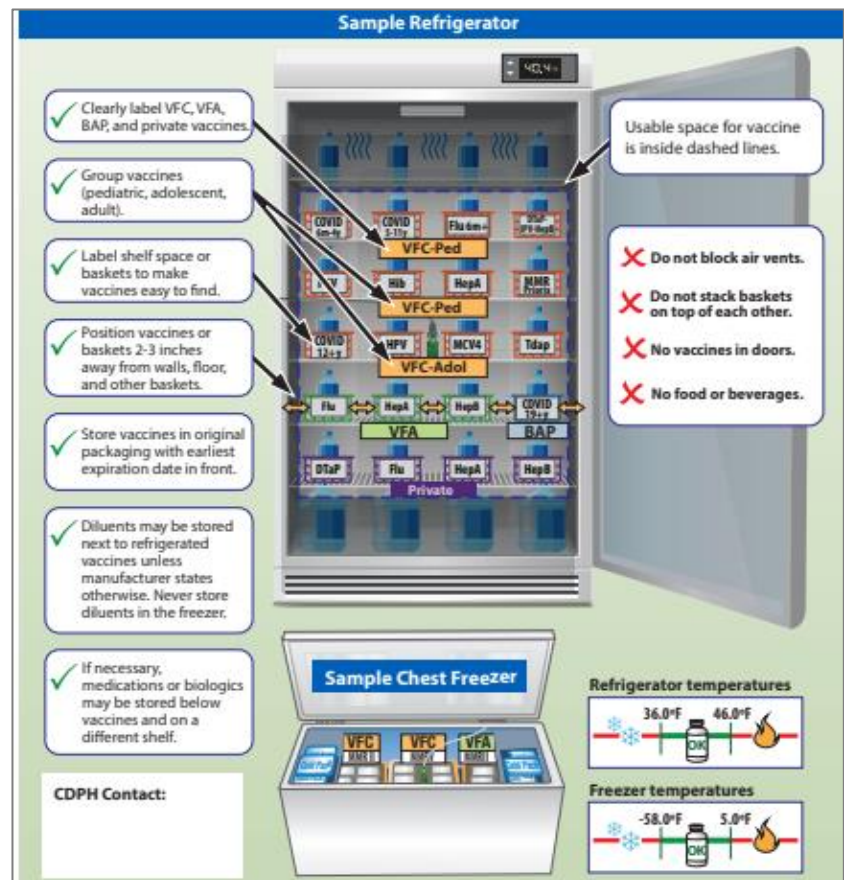
## Introducing New Vaccines in Your Practice (Cont.)

When new vaccines are introduced into your practice's supply, ensure staff are properly trained on what's new and reinforce storage and handling basics staff already know. Follow this guidance to introduce a new vaccine into your practice.

### Organize Storage Units to Reduce Administration Errors

[Set up storage units](#) to ensure staff can locate the correct vaccine quickly to reduce inadvertent administration of products similar in packaging or close in age indicators.

- Group adult vaccines together.
- Clearly label cartons, baskets, or shelf space in large lettering.
- Store vaccine and diluent together if storage requirements are the same; never freeze diluent.



### Update Systems or Infrastructure

- Update your EHR/EMR for the new vaccine product.
- Update your appointment scheduling systems and bolster capacity for call center and website, as needed, to handle additional volume.



## Changing Staff or Contacts

Introducing new staff into an existing vaccination program and practice protocols requires proper training for a smooth transition. This section identifies resources to help with preparation and training for Vaccine Coordinators, vaccinators, and other vaccine-related roles.

### Training Resources

Role	Training
Organization Vaccine Coordinators	<a href="#">Ensure Coordinators Are Set Up</a>
Vaccine Coordinators	<ul style="list-style-type: none"> <li>• <a href="#">Ensure Vaccine Coordinators Are Trained on Products</a></li> <li>• Review the list of <a href="#">routine and recurring tasks</a> and their frequencies.</li> </ul>
VaccineFinder Reporting Contacts	CA BAP locations no longer need to be displayed on Vaccines.gov.
Scheduling Desk, Check-In Staff, Vaccinators, Clinicians, Medical Support Staff, Administrative Support Staff, Billing, Supervisors	<a href="#">Train Other Staff with Vaccine-Related Responsibilities</a>
Updated training logs with completions	<a href="#">Determine Where You'll Track Training</a>

### Additional Resources

- [Register](#) for Provider Office Hours!
- Bookmark EZIZ's [Bridge Access Program](#) to find additional job aids!
- And the Provider Call Center is here to help: [providercallcenter@cdph.ca.gov](mailto:providercallcenter@cdph.ca.gov), (833) 502-1245 Mon-Fri, 8AM-6PM



## Setting Up a New Storage Unit & Data Logger

This section identifies resources than may assist with selection of storage unit types and subsequent setup. CDC and CDPH do not recommend specific brands or equipment. Providers agree to follow CDC's [Vaccine Storage & Handling Toolkit](#) & COVID-19 Addendum.

### Storage Unit Selection



Use *purpose-built* or *pharmaceutical-grade units* designed for storage of refrigerated or frozen biologics, including vaccines. These units can be compact, under-the-counter style or large. These units often have:

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor)
- Fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from out-of-range temperatures.

If not an option, *commercial* or *household standalone units* are acceptable; as the name implies, these units are designed and marketed for home use.

If necessary, *combination units* may be used—but frozen vaccines must be stored in a standalone freezer.

**Never store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit.**

### Placement

Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment. The unit should be firm and level with the bottom of the unit above the floor. Most units work best when placed in an area with standard room temperatures between 20° C and 25° C (68° F and 77° F).

Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit. If not secured properly, unit doors pose a particular risk to maintaining appropriate internal temperatures for vaccine storage.

Check manufacturer-supplied owner's manual for additional guidance on placement.





## Setting Up a New Storage Unit & Data Logger (Cont.)

This section identifies resources than may assist with selection of storage unit types and subsequent setup. CDC and CDPH do not recommend specific brands or equipment. Providers agree to follow CDC's [Vaccine Storage & Handling Toolkit](#) & COVID-19 Addendum.

### Digital Data Logger



Storage units must be equipped with a digital data logger; devices with a buffered probe provide more accurate readings.

For ultra-cold storage units, device must use an air-probe or a probe designed for ultra-low temperatures.

Keep a backup device on hand for vaccine transports and should primary devices fail.

Devices must have a current and valid Certificates of Calibration Testing.

Refer to CDC's [Vaccine Storage & Handling Toolkit](#) for device specifications and calibration.

### Equipment Setup

New storage units and data loggers must be properly setup and stable temperatures must be recorded for new storage units over several days before storing vaccines.

Refer to [this setup guidance](#) to minimize inaccurate temperature readings that can damage vaccines.



# 7. Appendices



## Audience

Vaccine Coordinators



[Important Contacts](#)



# Important Contacts



Type of Support	Description
Provider Call Center	<p>The Call Center for Providers and Local Health Departments is dedicated to medical providers in California and their COVID-19 response, specifically addressing questions about State program requirements, enrollment, and vaccine distribution, including the Vaccine Marketplace.</p> <ul style="list-style-type: none"><li>• Hours: Mon - Fri from 8AM-5PM</li><li>• Phone: (833) 502-1245</li><li>• For myCAvax Help Desk inquiries: <a href="mailto:myCAvax.HD@cdph.ca.gov">myCAvax.HD@cdph.ca.gov</a></li><li>• For My Turn Clinic Help Desk inquiries: <a href="mailto:MyTurn.Clinic.HD@cdph.ca.gov">MyTurn.Clinic.HD@cdph.ca.gov</a></li><li>• For all other inquiries: <a href="mailto:providercallcenter@cdph.ca.gov">providercallcenter@cdph.ca.gov</a></li></ul>
Archived Communications	Website: EZIZ <a href="#">Archived Communications</a>

