# PROVIDER ENROLLMENT WORKSHEET



Use this worksheet to gather information needed ahead of time to complete the online enrollment form on COVIDReadi. As you fill out this worksheet for CDC Provider Agreement Section B, only record affiliated vaccination locations that will receive or administer COVID-19 vaccines.

### DO NOT SUBMIT THIS WORKSHEET TO CDPH.

# **Pre-screening Questions:**

My organization meets the following Phase 1 Enrollment Criteria.

Have storage capacity and can meet these storage and handling requirements: (Nat: This looks like placeholder content)

Can accommodate initial minimum orders of at least 1,000 doses

Report dose-level data within 24 hours of vaccination and doses inventory daily to the national Vaccine Finder website

Can accommodate the temperature requirements of either ultra-cold storage for vaccines or can obtain dry ice

Have staffing levels and capacities to begin vaccination shortly after vaccine receipt including capacities to

Use social distancing and infection control guidelines

Coordinate delivery of two-dose COVID-19 vaccine within 21 or 28 days apart

Deliver vaccines during peak influenza season or disease outbreak

Report dose-level data within 24 hours of vaccination

Comply with state and federal requirements for COVID-19 providers

# **Required training**

My organization's providers and key practice staff (overseeing or handling COVID-19 vaccines) have completed all **required training** for successful participation in the California COVID-19 Vaccination Program.

# CDC COVID-19 Vaccination Program Provider Agreement



### Please complete Sections A and B of this form as follows:

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement (Section A) **in COVIDReadi.** In addition, the CDC COVID-19 Vaccination Program Provider Profile Information (Section B) must be completed for each vaccination location (Location) covered under the Organization listed in Section A.

# Section A. COVID-19 Vaccination Program Provider Requirements and Legal Agreement

Organization identific	ation			
Organization's legal name:				
Number of affiliated vaccination	n locations covered by this agreem	ent:		
Organization telephone:				
Email:	(must be monito	red and will serve as d	edicated contact method for the	COVID-19 Vaccination Program)
Street address 1:			Street address 2:	
City:	County:		State:	ZIP:
Responsible officers				
For the purposes of this agreem	ent, in addition to Organization, Re ement. The individuals listed below			
Chief Medical Officer (or	Equivalent) Information			
Last name:	Fi	irst name:		Middle initial:
Title:	Li	icensure state:	Licensure number:	
Telephone:	E	mail:		
Street address 1:			Street address 2:	
City:	County:		State:	ZIP:
Chief Executive Officer (	or Chief Fiduciary) Informati	on		
Last name:	Fi	irst name:		Middle initial:
Telephone:	E	mail:		
Street address 1:			Street address 2:	
City	County:		State	7ID-

#### **Agreement requirements**

I understand this is an agreement between Organization and CDC. This program is part of a collaboration under the relevant state, local, or territorial immunization program's cooperative agreement with CDC.

To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:

- 1. Organization must administer COVID-19 vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).<sup>1</sup>
- 2. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine Administration Data) for reporting can be found on CDC's website.<sup>2</sup> Organization must submit Vaccine Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.<sup>2</sup> Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
- 3. Organization must not sell or seek reimbursement for COVID-19 vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.

**4.** Organization must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees or coverage status. Organization may seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient. Organization may not seek any reimbursement, including through balance billing, from the vaccine recipient.

5. Before administering COVID-19 vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.

- 6. Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines.<sup>3</sup>
- 7. Organization must comply with CDC requirements for COVID-19 vaccine management. Those requirements include the following:
  - a) Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 vaccine;
  - **b**) Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance in CDC's Vaccine Storage and Handling Toolkit<sup>4</sup>;
  - c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;
  - d) Organization must monitor and comply with COVID-19 vaccine expiration dates; and
  - e) Organization must preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
- 8. Organization must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.

9. Organization must comply with all federal instructions and timelines for disposing of COVID-19 Vaccine and adjuvant, including unused doses.<sup>5</sup>

**10.** Organization must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or

http://vaers.hhs.gov/contact.html).

11. Organization must provide a completed COVID-19 vaccination record card to every COVID-19 vaccine recipient, the adult caregiver

accompanying the recipient, or other legal representative. Each COVID-19 vaccine shipment will include COVID-19 vaccination record cards.

- **12. a)** Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 vaccine.
  - b) Organization must administer COVID-19 vaccine in compliance with all applicable state and territorial vaccination laws.

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

<sup>5</sup> The disposal process for remaining unused COVID-19 vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.

<sup>&</sup>lt;sup>1</sup> www.cdc.gov/vaccines/hcp/acip-recs/index.html

<sup>&</sup>lt;sup>2</sup> www.cdc.gov/vaccines/programs/iis/index.html

<sup>&</sup>lt;sup>3</sup> www.cdc.gov/vaccines/pandemic-guidance/index.html

<sup>&</sup>lt;sup>4</sup> https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

<sup>&</sup>lt;sup>6</sup> See Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15, 198, 15, 202 (March 17, 2020).

By signing the form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 vaccine understand and will comply with the agreement requirements listed above and that the information provided in sections A and B is true.

The above requirements are material conditions of payment for COVID-19 vaccine administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare, Medicaid, and the Health Resources and Services Administration COVID-19 Uninsured Program. Reimbursement for administering COVID-19 vaccine is not available under any federal healthcare benefit program if Organization fails to comply with these requirements with respect to the administered COVID-19 vaccine dose. Each time Organization submits a reimbursement claim for COVID-19 vaccine administration to any federal healthcare benefit program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose.

Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

By entering Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.<sup>6</sup>

### Section B. CDC COVID-19 Vaccination Program Provider Profile Information If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, collect information for each location. Each

If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, collect information for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

Organization identifi	ication for individual l	ocations				
Organization location name:			n location order COVID-19 vaccir	ne for this site?		
		☐ If YES; provide Organiz	ation name:			
Contact information	for location's primary					
				Middle initial:		
Last name:		First name:	First name:			
Telephone:		Email:	Email:			
Contact information	for location's backup	COVID-19 vaccine coo	rdinator			
Last name:		First name:	First name:			
Telephone:		Email:				
Organization location	n address for receipt o	of COVID-19 vaccine s	ninmonts			
organization locatio	in address for receipt o	in covid-19 vaccine si	inpinents			
Street address 1:			Street address 2:			
City:	ity: County:		State:	ZIP:		
Telephone:		Fax:				
Organization address	s of location where CO	VID-19 vaccine will b	e administered			
(if different from receiv						
Street address 1:			Street address 2:			
City:	County:		State:	ZIP:		
	<b>,</b>	_				
Telephone:		Fax:				
			COVID-19 vaccine ship			
Monday	Tuesday	Wednesday	Thursday	Friday		
AM:	AM:	AM:	AM:	AM:		
PM:	PM:	PM:	PM:	PM:		
For official use only:						
VTrckS ID for this location, if a	pplicable: Va	ccines for Children (VFC) PIN, if	applicable: IIS ID,	if applicable:		
Unique COVID-19 Organizatio	on ID (from Section A):		Unique Location ID**:			

\*\*The jurisdiction's immunization program is required to create an additional unique Location ID for each location completing Section B. The number should include the awardee jurisdiction abbreviation. For example, if an organization (Section A) in Georgia (e.g., GA123456A) has three locations (main location plus two additional) completing section B, they could be numbered as GA123456B1, GA123456B2, and GA123456B3).

COVID-19 vaccination provider type for this location (select one)				
□ Commercial vaccination service provider	Medical practice – other specialty			
□ Corrections/detention health services	🗌 Pharmacy – chain			
$\Box$ Health center – community (non-Federally Qualified Health Center/	🗌 Pharmacy – independent			
non-Rural Health Clinic)	$\Box$ Public health provider – public health clinic			
$\Box$ Health center – migrant or refugee	Public health provider – Federally Qualified Health Center			
Health center – occupational	Public health provider – Rural Health Clinic			
Health center – STD/HIV clinic	$\Box$ Long-term care – nursing home, skilled nursing facility, federally			
$\Box$ Health center – student	certified			
$\Box$ Home health care provider	$\Box$ Long-term care – nursing home, skilled nursing facility, non-federally			
□ Hospital	certified			
$\Box$ Indian Health Service	Long-term care – assisted living			
$\Box$ Tribal health	Long-term care – intellectual or developmental disability			
Medical practice – family medicine	$\Box$ Long-term care – combination (e.g., assisted living and nursing home			
Medical practice – pediatrics	in same facility)			
Medical practice – internal medicine	🗌 Urgent care			
Medical practice – OB/GYN	□ Other (Specify: )			

### **Setting(s) where this location will administer COVID-19 vaccine** (select all that apply)

Child care or day care facility	Pharmacy
College, technical school, or university	Public health clinic (e.g., local health department)
Community center	School (K – grade 12)
Correctional/detention facility	Shelter
Health care provider office, health center, medical practice, or	Temporary or off-site vaccination clinic – point of dispensing (POD)
outpatient clinic	Temporary location – mobile clinic
Hospital (i.e., inpatient facility)	Urgent care facility
In home	Workplace
Long-term care facility (e.g., nursing home, assisted living,	Other (Specify:
independent living, skilled nursing)	

### Approximate number of patients/clients routinely served by this location

Number of children 18 years of age and younger:	(Enter "0" if the location does not serve this age group.)	Unknown
Number of adults 19 – 64 years of age:	(Enter "0" if the location does not serve this age group.)	Unknown
Number of adults 65 years of age and older:	(Enter "0" if the location does not serve this age group.)	Unknown
Number of unique patients/clients seen per week on average:		Unknown
Not applicable (e.g. for commercial vaccination service prov	(idors)	

Not applicable (e.g., for commercial vaccination service providers)

### Influenza vaccination capacity for this location

Number of influenza vaccine doses administered during the peak week of the 2019–20 influenza season:			Unknown
(F , "0":C ; C			

(Enter "0" if no influenza vaccine doses were administered by this location in 2019-20.)

### **Population(s) served by this location** (select all that apply)

General pediatric population	Pregnant women
General adult population	Racial and ethnic minority groups
Adults 65 years of age and older	Tribal communities
Long-term care facility residents (nursing home, assisted living, or	People who are incarcerated/detained
independent living facility)	People living in rural communities
Health care workers	People who are underinsured or uninsured
Critical infrastructure/essential workers (e.g., education, law	People with disabilities
enforcement, food/agricultural workers, fire services)	People with <u>underlying medical conditions</u> * that are risk factors for
Military – active duty/reserves	severe COVID-19 illness
Military – veteran	Other people at higher risk for COVID-19 (Specify: )
People experiencing homelessness	

# Does your organization currently report vaccine administration data to the state, local, or territorial immunization information system (IIS)?

If YES [List IIS Identifier: ]

If **NOT**, please explain planned method for reporting vaccine administration data to the jurisdiction's IIS or other designated system as required:

#### If NOT APPLICABLE, please explain:

Estimated number of 10-dose multidose vials (MDVs) your location is able to store during peak vaccination periods (e.g., during back-to-school, influenza season) at the following temperatures:				
Refrigerated	(2°C to 8°C):	No capacity <b>OR</b>	Approximately	additional 10-dose MDVs

Frozen	(-15°C to -25°C):	No capacity <b>OR</b>	Approximately	additional 10-dose MDVs
Ultra-frozer	n (-60°C to -80°C):	No capacity <b>OR</b>	Approximately	additional 10-dose MDVs

#### Storage unit details for this location

List brand/model/type of storage units to be used for storing COVID-19 vaccine at this location:

Medical/pharmacy director or location's vaccine coordinator must attest that each unit listed will maintain the appropriate temperature range indicated above.

1.	 	 	
2.			
3.			
4.	 	 	
5.			

### Providers practicing at this facility (additional spaces for providers at end of form)

Instructions: List below all licensed healthcare providers at this location who have prescribing authority (i.e., MD, DO, NP, PA, RPh) or will have oversight of the handling or administration of COVID-19 vaccines.

Provider Name	Title	License No.

# **CALIFORNIA-SPECIFIC INFORMATION FOR THIS LOCATION**

## **Temperature monitoring equipment**

#### Fridge thermometer type

Digital data logger Networked continuous temperature monitoring system Min-Max thermometer Other, please specify:

Thermometer model and serial number:

Networked continuous temperature

**Ultra-Low Freezer thermometer type** 

Min-Max thermometer

Digital data logger

monitoring system

Other, please specify:

Thermometer model and serial number:

Calibration expiration date: \_\_\_\_\_

Calibration expiration date: \_\_\_\_\_

### Freezer thermometer type

Digital data logger Networked continuous temperature monitoring system Min-Max thermometer Other, please specify:

Thermometer model and serial number:

Calibration expiration date: \_\_\_\_\_

## **California Vaccine Programs**

### Are you currently enrolled in any of the programs listed below?

California Vaccines for Children program: Provider Identification Number (PIN):

Receiving state influenza vaccines directly

Location administered H1N1 vaccines

## **Estimated Health Care Worker Populations served by this location**

Select all that apply

**High risk:** contact with patients with known or suspected COVID-19; contact with patients at high risk of severe COVID-19

**Moderate risk:** contact with patients who may be infected with COVID-19; but are not known or suspected to be ill

Low risk: no or physically distant contact with patients