

CDC COVID-19 Vaccination Program Tribal Health Program 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 Tribal Health Program’s participation in the CDC COVID-19 Vaccination Program being coordinated through the Indian Health Service (IHS). The Tribal Health Programs that are permitted to execute this Agreement are defined at 25 U.S.C. § 1603(25). Tribal Health Program may enroll in the CDC COVID-19 Vaccination Program coordinated through IHS, or alternatively through the relevant state or local jurisdiction. Tribal Health Program must complete this Agreement if it is enrolling in the CDC COVID-19 Vaccination Program coordinated through IHS. Tribal Health Program’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 Tribal Health Program has multiple hospitals or clinics where COVID-19 vaccine will be administered, the *CDC COVID-19 Vaccination Program Provider Profile Information* (Section B) must be completed for each hospital or clinic through which it will be administered.

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

TRIBAL HEALTH PROGRAM IDENTIFICATION		
Tribal Health Program’s legal name:		
Number of affiliated hospitals or clinics covered by this Agreement: _____		
Telephone number:	Email (<i>must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program</i>):	
Address:		
RESPONSIBLE OFFICERS		
For the purposes of this Agreement, in addition to Tribal Health Program, Responsible Officers named below will also be accountable for compliance with the conditions specified in this Agreement. The Responsible Officers 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 Tribal Health Program Contact for CDC COVID-19 Vaccination Program

Last name	First name	Middle initial
Title		
Telephone number:	Email:	
Address:		

AGREEMENT REQUIREMENTS

I understand this is an agreement between Tribal Health Program and CDC. This program is a part of collaboration between IHS and CDC.

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

- | | |
|-----------|---|
| 1. | Tribal Health Program 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, Tribal Health Program 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. |
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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. Tribal Health Program must monitor such identified guidance for updates. Tribal Health Program must comply with such updates.

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<p>2.</p>	<p>Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Tribal Health Program 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>Tribal Health Program must submit Vaccine Administration Data to IHS according to CDC documentation and data requirements.³ In addition to submitting the data to IHS, Tribal Health Program also may report this data to state or local jurisdiction Immunization Information Systems (IIS).</p> <p>Tribal Health Program 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>
<p>3.</p>	<p>Tribal Health Program, as a result of enrolling in the CDC COVID-19 Vaccination Program coordinated through IHS, must order COVID-19 Vaccine through IHS.</p> <p>Tribal Health Program 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 Tribal Health Program. Tribal Health Program will not sell or seek reimbursement for administration of COVID-19 Vaccine doses to an individual.</p>
<p>4.</p>	<p>Tribal Health Program must administer COVID-19 Vaccine regardless of the vaccine recipient’s ability to pay COVID-19 Vaccine administration fees or coverage status. Tribal Health Program 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 and, if applicable, for services to non-beneficiaries. Tribal Health Program may seek reimbursement, to the extent authorized, from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient. Tribal Health Program may not seek any reimbursement, including through balance billing, from the vaccine recipient.</p>
<p>5.</p>	<p>Before administering COVID-19 Vaccine, Tribal Health Program 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, Tribal Health Program 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 Tribal Health Program.</p>
<p>6</p>	<p>Tribal Health Program’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>
<p>7.</p>	<p>Tribal Health Program must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following:</p> <p>a) Tribal Health Program 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</p>

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

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

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

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	<p>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;</p> <p>b) Tribal Health Program must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC’s Vaccine Storage and Handling Toolkit⁶;</p> <p>c) Tribal Health Program must comply with each relevant jurisdiction’s immunization program guidance for dealing with temperature excursions;</p> <p>d) Tribal Health Program must monitor and comply with COVID-19 Vaccine expiration dates; and</p> <p>e) Tribal Health Program 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.</p>
8.	Tribal Health Program 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.
9.	Tribal Health Program must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses. ⁷
10.	<p>Tribal Health Program 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>Tribal Health Program 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>Tribal Health Program is also encouraged to report to VAERS any AEs considered to be clinically significant.</p> <p>When completing the VAERS report, Tribal Health Program will enter “IHS” into item #26 (Immunization Project Report Number). This identifies the reporting Tribal Health Program as part of the Indian Health</p>

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

⁶ *Id.*

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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	System comprising Federal, Tribal, and Urban programs for purposes of analyzing, monitoring, and reporting on patient safety.
11.	Tribal Health Program 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) Tribal Health Program 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) Tribal Health Program must administer COVID-19 Vaccine in compliance with all applicable federal and state vaccination laws. c) Tribal Health Program must comply with applicable patient consent requirements for administering of the COVID-19 Vaccine.

By signing this form, I certify that all relevant officers, directors, employees, and agents of Tribal Health Program 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 Tribal Health Program to any federal healthcare program, including but not limited to Medicare, Medicaid, and the Health Resources & Services Administration COVID-19 Uninsured Program (for uninsured, non-IHS beneficiaries receiving the vaccine). Reimbursement for administering COVID-19 Vaccine is not available under any federal healthcare program if Tribal Health Program fails to comply with these requirements with respect to the administered COVID-19 Vaccine dose. Each time Tribal Health Program submits a reimbursement claim for COVID-19 Vaccine administration to any federal healthcare program, Tribal Health Program 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 Tribal Health Program.

CDC may also terminate this Agreement with two weeks written notice.

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

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

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By entering Agreement, Tribal Health Program does not become a government contractor under the Federal Acquisition Regulation. This Agreement is separate from any Indian Self-Determination and Education Assistant Act compact or contract that Tribal Health Program has with the federal government, including IHS.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Tribal Health Program 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:

For official use only:

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

IIS ID, if applicable: _____

Unique COVID-19 Tribal Health Program ID (Section A) *: _____

***IHS will create a unique COVID-19 ID for Tribal Health Program. This ID is needed for CDC and IHS to match Tribal Health Program (Section A) with one or more hospitals or clinics (Section B). These unique identifiers are required even if there is only one location associated with Tribal Health Program.*

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).

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

Please complete and sign this form for your Tribal Health Program hospital or clinic. If you are enrolling more than one Tribal Health Program hospital or clinic, complete and sign this form for each location. Each individual Tribal Health Program vaccination location must adhere to the requirements listed in Section A.

TRIBAL HEALTH PROGRAM IDENTIFICATION FOR INDIVIDUAL HOSPITAL OR CLINIC				
Tribal Health Program hospital or clinic name:		Will another hospital or clinic 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:		
TRIBAL HEALTH PROGRAM HOSPITAL OR CLINIC ADDRESS FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS				
Street address 1:		Street address 2:		
City:	County:		State:	ZIP:
Telephone:			Fax:	
TRIBAL HEALTH PROGRAM 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 Tribal Health Program 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 FACILITY				

CDC COVID-19 Vaccination Program Provider Profile Information

Tribally-operated health care facility

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

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

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

CDC COVID-19 Vaccination Program Provider Profile Information
