COVID 19 Vaccinations & LA Health Centers
Frequently Asked Questions
Version: January 19, 2021

The following outlines many of health centers' frequently asked questions related to COVID-19 vaccines. The answers reflect the most current information available as of the revision date of this FAQ. New or revised information is indicated by gray highlighting. CCALAC will continue to expand and refine the document as more information is available. Health centers should continue to send their questions to CCALAC to include in future versions of this FAQ. *Standard disclaimer: this is not legal advice.*

SYSTEMS AND REGISTRATION

CovidReadi/CalVax

Q: Do I have to register for CovidReadi?
Only register for CovidReadi if you plan to vaccinate your staff and/or patients.

Q: On the COVIDReadi application, are most clinics attesting yes to the line on accommodation for ultra-low temps or ability to purchase dry ice?
You will be able to complete registration without checking that box. Per LADPH, you do not need to invest in ULT. You do not need a regular freezer either if you do not already have one. Please only respond yes if in possession of ultra-low temperature freezers. Only clinics that meet this requirement should respond yes.

Q: Do I have to register for CalVax?
Starting Monday, January 11, COVIDReadi will transition into CalVax. All previously COVIDReadi registered clinics do not need take any further action. If your registration is incomplete, you will need to register via the CalVax portal.

PrepMod/CAIR

Q: How do I register for PrepMod?
Once your COVIDReadi registration is approved, you will receive an invitation to log into PrepMod. The email will come from "Vaccination Clinics" at no-reply@multistatep4p.com.
Organizations that do not receive this invitation should reach out to LADPH or prepmod@cdph.ca.gov.

Q: Can you clarify the role and use of the CAIR registry in addition to PrepMod?
CAIR2 interfaces with PrepMod.

Q: Do we have to build an interface for PrepMod with our EHR?
No. PrepMod interfaces to CAIR, not to the EHR. Data export from PrepMod is possible for EHR upload.

Q: When will staff register for PrepMod to get their vaccine? How will they be notified?
If you are vaccinating your staff, you can send them a link to the "private" clinic in PrepMod.
If you are not vaccinating your staff, LADPH will provide you with information to give your staff.

Q: How can I get more information/questions answered from LADPH and/or about PrepMod?

LADPH is hosting several recurring webinars/conference calls:

The General Vaccinator Office Hours
7 days a week, 9-9:30am. Open to all vaccinators in the County (super basic information)
Click here to join the meeting
Or call in (audio only)
+1 323-776-6996,,973498904# United States, Los Angeles
Phone Conference ID: 973 498 904#
Find a local number | Reset PIN
Learn More | Meeting options

PrepMod Office hours
M-F, 2:30-3pm. Open to all vaccinators in the County
Click here to join the meeting
Or call in (audio only)
+1 323-776-6996,,926089857# United States, Los Angeles
Phone Conference ID: 926 089 857#
Find a local number | Reset PIN
Learn More | Meeting options

TRAINING

Q: What trainings are required to provide the vaccine? How do we get trained to provide the vaccine?

- Required and recommended trainings are located on the CDPH site here.
- Providers and key practice staff handling or administering COVID-19 vaccines are responsible for knowing
- the topics covered under the "required" training. Previous training courses covering this information count towards completion as long they are recent.
- Most of the 9 required training elements consist of PDF documents to review, one is a CDC module. Estimated completion times range from 1 minute to 30 minutes.

VACCINE ADMINISTRATION

Vaccinating Other Healthcare Workers

Q: What happens once I report to LADPH that my organization has capacity to vaccinate outside staff?

Additional information will be provided by LADPH directly to your organization. In short, vaccination entities will be designated as open or closed medical Points of Dispensing, a.k.a. "PODs." A closed POD is a facility that will be used temporarily to dispense vaccines to a pre-identified group of people. (In contrast, an Open POD would be a location open to the public). In the current effort to vaccinate health care workers, clinics who have capacity to vaccinate other health care workers would be considered Closed PODs. Once identified, LADPH will work directly and will execute an MOU with interested organizations.

Monitoring/Observation

Q: What are the rules related to monitoring a vaccine recipient after receiving the vaccine?

- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine. Vaccine providers should observe patients with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination.
- All other persons should be observed for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions. Further information on preparing for the potential management of anaphylaxis at COVID-19 vaccination sites has been published.

Past or Current COVID-19

Q: What are the vaccine recommendations for people who have had COVID-19 in the past 90 days?

- Vaccination of persons with known *current* infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose.
- While there is no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

HIV+ Individuals

Q: What guidance is there on vaccinating people who are HIV+?

- Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. Data are not currently available to establish vaccine safety and efficacy in these groups. Persons with stable HIV infection were included in mRNA COVID-19 vaccine clinical trials, though data remain limited.
- Immunocompromised individuals may still receive COVID-19 vaccination if they have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19.

MALPRACTICE & LICENSING

FTCA, Scope & UDS - SECTION UPDATED 1/14 & 1/19.

Q: What liability protections apply to health center providers administering vaccinations?

FTCA: Health centers that have been deemed as federal employees through the Health Center FTCA Program are eligible for liability protection for grant-supported activities by "covered providers" and deemed volunteer health professionals.

PREP Act: Pursuant to the Public Readiness and Emergency Preparedness (PREP) Act, the Secretary of HHS has also issued a declaration (and amendments) concerning medical countermeasures against COVID-19, which declared that COVID-19 vaccines are also covered countermeasures for the purposes of liability protection under the PREP Act. If all requirements set forth in the Secretary's declaration are met, a covered person is immune from liability except for "willful misconduct" with respect to all claims for loss caused by, arising out of, relating to, or resulting from the manufacture, testing, development, distribution, administration, and use of a COVID-19 vaccine.

Countermeasures Injury Compensation Program: An individual who sustains a covered serious physical injury or death as a direct result of the administration or use of a covered countermeasure (or estates and survivors of such individual) may be eligible for certain benefits under the Countermeasures Injury Compensation Program (CICP), which is administered by HRSA. Information about the CICP and filing a claim are available toll-free at 1-855-266-2427, or at the CICP website.

Q: How do I determine if my organizations' planned activities are in scope?

Considerations for Health Center Scope of Project and the Public Health Emergency includes a checklist a health center can use to ensure that their activities meet current guidelines to be in scope and covered by FTCA.

Q: Can my organization administer vaccinations to patients and non-patients at community locations outside of our service sites?

Yes. The Health Center Program views providing COVID-19 vaccinations as an element of in-scope general

primary care and immunization services, as reflected on Form 5A: Services Provided. Health centers may administer COVID-19 vaccinations to health center patients and to individuals who are not health center patients within their scope of project both at the health center and at locations within the community that are not a health center's service sites, as documented on Form 5B or 5C as appropriate (see next question). As with all in-scope services, health centers should maintain records of immunizations they provide consistent with applicable standards of practice.

Q: If I am planning to administer vaccinations at an off-site location, do I add the locations on Form 5B as service sites or on Form 5C as "Other Activities/Locations"?
Health centers may set up temporary sites that are "within the health center's service area or a county, parish, or other political subdivision adjacent to the health center's service area" (for in-scope services).

Sites recorded on Form 5B: Service Sites must be locations that meet the definition of a service site in PIN 2008-01: Defining Scope of Project and Policy for Requesting Changes. To determine whether locations where COVID-19 vaccination is being provided should be listed on Form 5B: Service Sites, a health center must determine if the location meets all of the following criteria:

- Health center encounters are generated by documenting in the patients' records face-to-face contacts between patients and providers;
- Providers exercise independent judgment in the provision of services to the patient;
- Services are provided directly by or on behalf of the grantee, whose governing board retains control and authority over the provision of the services at the location; and
- Services are provided on a regularly scheduled basis (e.g., daily, weekly, first Thursday of every month). However, there is no minimum number of hours per week that services must be available at an individual site.

If a health center, on its own behalf, plans to provide vaccinations to individuals within the community at a location that is not an approved service site, such activity may be within the scope of project and documented on Form 5C: Other Activities/Locations. As described in PIN 2008-01, the criteria for activities to be included on Form 5C are those that (1) do not meet the definition of a service site, (2) are conducted on an irregular timeframe/schedule, and (3) offer a limited activity from within the full complement of health center activities included within the scope of project.

HRSA's streamlined process for adding temporary sites during emergencies is described in PAL 2020-05: Requesting a Change in Scope to Add Temporary Service Sites in Response to Emergency Events (process starts at bottom of page 6). The information must be submitted to HRSA as soon as practicable but no later than 15 days after initiating emergency response activities.

Q: Does an FQHC have to create a patient record in order to be covered by FTCA?
Yes. HRSA issued a particularized determination earlier this year (Determination of Coverage for COVID-19-Related Activities by Health Center Providers) that makes clear that treatment to individuals who are not already established patients IS covered by FTCA. It also stipulates that health centers **should maintain "a record of each encounter** that identifies the patient, the service(s) provided, the location where services were administered, the name of the provider(s) administering the services, and the date and time the services were administered."

For more information, see additional information on Considerations for Health Center Scope of Project During the COVID-19 Public Health Emergency.

Q: Will creating a patient record for administering vaccine to non-patients impact my Uniform Data System (UDS) reporting?
If there is no treatment or examination that are typical with evaluation and management services (i.e., assessment of health status, examination, medical decision making) provided by the health center during the reporting year

then this individual and encounter are not counted anywhere in the UDS (see also page 22 of the 2020 UDS Manual (PDF - 1.8 MB) for services and persons not reported). (Source: HRSA UDS Novel COVID-19 Reporting).

Health centers will report the count of patients who received the vaccine on the UDS Other Data elements Form, Appendix E. Vaccine only visits/patients will not count toward other UDS tables (such as eCQM's or patient demographics). (Source: See page 22 of the 2020 UDS Manual under sub-header Dispensing or administering medications: "Do not count giving any injection (including for vaccines, allergy shots, or family planning), regardless of education provided at the same time").

Licensing

Q: Can I conduct vaccination activities in parking lots/external areas or at intermittent sites? How do I ensure these are covered in the state license?
The guidance for temporary waivers of licensing requirements that was in place for testing is also applicable for vaccination. AFL 20-30.1 (https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-30.aspx) covers all COVID-19 activities including providing services in parking lots or other external areas, via drive-thru/walk-up, and allows for an intermittent clinic to extend operating hours beyond 40 hours per week. Clinics do not need to submit individual program flexibility requests for the regulations specified in the AFL. The AFL is currently valid through March 1, 2021.

REIMBURSEMENT FOR VACCINE ADMINISTRATION

Q: What reimbursement is available to providers for administering COVID-19 vaccines?
As the federal government is paying for the initial vaccines, there is no provider reimbursement for the COVID-19 vaccine itself at this time. Most payers are currently, or planning to, reimburse for vaccine administration at the Medicare rate (there should be no cost to the patient).

- One dose vaccines: $28.39 upon administration
- Two dose vaccines: $16.94 upon administration of the first dose; $28.39 upon administration of the second

Medi-Cal
For FQHCs, DHCS will pay the applicable Prospective Payment System (PPS) **if the vaccination is administered during an in-person visit that meets the requirements of a billable office visit i**n the clinic setting. If not, the FQHC can bill Medi-Cal FFS as described below. CPCA is engaging with the state regarding other reimbursement/support for FQHCs.

DHCS will carve out the COVID-19 vaccine from Medi-Cal managed care and will reimburse providers under the FFS delivery system for both medical and pharmacy claims. Medi-Cal plans to reimburse the vaccine administration fee at the allowable Medicare rate for claims (medical, outpatient and pharmacy) based on the number of required doses. Providers will bill for administration of the COVID-19 vaccine on a medical, outpatient or pharmacy claim, based on current policy.

FQHCs should NOT start billing for the FFS administration fee until instructed, as DHCS is still making system and operational changes needed to enable adjudication**. Specifically, DHCS needs to set up a billing mechanism that will allow FQHCs to bill in the FFS system.**

- DHCS is seeking federal approval (State Plan Amendment 20-0040) to cover the cost of the vaccine administration for Medi-Cal beneficiaries who are in restricted scope coverage, the COVID-19 Uninsured population and enrollees in Family PACT).
- DHCS is seeking federal approval to pay FQHCs for the vaccine administration fee outside of PPS. (CPCA submitted a letter to the administration requesting full PPS for vaccine administration, the

administration thus far indicates it intends only to pay Medicare FFS rates).
- DHCS is seeking federal approval to pay the pharmacy claims at the Medicare administration rate, which is different than the current pharmacy administration fee.

Access DHCS' policy guidance HERE (last updated Jan. 6, 2021)

Medicare
- Medicare COVID-19 Vaccine Shot Payment: General information, including rates (as above), etc.
- Medicare Billing for COVID-19 Vaccine Shot Administration
- Medicare Coding for COVID-19 Vaccine Shots

Commercial/Private Insurance
In alignment with the CARES Act and CMS guidance, The California Department of Managed Health Care (DMHC) issued guidance December 11 reminding health plans that all qualified, approved COVID-19 vaccines must be provided with **no cost-sharing for health plan enrollees, regardless of whether the enrollee receives the vaccine from an in-network or out-of-network provider**.
- DMHC APL 20-039 – Health Plan Coverage of COVID-19 Vaccines: requires health plans regulated by the Department to cover the administration costs without any cost-sharing to health plan enrollees regardless of whether the vaccines are administered by in-network or out-of-network providers.
- For non-contracted providers, federal law requires health plans to reimburse providers at a "reasonable" rate for the cost of administering qualifying COVID-19 vaccines. Guidance issued by CMS suggests that an example of "reasonable" reimbursement for non-contracted providers would be the Medicare rate for administration of COVID-19 vaccines.
- A patient Fact Sheet is available HERE.

VACCINE DISTRIBUTION, SUPPLY AND STORAGE

Q: Is there a limit to the number of vaccines each community health center receives?
The limit of vaccines is dependent on LA County supply. Health center will receive enough vaccine to immunize their staff, if they are administering the vaccine. DPH will use the survey data for non-vaccinators to ensure that other administering entities will have supply to vaccine their staff. Vaccine ordering is shifting to the CalVax online platform in mid-January. Health centers should have received instructions for log-in.

Q: What is the shelf life for the vaccine?
- Pfizer: 6 months at ultra-low temperature (ULT); 120 hours or 5 days at refrigerated temperature, not reconstituted (FDA fact sheet)
- Moderna: 6 months at -20°C (FDA fact sheet), 30 days refrigerated

Q: How are health care workers and other groups being prioritized for vaccinations?
LA is now on Phase 1a Tier 2. Click here for an updated listing of what groups are being vaccinated, and which are coming up next. While DPH guidelines indicate that vaccinators only vaccinate those in the active tiers, they recognize that a vaccine administrator may have doses at the end of the day that they could use on an individual in a later tier in order to prevent wasted vaccines. CCALAC is advocating for all health center patients to be considered in phases 1b and 1c, which includes essential service workers and patients with underlying conditions. Refer to communication/information **from LADPH** regarding which tier/phase we are in locally and who is eligible to receive vaccinations.