

CDC COVID-19 Vaccination Program Urban Indian Organization Agreement - Vaccines Coordinated through IHS



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

The Centers for Disease Control and Prevention (CDC) greatly appreciates the Urban Indian Organization’s (Organization) participation in the CDC COVID-19 Vaccination Program being coordinated through the Indian Health Service (IHS). The organizations that are eligible to execute this Agreement must meet the definition at 25 U.S.C. § 1603(29) and receive funding from IHS under the Indian Health Care Improvement Act (IHCA). Organization may enroll in the CDC COVID-19 Vaccination Program coordinated through IHS, or alternatively through the relevant state or local jurisdiction. Organization must complete this Agreement if it is enrolling in the CDC COVID-19 Vaccination Program coordinated through IHS. 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). If Organization has multiple clinic or other vaccination locations where COVID-19 vaccines will be administered, the *CDC COVID-19 Vaccination Program Provider Profile Information* (Section B) must be completed for each location.

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 number:	Email (<i>must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program</i>):	
Organization address:		
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 Chief Medical Officer and Chief Executive Officer listed below must provide their signature after reviewing the Agreement requirements.		
Chief Medical Officer (or Equivalent) Information		
Last name	First name	Middle initial
Title	Licensure (state and number)	
Telephone number:	Email:	
Address:		
Chief Executive Officer (or Chief Fiduciary) Information		
Last name	First name	Middle initial

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Telephone number:	Email:	
Address:		
Primary Organization Contact for CDC COVID-19 Vaccination Program		
Last name	First name	Middle initial
Title		
Telephone number:	Email:	
Address:		

AGREEMENT REQUIREMENTS	
<p>I understand this is an Agreement between Organization and CDC. This program is part of a collaboration between IHS and CDC.</p> <p>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:</p>	
1.	<p>Organization must administer COVID-19 Vaccine in accordance with all requirements, recommendations, and guidance of CDC and CDC’s Advisory Committee on Immunization Practices (ACIP).¹ However, Organization may deviate from CDC/ACIP prioritization groups to immunize under other priorities that meet the spirit of the CDC/ACIP designated priorities within allocations of COVID-19 Vaccine received. Records of any such prioritization decisions shall be maintained for at least six years, and be provided, upon request, to CDC, IHS, and relevant jurisdictions.</p>
2.	<p>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 IHS. Details of required information (collectively, Vaccine Administration Data) for reporting can be found on CDC’s website².</p> <p>Organization must submit Vaccine Administration Data to IHS according to CDC documentation and data requirements.³ In addition to submitting the data to IHS, Organization also may report this data to state or local jurisdiction Immunization Information Systems (IIS).</p> <p>Organization must preserve the vaccine recipients’ records for at least six (6) years following vaccination, or longer if required by applicable law. Such records must be made available to any federal (including IHS), state, local, or tribal public health department to the extent authorized by law.</p>

¹ <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>. 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.

² <https://www.cdc.gov/vaccines/programs/iis/index.html>

³ <https://www.cdc.gov/vaccines/programs/iis/index.html>

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3.	<p>Organization, as a result of enrolling in the CDC COVID-19 Vaccination Program coordinated through IHS, must order COVID-19 Vaccine through IHS.</p> <p>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. Organization will not sell or seek reimbursement for administration of COVID-19 Vaccine doses to an individual.</p>
4.	<p>Organization must administer COVID-19 Vaccine regardless of the vaccine recipient’s ability to pay COVID-19 Vaccine administration fees or coverage status. Organization must ensure that any federal funding, including from IHS, that it intends to use for the costs of administering the COVID-19 Vaccine is authorized for that purpose. Furthermore, Organization may use funding received from IHS under its IHCA contracts and grants only to administer the vaccine to eligible urban Indians. For vaccines administered to patients who are not eligible urban Indians, Organization must use other, non-IHS funds that are authorized for that purpose. Organization may seek reimbursement, to the extent authorized, 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.</p>
5.	<p>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 (if applicable), or other legal representative (if applicable). If the EUA fact sheet or VIS is available electronically, Organization may provide it in electronic form to the recipient, adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable), if such person agrees to accept it electronically in the file format offered by Organization.</p>
6	<p>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:⁴</p>
7.	<p>Organization must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following:</p> <ul style="list-style-type: none"> 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 Toolkit⁵, which will be updated to include specific information related to COVID-19 Vaccine; b) Organization must monitor vaccine-storage-unit temperatures 24 hours a day using equipment and practices that comply with guidance located in CDC’s Vaccine Storage and Handling Toolkit⁶; 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 six (6) years, or longer if required by state or local law
8.	<p>Organization must report to IHS the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by CDC</p>

⁴ <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>

⁵ <https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html>

⁶*Id.*

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9.	Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses. ⁷
10.	<p>Organization must report the following adverse events (AEs) after vaccination, and other AEs if later revised by CDC, to the Vaccine Adverse Event Reporting System (VAERS):⁸</p> <ul style="list-style-type: none"> a. Vaccination administration errors, whether or not associated with an AE; b. Severe COVID-19 illness (e.g., resulting in hospitalization); c. Serious AEs regardless of causality. Serious AEs are defined as: <ul style="list-style-type: none"> i. Death; ii. A life-threatening AE; iii. Inpatient hospitalization or prolongation of existing hospitalization; iv. Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; v. A congenital anomaly/birth defect; and vi. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above. <p>Organization will also report any additional select AEs and/or any revised safety reporting requirements per FDA’s conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under EUA.</p> <p>Organization is also encouraged to report to VAERS any AEs considered to be clinically significant.</p> <p>When completing the VAERS report, Organization will enter “IHS” into item #26 (Immunization Project Report Number). This identifies the reporting organization as part of the Indian Health System comprising Federal, Tribal, and Urban programs for purposes of analyzing, monitoring, and reporting on patient safety.</p>
11.	Organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable). Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.
12.	<ul style="list-style-type: none"> 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 federal and state vaccination laws. c) Organization must comply with applicable patient consent requirements for administering the COVID-19 Vaccine.

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 program, including but not limited to Medicare, Medicaid,

⁷ The disposal process for remaining unused COVID-19 Vaccine and adjuvant may be different from the process for other vaccines; unused vaccines (but still usable—e.g., unexpired and properly maintained) must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.

⁸ <https://vaers.hhs.gov/reportevent.html>

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and the Health Resources & Services Administration COVID-19 Uninsured Program (for uninsured patients who are not eligible urban Indians and who receive the vaccine). Reimbursement for administering COVID-19 Vaccine is not available under any federal healthcare 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 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.

This Agreement expires at the end of CDC’s COVID-19 Vaccination Program or IHS’s coordination of the CDC COVID-19 Vaccination Program for Organization.

CDC may terminate this Agreement with two weeks written notice.

Organization may cease its participation in the CDC COVID-19 Vaccination Program. To do so, Organization must provide written notice to CDC and IHS no later than two weeks before Organization wishes to end its participation. During that period, Organization must comply with Agreement and Organization will not receive any further deliveries of COVID-19 Vaccine.

Having chosen to participate in the CDC COVID-19 Vaccination Program coordinated through IHS, Organization certifies that it will not sign participation agreements in the CDC COVID-19 Vaccination Program through a state or local jurisdiction.

By entering Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation (FAR). This Agreement is separate from any other FAR contract that Organization has with the federal government, including IHS.

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.⁹

Chief Medical Officer (or Equivalent)

Last name	First name	Middle initial
Signature:		Date:

Chief Executive Officer (or Chief Fiduciary)

Last name	First name	Middle initial
Signature:		Date:

⁹ See Pub. L. No. 109-148, Public Health Service Act § 319F-3 and § 319F-4, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

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For official use only:

Vaccines for Children (VFC) PIN, if applicable: _____ Other PIN (e.g., state, 317): _____

IIS ID, if applicable: _____

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

***IHS will create a unique COVID-19 ID for Organization. This ID is needed for CDC and IHS to match Organization with one or more Locations (Section B). These unique identifiers are required even if there is only one location associated with 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 more than one 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? <input type="checkbox"/> Yes; provide Organization name: _____ <input type="checkbox"/> No		
CONTACT INFORMATION FOR LOCATION'S PRIMARY COVID-19 VACCINE COORDINATOR				
Last name:		First name:	Middle initial:	
Telephone:		Email:		
CONTACT INFORMATION FOR LOCATION'S BACK-UP 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:
<i>For official use only:</i> Vaccines for Children (VFC) PIN, if applicable: _____ IIS ID, if applicable: _____ Unique COVID-19 Organization ID (from Section A): _____ Unique Location ID**: _____ **IHS will create an additional unique Location ID for each location completing Section B.				
COVID-19 VACCINATION PROVIDER TYPE FOR THIS LOCATION				
<input type="checkbox"/> Urban Indian Organization that receives funding from IHS under the IHCA				

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SETTING(S) WHERE THIS ORGANIZATION WILL ADMINISTER COVID-19 VACCINE (SELECT ALL THAT APPLY)

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

- Unknown

POPULATION(S) SERVED BY THIS LOCATION (SELECT ALL THAT APPLY)

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- 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
- Pregnant women
- Racial and ethnic minority groups
- Tribal communities
- People who are incarcerated/detained
- People living in rural communities
- People who are under-insured or uninsured
- People with disabilities
- People with underlying [medical conditions](#)* 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 OR LOCAL IMMUNIZATION INFORMATION SYSTEM (IIS)?

- Yes [List IIS Identifier: _____]
- No
- Not applicable

ESTIMATED NUMBER OF 10-DOSE MULTIDOSE VIALS (MDVs) YOUR LOCATION IS ABLE TO STORE DURING PEAK VACCINATION PERIODS (E.G., DURING BACK-TO-SCHOOL OR INFLUENZA VACCINE SEASON) AT THE FOLLOWING TEMPERATURES:

Refrigerated (2°C to 8°C):	<input type="checkbox"/> No capacity	<input type="checkbox"/> Approximately _____ additional 10-dose MDVs
Frozen (-15° to -25°C):	<input type="checkbox"/> No capacity	<input type="checkbox"/> Approximately _____ additional 10-dose MDVs
Ultra-frozen (-60° to -80°C):	<input type="checkbox"/> No capacity	<input type="checkbox"/> 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:

1. Example: CDC & Co/Red series two-door/refrigerator
- 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

PROVIDERS PRACTICING AT THIS LOCATION *(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).

Provider Name	Title	License No.
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* <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-increased-risk.html>

