

# COVID-19: Vaccination Primer for California Hospitals

February 2, 2021

## Overview

Hospitals continue to be on the front lines of COVID-19 in myriad ways, including vaccinating Californians. Since the first vaccinations in December, implementation by the state and local health departments has evolved, with more changes anticipated from the federal and state governments.

On Jan. 25, Gov. Newsom announced a package of efforts to enhance the state's vaccination program. This includes three key components described in a Jan. 26 [press release](#) by the Government Operations Agency and California Health and Human Services Agency:

1. *Statewide Vaccine Delivery Network*: Through a third-party administrator, the state will determine vaccine allocations to providers. Blue Shield has been announced as the third-party administrator, with support from Kaiser Permanente. This will replace the current system, in which the California Department of Public Health (CDPH) determines allocations to multi-county entities and state departments, and local health departments determine allocations to all other providers. A timeline for when this will go into effect has not yet been announced.
2. *State Standardization of Prioritization*: Future groups will become eligible based on age. This statewide standard will move in unison across all 58 counties and will take effect after the current state phases (phases 1a and 1b of tier one). Such standardization statewide is in contrast to the layering of both state and local health department prioritizations that has occurred to date.
3. *Provider Data Reporting Through My Turn or Electronic Health Record with Interface*: Providers will be required to either administer vaccines via the [My Turn](#) scheduling system or an electronic health record (EHR) that interfaces with the state's system. The state anticipates this will reduce data lags and give it real-time information on vaccination progress at the local and statewide levels.

CHA is seeking more information from the Government Operations Agency, California Health and Human Services Agency (which oversees CDPH), and CDPH about how the state will implement this plan. As soon as more information is available, CHA will share it with hospitals and health systems.

In the meantime, as vaccinations continue under current processes, CHA has compiled the latest information on the following topics to assist California hospitals in preparing to administer the COVID-19 vaccination:

- Communications from CDPH
- Allocation and Distribution
- Vaccine Administration
- Vaccine Provider Enrollment
- Safe Storage and Handling
- IT and Data Reporting

- Vaccine Prioritization
- Protection From Lawsuits/Immunity

## Communications from CDPH

CDPH continues to hold webinars for providers on Fridays from 9 to 10 a.m. (PT). The department distributes the link to access each webinar via the California COVID Call Center email distribution list and is posting to its COVID-19 Vaccination [website for hospitals and other providers at EZIZ.org](#). On this site, CHA is also posting slides and recordings from its past webinars and regularly updating [FAQs with key questions](#) received from providers.

CDPH has established a [Community Vaccine Advisory Committee](#), on which CHA is represented. The committee provides feedback on CDPH's ongoing planning and engagement efforts to ensure equitable vaccine distribution and allocation. Information on how to listen to the meetings and to review the meeting materials is posted on the [CDPH website](#).

## Allocation and Distribution

As described above, the state has plans for significant enhancements to the vaccination program in California. Currently, and until this new system is launched, there are five steps in the allocation and distribution of doses to hospitals:

1. Federal government allocates doses to California.
2. CDPH allocates doses to multi-county entities, which are health systems with hospitals in three or more counties that have agreed to be designated as such; state departments (e.g., for the state prisons); and local health departments.
3. Local health departments will allocate to remaining hospitals (those not designated to be part of a multi-county entity). These redistributions each require approval by CDPH.
4. Manufacturer (for the Pfizer vaccine) or the distributor (McKesson for the Moderna and AstraZeneca vaccines) ships doses to the hospital.
5. Hospital administers the vaccine(s).

## Vaccine Administration

### Who May Order and Administer Vaccines

An order by a person legally authorized to prescribe is required [42 C.F.R. Section 482.23(c) and Title 22, California Code of Regulations, Section 70263(g)]. Most hospitals are asking an employee health physician, chief medical officer, or occupational health physician to write standing orders. CDPH has posted a [chart](#) showing which types of health care professionals can independently order vaccines, and which can administer vaccines, under state law. Gov. Newsom released an [executive order](#) on Jan. 27 granting protection from liability to any health care professional administering COVID-19 vaccines. The federal [Public Readiness and Emergency Preparedness \(PREP\) Act](#) also provides immunity for vaccine administrators, including additional types of health care professionals. More details can be found under "Protection from Lawsuits/Immunity."

## Vaccine Provider Enrollment

### Provider Enrollment and Agreements

Hospitals that administer COVID-19 vaccines are required to register online with CDPH at [CalVax](#) and submit a [Provider Agreement](#) issued by the Centers for Disease Control and Prevention (CDC). In addition, a hospital that will accept a shipment of vaccines and share/redistribute some of them with another administration site must sign a [Redistribution Agreement](#). Full instructions for enrollment preparation are available on the [CalVax](#) website.

Questions can be directed to [COVIDCallCenter@cdph.ca.gov](mailto:COVIDCallCenter@cdph.ca.gov).

### **Enrollment Approval Considerations**

Once enrollment is approved, local health departments can determine whether and how much vaccine to order for the hospital. If the application is not approved, it could be pending or incomplete. The pending applications need verification of their Immunization Identification IIS ID (through their local California Immunization Registry — [CAIR2](#), Regional Immunization Data Exchange (CAIR San Joaquin), and San Diego Regional Immunization Registry (CAIR San Diego) medical license verification on part B of the form, and if a current vaccine provider, there must be a match with the new enrollment number. If an application is incomplete, it is missing the exact address for vaccine shipment.

### **Vaccine Finder**

Vaccine Finder is the CDC's inventory reporting system that provides national visibility on vaccine distribution. All COVID-19 vaccination providers must report COVID-19 vaccine inventory daily into Vaccine Finder. More information can be found on the state's [COVID-19 one-stop shop](#) for immunization training and resources.

### **Safe Storage and Handling**

Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune response and poor protection against disease. The vaccines' cold chain is a temperature-controlled environment requiring proper storage until they are administered.

The Pfizer and Moderna vaccines have stringent requirements for refrigeration. For example, the Moderna vaccine requires cold storage, while the Pfizer vaccine requires storage at ultra-low temperatures. It is important for hospitals to understand all potential requirements of vaccine storage and transportation to ensure they have the necessary equipment and supplies to execute vaccination plans. Hospitals and health systems should work with materials managers, engineers, and risk managers to establish facility guidelines for what is possible and establish what is not possible. This should entail ensuring that receiving teams understand the process for receiving vaccine deliveries, including performing a temperature check. For additional details, see [Vaccine Management](#) storage and handling requirements.

### **Required Training**

CDC [storage and handling education](#) for vaccines is located on [CDPH's required training and resource page](#). Providers and key practice staff (overseeing or handling COVID-19 vaccines) will need to complete training before enrolling in the California COVID-19 Vaccine Program. Training topics include:

- Program requirements
- COVID-19 vaccine storage and handling
- Vaccine administration
- Vaccine management

### **First and Second Dose Distributions**

Both the Pfizer and Moderna vaccines require two doses: Pfizer's must be at least 21 days apart and Moderna's must be at least 28 days apart. In all cases, according to CDPH, the initial shipment is to be used solely for the first dose and should not be reserved for the second dose. If a facility receives a certain amount of vaccine, the same amount will be held in reserve for the second dose. If all the vaccine is used by the facility, the full amount held in

reserve will be sent to the facility. Re-distribution might be easier with a vaccine such as Moderna, which does not require ultra-cold storage.

## IT and Data Reporting

Hospitals must undertake several IT and data reporting projects to track vaccination doses and report adverse events. Below are several steps California hospitals can take to prepare their IT systems for vaccination data reporting.

### Reporting Doses

Hospitals and providers administering COVID-19 vaccination doses are required to report this information to the California Immunization Registry (CAIR) within 24 hours of vaccine administration. To do this, they must be registered with CAIR and have an immunization information system ID number. Information on how to register with local CAIR contacts in each region is available [here](#). Providers can submit dose administration information to CAIR through two established methods, including data interface with the provider's EHR; or the state's platform, [MyTurn](#), which will automatically report vaccination information into the state data system if a hospital is not interfacing through its EHR. The state's goal is for these two approaches to reduce data lags and provide real-time information on vaccine allotment and administration.

MyTurn can also be used as an appointment system for Californians to learn when they are eligible to be vaccinated and make an appointment when eligible.

### Reporting and Requesting Vaccine Inventory

Vaccine re-orders are submitted by enrolled providers through CalVax. Provider re-orders for COVID-19 vaccines will require reporting on-hand inventory at the time of the vaccine order and a summary of vaccine doses administered. Any vaccine waste or authorized transfer must be reported through the same system. Vaccine re-order requested by enrolled providers will be forwarded to the respective local health department for review, re-allocation, and approval. CDPH anticipates that local health departments will consider whether hospitals have reported administration of doses as one factor in determining whether to allocate further doses to them, making the reporting of doses additionally important.

[As of Jan. 22](#), if a local health officer (LHO) determines that a registered provider has not used at least 65% of the vaccine in their possession for more than one week, the LHO shall give notice of such to the provider. Within 24 hours of receipt of the notice, the registered provider must develop and submit to the LHO, for approval, a plan for administering their remaining vaccine to prioritized populations within 96 hours of notice.

### Reporting Adverse Events

To enroll for receipt of COVID-19 vaccines, providers must report moderate and severe adverse events following vaccination to the [Vaccine Adverse Event Reporting System \(VAERS\)](#). For further assistance on reporting to VAERS, hospitals can contact VAERS directly at [info@VAERS.org](mailto:info@VAERS.org) or (800) 822-7967.

## Vaccine Prioritization

As of Jan. 22, California has [revised its vaccine allocation guidelines](#). Under these revised guidelines, California will prioritize vaccinating health care personnel, including vaccinators, and all persons 65 years of age or older. This policy is to be carried out with a deep commitment to equity, without profiteering, and in a manner that ensures no doses are wasted. All vaccination providers should:

1. Continue vaccinating everyone in Phase 1a (health care workers and long-term care residents).

2. Begin vaccinating persons age 65 or older. Based on available supply, prioritize and target outreach efforts as follows:
  - **Age**, with persons 75 years or older prioritized due to increased risk of mortality and other severe disease
  - **Occupational risk exposure**, individuals working in sectors in Phase 1b, Tier 1 with high occupational exposure in the following sectors: education and childcare, emergency services, food and agriculture
  - **Residence in vulnerable communities**, as determined by the California Healthy Places Index or comparable local health department knowledge, to address equity and communities disproportionately affected by the pandemic

Health departments and providers may offer doses promptly to people in lower priority groups when:

- Demand subsides in the current groups
- Doses are about to expire according to labeling instructions
- Doses that have been thawed would otherwise go to waste

Altering prior guidance that providers retain 50% of the doses they receive for second vaccines, **CDPH now instructs providers to use all first doses immediately and not hold first doses for second doses.**

CDPH advises that these recommendations continue to be subject to review and further revisions, so providers should continue to monitor prioritization guidance for further changes.

### **Protection from Lawsuits/Immunity**

Federal law provides protection from lawsuits for COVID-19 vaccinators. The PREP Act authorizes the U.S. Department of Health and Human Services Secretary to issue a declaration to provide immunity from liability for the manufacture, distribution, administration, or use of “medical countermeasures,” except for claims involving willful misconduct. A medical countermeasure is a drug, device, or biological product that is used, developed, to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic. To be a covered countermeasure, a product must be approved, cleared, or authorized for emergency use by the Food and Drug Administration or licensed under the Public Health Service Act.

On March 17, 2020, the Secretary issued a [declaration under the PREP Act](#) for medical countermeasures used against COVID-19, including COVID-19 vaccines, remdesivir, and other products.

PREP Act immunity covers claims under tort or contract law, as well as claims related to compliance with state/local laws. Any lawsuit seeking an exception to PREP Act immunity must be brought before a special three-judge court in U.S. District Court in Washington, D.C. To win, the plaintiff must prove willful misconduct was the proximate cause of death or serious injury by clear and convincing evidence. The PREP Act also establishes a program to compensate individuals for serious physical injury or death caused by a covered countermeasure.

In addition to PREP Act immunity, state law provides protection from lawsuits for physicians, hospitals, pharmacists, nurses, respiratory care practitioners, dentists, and others who render services during a state of emergency at the express or implied request of any responsible state or local official or agency. On Jan. 27, Gov. Newsom issued [Executive Order N-02-21](#), explicitly invoking this immunity protection for hospitals and other providers participating in the state’s vaccine administration program.