

COVID-19: Vaccination Primer for California Hospitals

December 22, 2020

Overview

California anticipates having 40% of the first doses needed to vaccinate Phase 1a populations for California by December 28. These total 1.2 million doses and are for the 3 million individuals who meet Phase 1a criteria (e.g. front-line health care workers and long-term care residents) and are arriving in four tranches:

- Pfizer first shipment (scheduled to have arrived by Dec. 17): 327,600
- Moderna first shipment (scheduled to arrive Dec. 21-27): 672,600
- Pfizer CDC Long-Term Care Partnership: 45,825
- Pfizer second shipment: 187,200

Hospitals are playing a pivotal role in administering the vaccine during the first phase, referred to as Phase 1a by the California Department of Public Health (CDPH), when front-line health care workers are among those prioritized. For more details on how the December distribution of the vaccine will be allocated in California, see “Vaccine Prioritization.” Hospitals are pivotal in distributing the Pfizer vaccine due to the requirement to store it at an ultra-low temperature (-80 degrees Celsius) or repacking with dry ice (which many settings do not have access to), and the large amounts shipped as a minimum allocation (975 doses are in each shipment). Hospitals are offering 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 have been prioritized.

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](#)
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- [Vaccine Provider Enrollment](#)
- [Safe Storage and Handling](#)
- [IT and Data Reporting](#)
- [Vaccine Prioritization](#)
- [Protection From Lawsuits/Immunity](#)

Communications from CDPH

CDPH will hold Office Hours for hospitals and other providers on Dec. 29 from 9 to 10 a.m. (PT). The department 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 has created a new COVID-19 Vaccination [website for hospitals and other providers](#) with operational information on vaccine management, program enrollment, reporting requirements, and vaccine administration.

CDPH is also posting updates 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](#).

In addition, CDPH has established a [Community Vaccine Advisory Committee](#), on which CHA is represented. The committee will provide 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 also posted on the [CDPH website](#).

Allocation and Distribution

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

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; 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 did not allocate to the multi-county entities. Instead, those doses, as with all hospitals', were allocated by local health departments.*
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 1a by CDPH, when front-line health care workers are prioritized, to its employees and staff. Many hospitals volunteer to serve as closed points of dispensing for the staff and residents of skilled-nursing facilities and similar settings for those who are older or medically vulnerable, paramedics, and other prioritized health care workers.

Vaccine Administration

Who May Issue Vaccine Orders

Most hospitals are asking an employee health physician, chief medical officer, or employee health physician to write standing orders. 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)]. Also, the U.S. Department of Health and Human Services (HHS) allows [pharmacists](#) to order and administer COVID-19 vaccines; this guidance preempts state law and confers immunity from liability under the federal Public Readiness and Emergency Preparedness (PREP) Act. California has also issued a [waiver](#) allowing pharmacists to initiate and administer COVID-19 vaccines (and to initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction). After Jan. 1, 2021, the waiver will not be needed for a physician to initiate a COVID-19 vaccine, as Business and Professions Code Section 4052.8 will allow this permanently.

Who May Administer Vaccines

The COVID-19 vaccine may be administered by physicians, pharmacists, allopathic and osteopathic physicians, naturopathic doctors, registered nurses, nurse practitioners, clinical nurse specialists, nurse anesthetists, nurse midwives, public health nurses, vocational nurses, physician assistants, medical assistants (as allowed per law and regulation under supervision), psychiatric technicians, and respiratory care practitioners. Nursing students with clinical training and demonstrated competency per Business & Professions Code section 2727(d) are also permitted to administer the vaccines (see [Bureau of Registered Nursing news release](#) and [Nursing Services During Epidemic At-A Glance Emergency Matrix](#)). In addition, HHS has allowed [pharmacists](#), [pharmacy interns](#) and [technicians](#) to administer COVID-19 vaccines; these guidance documents preempt state law and

qualify these providers for immunity from any related claims under the PREP Act. For more information, see the Centers for Disease Control and Prevention's [vaccine administration tutorial](#).

Vaccine Provider Enrollment

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 1a 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 prepare 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.

Enrollment Approval Considerations

To date, 321 hospitals have been approved in COVIDReadi statewide, and 55 are pending. Once 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 — CAIR, CAIR2, RIDE, or SDIR), 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 CDC's inventory reporting system that provides national visibility on vaccine distribution. Many enrollees have not received their CDC invitation email to Vaccine Finder. CDPH has learned that there is no mechanism for adding providers for onboarding by flagging them in the CDC's Vaccine Tracking System because it is not yet live; this process will be manual until the program is live. Pre-positioned sites and sites expecting vaccines the week of December 21 have been prioritized. ***Hospitals that haven't received their Vaccine Finder email invitation should begin vaccinating, report doses administered daily, and enter reporting information later when they receive their Vaccine Finder registration.*** The Vaccine Finder invitation will be sent to the COVIDReadi Section A organization email, which must be a personal email, rather than a general inbox. The point of contact should complete the account registration and confirm reporting options immediately. Hospitals may also need to have

their point of contact check their spam email folder for the Vaccine Finder information; the email will be from iisinfo@cdc.gov with “vaccine finder” included in the subject line.

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 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 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 Updates

- 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
- 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.
- Additional volume in vials: CDPH has advised that as the initial doses of Pfizer vaccine have been delivered and administered, immunizers have observed additional volume in the vials after proper reconstitution and administration of five doses. In response, the FDA has issued preliminary advice that it is acceptable to use every full dose obtainable (the sixth, or possibly even a seventh) from each vial, and it is critical to note that any further remaining product that does not constitute a full dose should not be pooled from multiple vials to create one.

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 and can be transported at refrigerated temperatures for no more than three hours
- 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
- The ancillary supply kit labels may not exactly indicate contents. Call McKesson if there are issues.

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 have jointly convened a [Scientific Safety Review Workgroup](#), which will review the vaccine candidates for their safety before a vaccine is distributed in these states. The workgroup has confirmed the safety of the Pfizer vaccine and recommended its administration.

Additional Resources From CDPH

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

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 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 1a 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 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.

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 on 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 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 1a receive the initial vaccines in the following prioritized tiers:

- Tier 1: acute care, psychiatric, and 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 initial 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 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. The prioritization plan for Phase 1b, which is expected to prioritize essential workers, among others, will be finalized shortly.

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 1a. For Phase 1b, 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 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.

On March 10, 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.

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.