

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 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 identification

Organization's legal name:

Number of affiliated vaccination locations covered by this agreement:

Organization telephone:

Email: *(must be monitored and will serve as dedicated 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 agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signatures after reviewing the agreement requirements.

Chief Medical Officer (or Equivalent) Information

Last name:

First name:

Middle initial:

Title:

Licensure state:

Licensure number:

Telephone:

Email:

Street address 1:

Street address 2:

City:

County:

State:

ZIP:

Chief Executive Officer (or Chief Fiduciary) Information

Last name:

First name:

Middle initial:

Telephone:

Email:

Street address 1:

Street address 2:

City:

County:

State:

ZIP:

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).¹
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.²
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.²
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.³
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*;
 - 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.⁵
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.

¹ www.cdc.gov/vaccines/hcp/acip-recs/index.html

² www.cdc.gov/vaccines/programs/iis/index.html

³ www.cdc.gov/vaccines/pandemic-guidance/index.html

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

⁵ 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.

⁶ 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 this 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.⁶

Organization Medical Director (or equivalent)

Last name: _____ First name: _____ Middle initial: _____

Signature: _____ Date: _____

Chief Executive Officer (chief fiduciary role)

Last name: _____ First name: _____ Middle initial: _____

Signature: _____ Date: _____

For official use only:

IIS ID, if applicable: _____ Application Received

Unique COVID-19 Organization ID (Section A)*: _____

**The jurisdiction's immunization program is required to create a unique COVID-19 ID for the organization named in Section A that includes the awardee jurisdiction abbreviation (e.g., an organization located in Georgia could be assigned "GA123456A." This ID is needed for CDC to match Organizations (Section A) with one or more Locations (Section B). This unique identifier is required even if there is only one location associated with an organization.*

Section B. CDC COVID-19 Vaccination Program Provider Profile Information

Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

Organization identification for individual locations

Organization location name:

Will another Organization location order COVID-19 vaccine for this site?

Provide the Organization name:

Contact information for location's primary COVID-19 vaccine coordinator

Last name:

First name:

Middle initial:

Telephone:

Email:

Contact information for location's backup COVID-19 vaccine coordinator

Last name:

First name:

Middle initial:

Telephone:

Email:

Organization location address for receipt of COVID-19 vaccine shipments

Street address 1:

Street address 2:

City:

County:

State:

ZIP:

Telephone:

Fax:

Organization address of location where COVID-19 vaccine will be administered

(if different from receiving location)

Street address 1:

Street address 2:

City:

County:

State:

ZIP:

Telephone:

Fax:

Days and times vaccine coordinators are available for receipt of COVID-19 vaccine shipments

	Monday	Tuesday	Wednesday	Thursday	Friday
AM:		AM:	AM:	AM:	AM:
PM:		PM:	PM:	PM:	PM:

For official use only:

VTckS ID for this location, if applicable:

Vaccines for Children (VFC) PIN, if applicable:

IIS ID, if applicable:

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

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

- | | |
|--|---|
| <ul style="list-style-type: none"> Child care or day care facility College, technical school, or university Community center Correctional/detention facility Health care provider office, health center, medical practice, or outpatient clinic Hospital (i.e., inpatient facility) In home Long-term care facility (e.g., nursing home, assisted living, independent living, skilled nursing) | <ul style="list-style-type: none"> Pharmacy Public health clinic (e.g., local health department) School (K – grade 12) Shelter Temporary or off-site vaccination clinic – point of dispensing (POD) Temporary location – mobile clinic Urgent care facility Workplace Other (Specify: _____) |
|--|---|

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. If unknown, enter UNK)

Number of adults 19 – 64 years of age: _____ (Enter "0" if the location does not serve this age group. If unknown, enter UNK)

Number of adults 65 years of age and older: _____ (Enter "0" if the location does not serve this age group. If unknown, enter UNK)

Number of unique patients/clients seen per week on average: _____ (If unknown, enter UNK)

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: _____
 (Enter "0" if no influenza vaccine doses were administered by this location in 2019-20. If unknown, enter UNK.)

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

- | | |
|---|--|
| <ul style="list-style-type: none"> General pediatric population General adult population Adults 65 years of age and older Long-term care facility residents (nursing home, assisted living, or independent living facility) Health care workers Critical infrastructure/essential workers (e.g., education, law enforcement, food/agricultural workers, fire services) Military – active duty/reserves Military – veteran People experiencing homelessness | <ul style="list-style-type: none"> Pregnant women Racial and ethnic minority groups Tribal communities People who are incarcerated/detained People living in rural communities People who are underinsured or uninsured People with disabilities People with <u>underlying medical conditions</u>* that are risk factors for severe COVID-19 illness Other people at higher risk for COVID-19 (Specify: _____) |
|---|--|

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

[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 above:

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): Capacity	<u>Approximately</u>	<u>additional 10-dose MDVs</u>
Frozen (-15°C to -25°C): Capacity	<u>Approximately</u>	<u>additional 10-dose MDVs</u>
Ultra-frozen (-60°C to -80°C): Capacity	<u>Approximately</u>	<u>additional 10-dose MDVs</u>

Storage unit details for this location

- List brand/model/type of storage units to be used for storing COVID-19 vaccine at this location:
1. _____
 2. _____
 3. _____
 4. _____
 5. _____

I attest that each unit listed will maintain the appropriate temperature range indicated above (*please sign and date*):

Medical/pharmacy director or location’s vaccine coordinator signature:

Date: _____

