Program Requirements

California COVID-19 Vaccination Program
Thank You

Thank you for your service on the frontlines of this historic pandemic.

Immunization is a critical component of the U.S. strategy to help reduce COVID-19-related illnesses, hospitalizations, and deaths.

Vaccinators and their support staff provide key services necessary to restore full societal functioning.

We couldn’t do this without you.
Welcome

The California Department of Public Health is partnering with CDC and your local health department to distribute vaccines to providers who are vaccinating their communities at unprecedented rates.

This lesson prepares you to successfully implement the California COVID-19 Vaccination Program in your practice.

By the end of this lesson, you’ll be able to

• locate the program requirements,
• map requirements to roles in your practice, and
• bookmark key resources to guide you on the job.
What You’ll Learn

1. Program Overview
2. Program Requirements
3. Key Roles
CDC Provider Agreement

Program Overview

CDC’s Provider Agreement covers all aspects of COVID-19 immunization. Healthcare providers with an active license in California and who possess and administer vaccines are eligible to enroll. The agreement has two parts.

Organization’s point of contact completes this section in myCAvax to enroll the organization in the vaccination program. Section A is DocuSigned by your Chief Medical Officer (or equivalent) and Chief Executive Officer (or chief fiduciary).

Each vaccination location’s point of contact completes this section in myCAvax to enroll locations covered under the organization’s Provider Agreement. Your Medical or Pharmacy Director (or Vaccine Coordinator) DocuSigns this section and is responsible for the location’s adherence to Provider Agreement terms.
COVID-19 Vaccines

COVID-19 vaccines are procured and distributed by the federal government at no cost to approved providers enrolled in the COVID-19 Vaccination Program.

FDA issued an Emergency Use Authorization (EUA) of COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19). Vaccines may be FDA-approved over time. Available products include:

- **Pfizer 12Y+ (Gray Cap)**: Store in refrigerator or ULT freezer only
- **Pfizer 5-11Y (Orange Cap)**: Store in refrigerator or ULT freezer only
- **Pfizer 6M-4Y (Maroon Cap)**: Store in refrigerator or ULT freezer only
- **Moderna 12Y+ (Red Cap)**: Store in refrigerator or freezer
- **Moderna 6-11Y (Dark Blue Cap/Purple Border)**: Store in refrigerator or freezer
- **Moderna 6M-5Y (Dark Blue Cap/Magenta Border)**: Store in refrigerator or freezer
- **Janssen (J&J)**: Store in refrigerator only

**Resources:** Bookmark [COVID-19 Vaccine Product Guide](#) for product details.
Eligibility
Program Overview

As of April 15, 2021, all Californians are eligible for vaccinations. Any current age limits or prioritizations for available COVID-19 vaccine products are determined by current recommendations by ACIP, authorization by CDC, and concurrence by the Western States Scientific Safety Review Workgroup. (See who’s eligible.)

COVID Call Center will email provider sites if eligibility changes for any available vaccine products.

Resources: See Vaccine Administration at a Glance, Eligibility.
California is identifying communities most impacted and directing resources to address COVID-19 health inequities. Latino, Black, and Pacific Islander communities have been disproportionately affected by COVID-19. A healthy California for everyone requires partnership with private sector, local government, and community partners at all levels.

**Death rate for Latino people** is **13% higher** than the rate for all Californians.
- Deaths per 100K people: 255 Latino, 226 all ethnicities

**Case rate for Pacific Islander people** is **82% higher** than the rate for all Californians.
- Cases per 100K people: 43,627 NHOI, 22,457 all ethnicities

**Death rate for Black people** is **19% higher** than the rate for all Californians.
- Deaths per 100K people: 367 Black, 225 all ethnicities

**Case rate for communities with median income <$40K** is **19% higher** than the rate for all Californians.
- Cases per 100K people: 23,980 income <$40K, 23,457 all income brackets

**Resources:** See how communities are impacted to get county data.

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**Bookmark Key Resources**

- Vaccine Product Comparison Guide
- Vaccine Administration at a Glance
As Emergency Use Authorization (EUA) of COVID-19 vaccine products expand to include adolescents and children, VFC providers are well situated due to their direct access to younger patient populations and their familiarity with vaccine administration and federal vaccine programs.

While VFC providers must sign and adhere to the requirements of the CDC COVID-19 Vaccination Program Provider Agreement to receive and administer vaccines, sites already have the skills and equipment to help now. (Read more.)

**Resources:** See CDC’s [VFC vs. COVID-19 Vaccination Program](#).
What You’ll Learn

1. Program Overview
2. Program Requirements
3. Key Roles
Providers agree to periodic site visits. Site visits help ensure compliance with program requirements, including administration, documentation, accountability, and vaccine management.

Site visits are educational opportunities designed to improve compliance, highlight best practices and lessons learned, and reveal challenges for future program improvement efforts.

Items labeled with a key identify critical issues evaluated during compliance visits.
Providers, vaccinators and key practice staff who store, handle, manage, or administer COVID-19 vaccines must complete required training as a condition of enrollment.

Program training prepares sites to incorporate requirements into clinic protocols and identifies key resources for use on the job. Staff completing the CDC Provider Agreement will complete the program training in myCAvax before enrollment.

Product training teaches you to prepare, administer, store, and handle each vaccine product and report adverse events to VAERS. Prior to receiving shipments, complete COVID-19 Vaccine Product Training—only for products your location will order—to ensure staff are trained.

**Training by Role:** Providers and vaccinators not registering in myCAvax must complete all COVID-19 Required Training [here](#).
Comply with Manufacturer Fact Sheets

Program Requirements

Providers and vaccinators must comply with all manufacturer guidance summarized in each vaccine’s EUA Fact Sheets for HCPs. Fact sheets may be updated as any manufacturer-requested amendments are approved.

Topics include

- storage and handling;
- dosing and schedules;
- preparation & administration;
- contraindications, warnings & adverse events; and
- other clinical considerations for COVID-19 vaccines.

Resources: See Vaccine Administration at a Glance, EUA Fact Sheets for HCPs.
Comply with ACIP Recommendations

Program Requirements

The Advisory Committee on Immunization Practices provides guidance to CDC; recommendations adopted by CDC are published in the Morbidity and Mortality Weekly Report (MMWR).

Providers and vaccinators must administer COVID-19 vaccines in accordance with all requirements and recommendations of ACIP. Recommendations may change to reflect EUA amendments or as more data become available.

Recommendations may include

- clinical considerations,
- local or systemic reactions and adverse events,
- preparing for potential anaphylaxis, and more.

Resources: See Vaccine Administration at a Glance, ACIP & Clinical Considerations.
Clinic Operations during the Pandemic

Program Requirements

CDC has issued interim guidance for immunization services in a variety of clinical and alternative settings. Providers are required to implement this guidance when administering COVID-19 vaccines.

Guidance has been updated to reflect influenza season and coadministration of COVID-19 vaccines with other routine vaccines for children, adolescents, and adults (including pregnant people).

Additionally, CDC has offered guidance for those planning for satellite, temporary, or off-site vaccination clinics.

Resources: See Vaccine Administration at a Glance, Pandemic Planning.
Providers and vaccinators must administer COVID-19 vaccines in accordance with all requirements and recommendations of CDC.

CDC provides ongoing guidance in the form of interim clinical considerations for use of COVID-19 vaccines authorized and approved. Guidance may apply to primary series, additional doses, and booster doses.

Topics include

- interchangeability of COVID-19 vaccines,
- coadministration with routine vaccines,
- people who received COVID-19 vaccine outside the US,
- COVID-19 vaccination and SARS-CoV-2 infection, and more.

Resources: See Vaccine Administration at a Glance, ACIP & Clinical Considerations.
**Comply with CDC Clinical Guidance (Cont.)**

**Program Requirements**

**Additional Dose**

People with moderately to severely compromised immune systems may not have received sufficient protection after completing the primary series. CDC recommends that immunocompromised people receive a 3rd primary-series dose to increase recipient immune response and improve protection.

**Booster Dose**

Studies show that after getting vaccinated, protection against the virus may decrease over time due to waning immunity as well as the greater infectiousness of variants. Booster doses may be recommended for specific populations and vaccine recipients to increase immune response and improve protection.

**Resources:** See Vaccine Administration at a Glance, Additional & Booster Doses.
Patient Visit

Program Requirements

Participating providers must incorporate this checklist into practice protocols:

- Do not ask for citizenship, birth certificate, or photo ID; for minors, contact parents.
- Determine eligibility (quick guide) for primary series or additional/booster doses.
- Distribute EUA Fact Sheet for Recipients BEFORE administration.
- Prepare/administer vaccines and observe recipient per EUA Fact Sheet for HCPs.
- Request recipient’s mobile number and email (see Health Officer Order).
- Report administration data daily using My Turn (or EHR/EMR connected to CAIR).
- Report any adverse events to VAERS.
- Complete Vaccination Record Card for primary series & booster doses.
- Schedule next appointment (primary series, additional, or booster).
- Recommend v-safe and Digital COVID-19 Vaccination Record.

Resources: See Vaccine Administration at a Glance, Patient Visit Checklist.
Providers must follow CDC provider requirements:

- **must** administer COVID-19 vaccine at no out-of-pocket cost to the recipient
- may **not** deny vaccination based on recipient’s coverage or network status
- may **not** charge office visit/other fee if vaccination is sole medical service
- may **not** require additional medical services to receive vaccination
- may **not** seek reimbursement from recipient (e.g., co-pays or balance billing)
- **may** seek appropriate reimbursement from a program or plan that covers administration fees (e.g., private insurance, Medicare/Medicaid)

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<thead>
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<th>Medi-Cal Eligible</th>
<th>Uninsured</th>
<th>Underinsured</th>
<th>Fully Insured</th>
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<tr>
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<td>Do not bill</td>
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<tr>
<td><strong>Admin Fee</strong></td>
<td>Do not bill recipient (bill Medi-Cal)</td>
<td>Do not bill recipient (may seek reimbursement from DHCS COVID-19 Uninsured Group Program)</td>
<td>Do not bill recipient (bill private insurance)</td>
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- **Required Training**
- **Vaccine Administration at a Glance**
See **CMA Reimbursement Guide** for CPT codes and guidance by payor type.

Centers for Medicare and Medicaid Services updated Medicare payment rates for COVID-19 vaccine administration to approximately $40 for single-dose vaccines and $40/dose in the series including both additional and booster doses.

On April 5, 2022, the HRSA stopped accepting uninsured vaccination claims due to a lack of sufficient funds. Providers may wish to explore the [DHCS COVID-19 Uninsured Group](#) Program for reimbursement of COVID-19 vaccine admin services.

**Resources:** See [Vaccine Administration at a Glance](#), Billing for Vaccine Administration.
Providers agree to follow CDC’s Vaccine Storage & Handling Toolkit and addendum.

Use *purpose-built or pharmaceutical-grade units* designed for storage of biologics, including vaccines. If not an option, *commercial or household standalone units* are acceptable. 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.

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 UL temperatures. Keep a backup device on hand for transports and should primary devices fail. Devices must have a current and valid Certificates of Calibration Testing.

**Resources:** See Vaccine Management at a Glance, Storage Units, Data Loggers.
Vaccine Redistribution

Program Requirements

If your facility intends to receive vaccines as a central depot and redistribute to other vaccination locations, the organization must sign the CDC Redistribution Agreement and be approved. Other scenarios may apply.

Each location receiving vaccine must be covered under a signed CDC Provider Requirements (Section A) and complete and sign a Provider Profile (Section B).

Temporary or pop-up clinics: These clinics do not have to enroll separately—if the permanent provider location transports and administers vaccines for those clinics and has already enrolled.

Resources: See Vaccine Management at a Glance, Vaccine Redistribution.
Providers must incorporate this checklist into practice protocols:

- Store and handle vaccines in accordance with CDC’s Vaccine Storage and Handling Toolkit and COVID-19 Addendum.
- Record storage unit temperatures twice daily on a temperature log (see sample log) using equipment that complies with guidance in the toolkit.
- Report temperature excursions daily in myCAvax.
- Rotate stock to ensure vaccines soon to expire are used first.
- Monitor and comply with COVID-19 vaccine expiration dates; don’t dispose of expired vaccine without checking for extended expiration dates.
- After puncture, use labels or alternate method for marking use-by date/time.
- Report all nonviable vaccines in myCAvax & comply with guidance for disposal.

Vaccine Management Plan

Program Requirements

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 how your staff should perform routine storage and handling tasks and respond to vaccine-related emergencies.

Review and update it annually, or more frequently if changes occur, and include a review date and signature to validate it is current.

Work with your provider to ensure all key practice staff complete the required training and log training completions in your practice’s COVID-19 Vaccine Management Plan. Make available during site visits.

Record Management & Review

Program Requirements

Providers must maintain all electronic and paper COVID-19-related records for a minimum of 3 years and make records available for review upon request.

Such records include the following:

- COVID-19 vaccine or ancillary product packing slips
- transport logs
- temperature logs
- certificates of calibration testing (for data loggers)
- billing records
- vaccine administration records (including medical records of administration)
- vaccine ordering records and packing slips
- any other COVID-19-related records

**Resources:** See [Vaccine Management at a Glance](#), Record Keeping.

**Bookmark Key Resources**

- [Vaccine Storage & Handling Toolkit](#)
- [Vaccine Management at a Glance](#)
Due to the urgency of the pandemic, CDC closely monitors administration data, inventory, and wastage nationwide.

CDC mandates that sites report administration data daily into CAIR. Providers use this data to ensure primary series and additional or booster doses are administered with correct product and interval. Data are also used to generate secure and mobile Digital COVID-19 Vaccine Records.

CDC mandates that sites report inventory to VaccineFinder at least weekly by close of business on Fridays. Data help identify which communities have sufficient supply and how long vaccines sit on shelves. Data also help to measure how much vaccine is shipping to communities with health inequities.
Reporting Requirements (Cont.)

Program Requirements

Report vaccination data daily to CAIR using My Turn or an EHR/EMR connected to CAIR (unless already reporting to CAIR manually.)

- **Reporting at a Glance**
  - Report vaccination data daily to CAIR using My Turn or an EHR/EMR connected to CAIR (unless already reporting to CAIR manually.)
  - **Report doses spoiled, expired, or wasted** before disposal.
  - **Report shipment incidents** when discovered for vaccine product and kits, including temperature excursions, damage, or packing slip discrepancies.
  - **Report temperature excursions** daily (if any) and quarantine affected vaccines; contact vaccine manufacturer to determine if doses may be administered.
  - Report inventory to VaccineFinder at least weekly by close of business on Fridays upon initial shipment.

- **Resources:** Bookmark Reporting at a Glance for summary of requirements.
Providers are responsible for adhering to, and administering vaccines in accordance with, all requirements outlined in the CDC Provider Agreement and recommendations by CDC, ACIP, and FDA. Use of these products outside of those approved and authorized by FDA (i.e., “off-label use”) could expose providers to the following risks:

- Administration of the product off-label may not be covered under the PREP Act or PREP Act Declarations; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- Providers giving off-label doses would be in violation of the CDC Provider Agreement and may impact their ability to remain a provider in the CDC vaccination program.
- Administration fees may not be reimbursable by payers.
How to Stay Current
Program Requirements

Information surrounding COVID-19 continues to evolve at a rapid pace. Emails are sent to Organization and Location Coordinators from the COVID Call Center to announce changes and new resources to assist you.

Trending

• vaccine products, regulations, and clinical recommendations,
• trends in clinical issues reported to VAERS,
• eligibility and prioritizations,
• vaccine supply and shipment delays, and
• vaccine expiration-date extensions by product and lot numbers.
COVID-19 Vaccine Provider FAQs

Program Requirements

Answers to Provider Questions - Updated Weekly

• 1.1 Q: Are the Pfizer Infant/Toddler (6 months – 4 years) vaccine and the Moderna Infant/Toddler (6 months – 5 years) vaccine authorized for emergency use?

• 1.2 Q: Now that COVID-19 vaccine eligibility has expanded, have minor consent requirements changed?

• 1.3 Q: If a child moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), which dosage should they receive?

• 1.4 Q: Where can COVID-19 vaccine Providers find clinical talking points for recommending COVID-19 vaccines for children?

Resources: Bookmark Frequently Asked Questions for all things COVID.
What You’ll Learn

1. Program Overview
2. Program Requirements
3. Key Roles
Key Program Roles

Overview

Identify who will act as your **Organization Coordinator** before enrolling. This role will

- complete [Section A](#) (Provider Agreement) in myCAvax during provider enrollment,
- identify and invite provider locations to complete Section B during enrollment,
- register with VaccineFinder and determine whether Organization or Locations will report inventory daily,
- monitor all program communications, and
- may oversee program-related operations in affiliated provider locations.

**Resources:** See [Enrollment Kit](#) to get started.
Each location must have on-site primary and backup **Location Coordinators**, typically filled by vaccine coordinators. Identify who will act as your Location Coordinators before enrolling. This role:

- may complete [Section B](#) (Provider Agreement) in myCAvax to enroll their location;
- receives vaccines, monitors temperatures, and manages inventory;
- receive emails regarding orders, shipments, and temperature monitoring;
- plans for and responds to vaccine-related emergencies;
- may be delegated to report inventory to VaccineFinder;
- ensures providers and key practice staff complete the required training [here](#).

**Resources:** See [Enrollment Kit](#) to get started.
Summary

You have now completed the lesson. You should now be able to perform the following tasks:

• **locate the program requirements**
  CDC Provider Agreement

• **map requirements to roles in your practice**
  Download this lesson as a reference guide

• **bookmark key resources to guide you on the job**
  Vaccine Administration | Vaccine Management | Reporting.
Got Questions?

Go to eziz.org/covid for program updates, videos & job aids, provider support, alerts, and more!

Program Education and Support:
- Provider Office Hours
- myCAvax Training
- Weekly Calendar of Webinars and Trainings
- Frequently Asked Questions
- Guide to Other COVID-19 Vaccine Websites

Provider Support
COVID Call Center
Email: For Program Info
Phone: (833) 502-1245
Hours: Mon–Fri, 8AM–6PM

myCAvax Help Desk
Email: For Technical Support
Phone: (833) 502-1245, option 2

Alerts:
Medi-Cal News Flash
- FQHC, RHC and Tribal FQHC Providers May Now Submit Claims for COVID-19 Vaccine Administration

Updated Vaccination Schedule
- Interim Clinical Considerations Updated for 2nd Booster March 31
- COVID-19 Vaccine Timing by Age (Eligibility Chart)
  Spanish: Calendario de la Vacuna COVID-19 por Edad (Tabla de Elegibilidad)
- COVID-19 Vaccine Timing for 2nd Dose
- COVID-19, Myocarditis, and Vaccines Fact Sheet
Looking for myCAvax Training Resources?

The Knowledge Center now houses job aids and videos on use of myCAvax for Providers, LHDs, and MCEs.

Look for this prompt at the bottom of myCAvax system screens to access training resources:

Need help? View our job aids in the Knowledge Center, or contact us.
Done!

You have completed the **Program Requirements** lesson.

Click “EXIT” at the top of page.