

COVID-19: Vaccination Primer for California Hospitals

December 8, 2020

Overview

California anticipates having 327,600 doses of the Pfizer vaccine between approximately December 12 and December 15, with an additional 700,000 to 1 million doses in late December. Pfizer's emergency use authorization (EUA) is expected to be approved by the Food and Drug Administration as soon as December 10.

Hospitals will play a pivotal role in administering the vaccine during the first phase, referred to as Phase 1-A by the California Department of Public Health (CDPH), when front-line health care workers will be among those prioritized. For more details on how the December distribution of the vaccine will be allocated in California, see "[Vaccine Prioritization](#)". The Pfizer vaccine requires storage at an ultra-low temperature (-80 degrees Celsius) or repacking with dry ice, both of which many settings do not have access to, and given the large amounts shipped (975 doses are in each shipment). Hospitals will offer the vaccine to their employees and staff, and many hospitals are volunteering to serve as closed points of dispensing for skilled-nursing facility staff, paramedics, and other health care workers who are expected to be prioritized.

Moderna is expected to receive EUA in mid- to late-December. Its vaccine does not require storage at ultra-low temperatures, and CDPH might offer it to non-hospital settings given its less-challenging storage and handling requirements.

AstraZeneca is the next vaccine expected to receive an EUA, sometime after Moderna's. Its vaccine requires refrigerated versus ultra-cold storage.

CHA has compiled information on the following topics to assist California hospitals in preparing to administer the COVID-19 vaccination:

- [Communications from CDPH](#)
- [Allocation and Distribution](#)
- [Provider Enrollment](#)
- [Safe Storage and Transportation](#)
- [IT and Data Reporting](#)
- [Vaccine Prioritization](#)
- [Protection From Lawsuits/Immunity](#)

Communications from CDPH

CDPH will host an all-hospital webinar on December 18 from 9 to 10 a.m. (PT). CDPH will distribute the registration link via the California Health Alert Network, and CHA will distribute it via its *Coronavirus Response* email newsletter (to be added to the distribution, email info@calhospital.org). CDPH is also posting information on the [California COVID-19 Vaccination Program](#) and [COVID-19 Vaccine Planning](#) sections of its website. In addition, the state has set up a public-facing set of [questions and answers on COVID-19 vaccination](#). Hospitals can direct questions to CDPH on the upcoming webinar by emailing covidcallcenter@cdph.ca.gov or contacting their local health departments.

In addition, CDPH has established a [Community Vaccine Advisory Committee](#), on which CHA is represented. The committee will provide input and feedback for CDPH's ongoing planning and engagement efforts to ensure equitable vaccine distribution and allocation. According to CDPH, it will build on the [Scientific Safety Review Workgroup](#) and [California's COVID-19 Drafting Guidelines Workgroup](#). Information on how to listen to the meetings and to review the meeting materials is posted [here](#).

Allocation and Distribution

There are essentially five steps in the allocation and distribution of doses to hospitals during Phase 1-A:

1. Federal government allocates to doses to California.
2. CDPH allocates doses to multi-county entities, which are health systems in three or more counties; state departments (e.g., for the state prisons); and local health departments. *Note: For the first set of orders in early and mid-December, the state will not be able to allocate to the multi-county entities. Their doses, as with all hospitals, will be allocated by local health departments until the next set of orders in late December.*
3. Local health departments will allocate to remaining hospitals (those not considered a multi-county entity).
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 during the first phase, referred to as Phase 1-A by CDPH, when front-line health care workers will be prioritized, to its employees and staff. Many hospitals volunteer to serve as closed points of dispensing for skilled-nursing facility staff, paramedics, and other prioritized health care workers.

Provider Enrollment

Vaccine Provider Enrollment and Agreements

Hospitals that administer COVID-19 vaccines are required to register online with CDPH 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](#). The CDPH [COVIDReadi](#) system launched the week of November 16 for general acute care hospitals. Providers that are likely to be Phase 1-A vaccinators, which includes hospitals, should have received an invitation to enroll, instructions, and a link to the website.

Hospitals are encouraged to review the draft provider agreement now and start preparing to fulfill the requirements if they wish to administer and/or redistribute the vaccine. All providers that plan to receive and administer COVID-19 vaccines must be enrolled. To assist with the multi-step enrollment process, CDPH has provided these [instructions](#) and a [step-by-step guide](#). Questions can be directed to COVIDCallCenter@cdph.ca.gov.

Health systems with a consolidated management structure, with a chief medical officer (CMO) and CEO (or chief fiduciary/legal official) who will oversee multiple locations, must complete the enrollment, and sign the CDC provider agreement. Each location then needs to complete its own section of the provider enrollment form. Through this process, the organization's leadership does not have to sign enrollment agreements multiple times for all sites.

For hospitals that are independently managed, each site will need to be enrolled individually, as an organization, with leadership from each hospital (CMO and CEO) completing and agreeing with the participation agreement.

Additional Resources From CDPH:

- [COVID-19 Vaccination Program Participation Requirements](#)
- [Immunization Information System Participation](#)

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 will require cold storage, while the Pfizer vaccine requires storage at ultra-cold temperatures. It is important for hospitals to understand all potential requirements of vaccine storage and transportation to ensure their organization has 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 include ensuring that receiving teams understand the process for receiving vaccine deliveries, including performing a temperature check. For additional details, see [CDPH's COVID -19 Vaccine Planning PowerPoint presentation \(Nov. 13\)](#) and [CDPH's responses to questions from hospitals](#) about that presentation.

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

Pfizer Vaccine Storage

- Requires ultra-low temperature storage (-80 degrees Celsius)
- Shipped from Pfizer in its Ultra-Low Temperature Thermal Shipper container with dry ice
- Upon receipt, follow specific receipt instructions
- Three storage options: 1) ultra-cold temperature storage (-80 degrees Celsius), 2) storage in shipping container with dry ice pellets (can be recharged with dry ice pellets within 24 hours of receipt and every five days thereafter) or 3) refrigerate immediately and use in five days
- For vaccine viability, explicitly follow specific instructions for each of the storage options
- Ancillary supplies, such as diluent, syringes, needles, facemasks, alcohol pads, and vaccination record cards will be provided by the federal government and shipped in addition to the vaccine.
- For health systems with multiple locations, CDPH reports that Pfizer does not recommend distribution to one central location within the health system and then distributing to the individual medical centers/administration sites. Reasons include:
 - There are no guidelines for re-packing the ultra-cold vaccine at -80 degrees Celsius.
 - It can be stored at 2-8 degrees Celsius for 120 hours, so could be shipped directly by the manufacturer or distributor to other sites and administered within five days.

- The minimum shipment is 975 doses, which also creates logistics challenges.
- The company recommends the vaccine be shipped to the site where it will be administered. Each site that will be administering the vaccine can order it to be shipped directly to the administration site.

Moderna Vaccine Storage

- Requires frozen storage (-20 degrees Celsius)
- Shipped from McKesson administration sites requiring frozen storage (-20 degrees Celsius)
- If using refrigerated storage, must be at 2–8 degrees Celsius, for up to seven days
- Thaw times: Two hours in refrigerator, then 15 minutes at room temperature; or one hour at room temperature
- Can be used up to 12 hours at room temperature before administration, but the vial must be used within six hours after first entry/puncture

First and Second Dose Distributions

Both the Pfizer and Moderna vaccines require two doses: Pfizer's must be 21 days apart and Moderna's must be 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 the Moderna candidate — that does not require ultra-cold storage.

Scientific Safety Review Workgroup

California, Washington, Nevada, and Oregon are jointly convening a [Scientific Safety Review Workgroup](#), which will review the vaccine candidates for their safety before a vaccine is distributed in these states.

Additional Resources From CDPH

- [Ordering Vaccines](#)
- [Storage and Handling](#)
- [Temperature Monitoring](#)
- [Vaccine Administration](#)
- [Vaccine Management](#)

IT and Data Reporting

Hospitals must plan to address several IT and data reporting considerations 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. 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 your region is available [here](#). Providers can submit dose administration information to CAIR through several established methods, including data interface with the provider's electronic health record (EHR); PrepMod vaccine management software, which will be made available to all COVID-19 vaccination enrolled providers, CAIR2 Mass Vax online tools (an online spreadsheet); or manual data entry into one of California's CAIR software applications.

Most methods – except for manual entry – allow for real-time submission of dose information via standard HL7 VXU messages directly into CAIR. However, as Phase 1-A of COVID-19 vaccine administration will be primarily limited to health care workers, it is important for hospitals to consider how to reconcile and transmit data from employee health records to CAIR. CHA members have reported a number of methods, including building an interface from employee health records that transmits to CAIR, creating a separate system for employee health records within their EHRs, or manual data entry for employee immunizations.

In addition, hospitals should consider how their IT systems can support second dose reminders for vaccines that require two doses.

Reporting and Requesting Vaccine Inventory

Initial vaccine orders will be placed on behalf of new and existing providers by local health departments. Vaccine re-orders will be submitted by enrolled providers through COVIDReadi. 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 local health departments considering whether hospitals have reported administration of doses as part of whether to allocate further doses to them, making the reporting of doses additionally important.

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) at <https://vaers.hhs.gov/index>. For further assistance reporting to VAERS, hospitals can contact VAERS directly at info@VAERS.org or (800) 822-7967.

Additional Resources From CDPH: [Reporting Requirements](#)

Vaccine Prioritization

California anticipates having 327,600 doses of the Pfizer vaccine between approximately December 12 and December 15, with an additional 700,000 to 1 million doses in late December. [California's COVID-19 Drafting Guidelines Workgroup](#) and [Community Vaccine Advisory Committee](#) have recommended that health care workers and long-term care residents in Phase 1-A receive the initial vaccines in the following prioritized tiers:

- Tier 1: acute care, psychiatric, correctional facility hospitals, staff and residents of skilled-nursing facilities, assisted living facilities and similar settings, paramedics, EMTs, other emergency medical services providers, and dialysis centers
- Tier 2: intermediate care facilities; home health care and in-home supportive services; community health workers; public health field staff; primary care clinics, including federally qualified health clinics, rural health clinics, correctional facility clinics, and urgent care clinics
- Tier 3: specialty clinics, lab workers, dental/oral health clinics, pharmacy staff not working in settings of higher tiers

Within this limited distribution and subsequently limited supplies, it is necessary to prioritize access until enough doses become available to meet demand, which will likely be several months. Prioritization will need to occur both on a statewide, local, and hospital-by-hospital basis.

The Drafting Guidelines Workgroup continues to develop guidelines for how the state will best equitably distribute the vaccine, taking into account the populations to be targeted and how to most effectively use the initially scarce vaccine. It is expected to take several weeks for the Phase 1-B prioritization plan — which is expected to prioritize essential workers, among others — to be finalized.

Within these broad parameters, and informed by the resources identified below, hospitals should develop their own vaccine allocation plans, taking into account their own types and numbers of health care personnel in each category for purposes of Phase 1-A. For Phase 1-B, the demographics of their community that put people at higher risk of acquiring COVID-19 and suffering severe morbidity and mortality should be considered.

Protection From Lawsuits/Immunity

Federal law provides liability protection for COVID-19 vaccinators. The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the U.S. 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 manufactured, used, designed, developed, modified, licensed or procured 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 FDA or licensed under the PHS Act.

Immunity covers claims under tort or contract law, as well as claims related to compliance with state/local laws. Any lawsuit alleging an exception to PREP 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.

Remdesivir and other drugs/devices that have been used during this pandemic are also covered by this law.