This summary brief from the Indian Health Service (IHS) Tribal Self Governance Advisory Committee (TSGAC) provides an overview of the IHS COVID-19 Vaccination Plan to guide Tribes and Tribal organizations that choose to receive the COVID-19 vaccine through IHS.

TSGAC will continue to track and monitor updated guidance and resources.

December 2, 2020

Background

On November 19, 2020 the IHS released a Dear Tribal Leader Letter and the IHS COVID-19 Pandemic Vaccine Plan detailing how the Agency will prepare for and operationalize when a vaccine is available. The plan provides necessary guidance for IHS federal and tribal health programs (I/Ts) that choose to receive COVID-19 vaccinations through IHS. IHS developed the plan based on the Centers for Disease Control and Prevention's (CDC) COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, while recognizing tribal sovereignty and self-determination.

All I/Ts have the choice on how they receive the COVID-19 vaccine. As of November 25, 2020 337 IHS direct, tribal health programs, and urban Indian organizations (I/T/Us) have chosen to receive a COVID-19 vaccine from the IHS when available. The following IHS COVID-19 Vaccination Distribution list provides the number of I/T/Us who have made the final decision to receive a COVID-19 vaccination from IHS based on IHS Area.

IHS COVID-19 Vaccine Distribution List – IHS, Tribal Health Programs, and Urban Indian Organizations

Area	Number
Alaska Area	2
Albuquerque Area	27
Bemidji Area	35
Billings Area	13
California Area	61
Great Plains Area	28
Nashville Area	26
Navajo Area	27
Oklahoma City Area	62
Phoenix Area	33
Portland Area	21
Tucson Area	2
Total	**337**

The plan is based on current federal guidance and information that has been received, including tribal comments obtained during tribal consultation, initiated through an October 14, 2020 Dear Tribal Leader Letter. IHS will continue to assess and respond to additional vaccine developments and requirements once available.

The COVID-19 vaccine is anticipated to be distributed in three phases, including Phase 1 (limited), Phase 2 (large distribution), and Phase 3 (continued vaccination/shift to routine strategy). Phase 1 will consist of limited doses available per month to achieve coverage in the identified I/T priority populations. CDC has proposed the early vaccine distribution in Phase 1 to include 40 million vaccine doses by the end of December 2020. Phase 2 includes a large number of available doses, which will likely be sufficient to meet the demand to expand beyond initial populations. Phase 3 includes continued vaccination and a shift to routine strategy with a likely excess supply of vaccines. Administration of the vaccine in Phase 2 and Phase 3 will be through commercial and private partners.

The IHS Plan is outlined through seven sections, including: (1) vaccine prioritization; (2) vaccine distribution and allocation; (3) vaccine administration; (4) communication; (5) data management; and (6) safety and monitoring. Each section includes activities, assumptions, and specific actions IHS will take to coordinate vaccine distribution.

Areas of Action

IHS has developed an optional IHS COVID-19 Facility Planning Checklist in Appendix C as a tool for I/Ts in determining readiness for vaccine distribution. The following summarizes the main areas and activities for each section of the IHS Plan. For a copy of the full IHS plan, click here.

1. Vaccine Prioritization

Tribal nations hold the sovereign authority to determine the best for their communities. I/T facilities are able to decide their population estimates, which can be different than their IHS user population and may include non-American Indian/Alaska Natives (AI/AN). The collection and documentation of the population estimates from I/T facilities will advise the vaccine distribution plans. I/Ts will also identify their priority groups to receive the limited vaccine in Phase 1, which may differ from the CDC prioritization groups. Furthermore, I/Ts will coordinate with IHS to verify which vaccine(s) to receive and administer.

As of November 16, the aggregated critical population estimates provided by I/T facilities include the following:

Critical Population	Estimated Population
Healthcare Personnel (direct, non-direct & emergency medical services)	**43,783**
Essential Workers	**120,671**

(other emergency services, law enforcement, food & transportation, teachers, childcare providers)	
Patients in Tribal Long-Term Care Facilities	**76,311**
Elders	**374,411**
Patients at High-Risk for COVID-19	**894,260**
Total Estimation of Vaccinated Individuals	**2,056,347**

The final CDC Advisory Committee on Immunization Practices (ACIP) recommendations for priority populations for vaccination when supplies are limited have not been released as of November 2020. Health Care Personnel have been identified as the likely Phase 1 priority population that will receive the first 20-40 million vaccine doses. Additional priority groups may include essential workers, high-risk individuals with underlying medical conditions, elders, and residents of long-term care facilities and jails.

I/T Facility Key Activities for Prioritization

- I/Ts will develop their own process to determine needs, identify priority groups and ensure equitable distribution. I/T facilities shall identify AI/AN priority groups using guidance from CDC, the Advisory Committee on Immunization Practices (ACIP) (forthcoming), and the National Academies of Sciences Engineering Medicine (NASEM). The final ACIP prioritization recommendations (based on NASEM framework and vaccine performance data) will be made available as a guide.
- I/Ts will provide population estimates to the IHS Area Office Vaccine Point of Contact, who will then submit to the National Supply Service Center (NSSC) point of contact.

2. Vaccine Distribution and Allocation

Information and federal guidance regarding COVID-19 vaccine allocation and distribution is continuing to be developed. I/T facilities that choose to receive the COVID-19 vaccine through IHS, must complete a signed CDC COVID-19 Vaccination Program Agreement – Vaccines Coordinated through IHS. An I/T facility requesting to redistribute vaccines must submit the agreement along with the following information: vaccine and adjuvant, brand, lot expiration, quantity, redistribution location, and the CDC Vaccine Tracking System (VTrcks) ID to the NSSC for approval.

The initial approved COVID-19 vaccines are anticipated to be two-dose series, separated by 21 to 28 days. IHS shall distribute vaccine(s) per the choices of the I/T facilities as the vaccine is available. IHS developed a pre-planning tool to collect key vaccine planning information, which is included in Appendix B of the plan. The allocation will be based on the pre-planning estimates provided by the I/T facilities.

I/T facilities receiving vaccines through IHS should arrange for each vaccinated individual to receive two doses of the same brand. Current recommendations are to fully vaccinate the initial population before progressing to additional target populations. If there are not enough vaccines to distribute to each I/T facility's priority population, the IHS Vaccine Task Force will

determine an equitable distribution methodology. For example, if the total doses needed to service priority populations for all I/T facilities is 100,000 but IHS only has 60,000, then IHS will multiply each facility's requested amount by 60%. Appendix A in the plan provides CDC Phase 1 Planning Scenarios for three different scenarios with specific availability assumptions along with distribution and storage.

Delivery of the COVID-19 vaccine is being contracted by the U.S. government through McKesson's Med Surge Division. The COVID-19 vaccine and ancillary kits are being supplied at no cost to I/T facilities for McKesson delivery of COVID-19 vaccine and ancillary kits. Each ancillary kit will contain supplies to administer 100 vaccine doses including: needles, syringes, alcohol prep pads, surgical masks and face shields, vaccination record cards, vaccine needle guide, and a mixing kit if required (specifics included in IHS plan). The IHS plan provides that for ultra-cold vaccines, the vaccine and supplies will be provided at no cost, but the vaccine will ship directly from the manufacturer to the I/T facility. The National Supply Service Center (NSSC) is working to identify sources for additional supplies and personal protective equipment (PPE) for the vaccine administration that will not be included in the ancillary kits (e.g., sharps containers, bandages, and gloves).

I/T Facility Key Activities for Distribution and Ordering

- Complete a signed CDC COVID-19 Vaccination Program Agreement – Vaccines Coordinated through IHS (for distribution and redistribution).
- During Phase 1, I/T facilities can either receive direct allocation or request vaccine brand specific and quantities from their Area Vaccine Point of Contact (AVPOC) for ultra-cold vaccines. If an I/T does not wish to receive a specific vaccine brand during Phase 1, this should be coordinated with the AVPOC.
- Complete onboarding for inventory and ordering platform. After Phase 1, I/T facilities will order brand specific vaccines through an Operation Warp Speed oracle platform.
- I/T facilities should closely coordinate transport and delivery with the receiving facility to minimize vaccine loss due to the sensitive cold chain requirements.
- Access the ordering portal to be notified of order tracking information through an email or shipping link.

I/T Facility Key Activities for Inventory and Storage

- Vaccine inventory will be the responsibility of the I/T facilities as part of the ordering requirements per CDC.
- I/T facilities will be responsible for vaccine storage per manufacturer recommendations and CDC vaccine storage and handling recommendations.
- I/Ts must ensure cold-chain of the vaccine is maintained. Stand-alone refrigerators and freezers are recommended. If using a dual fridge/freezer, the unit must have dual controls and only the refrigerator may be used to store vaccines. Additionally, I/Ts must identify additional storage units as needed, including ultra-cold, standard

frozen, and refrigerated vaccines once the vaccine arrives at the facility and if transferred to another location.

- I/Ts should be able to accommodate the initial distribution and may need to store all second doses for up to 28 days, if vaccine requires a two-dose series.
- For temperature monitoring, I/Ts shall use continuous data loggers.
- Enlist pharmacies, when possible, for receiving, storing, and monitoring vaccine. Locations without pharmacies will need to meet the minimum requirements for storage and handling per the manufacturer and CDC.

I/T Facility Key Activities for Vaccine Wastage and Disposal

- I/T facilities must report and follow CDC standards for return of unused, wasted, expired vaccines , or redistribution plans for excesses.
- I/T facilities must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant.
- Significant wastage (more than 25% of distributed doses) will be reviewed by NSSC and the I/T facility should discuss with the NSSC the underlying wastage cause and potential solutions to minimize waste.

3. Vaccine Administration

Training of providers for COVID-19 vaccination is critical for safe and effective delivery. The IHS Vaccine Administration Team will provide education and training resources for administration. The Site Vaccine Point of Contact (SVPOC) will be responsible for ensuring completion of training. Consideration for expansion of vaccinating providers including traditional and non-traditional vaccinators (i.e., Community Health Workers, Pharmacy Technicians, Dentists, Optometrists, EMS, Fire/Rescue, Paramedics).

IHS estimates a hypothetical rate that vaccinators will spend 7 minutes to review consent, vaccinate, and document the vaccine administration. The maximum capacity per vaccinator will be approximately 65 vaccinations in an 8-hour day.

The COVID-19 vaccine and ancillary supplies will be acquired and distributed by the federal government at no cost to I/T facilities. Only a charge for an administration fee is eligible for third-party billing reimbursement. The Vaccine Administration Team is working to identify guidance and resources from the Centers for Medicare and Medicaid Services (CMS) for potential billing of vaccine administration fees. Medicaid reimbursement for administration will be state-by-state specific.

I/T Facility Key Activities for Vaccine Administration

- I/Ts should take into consideration the IHS hypothetical rate for vaccinators to assess capacity.
- Ensure brand consistency in multi-dose vaccine series, including ordering appropriate brands for series, or keeping the second dose on reserve.

- Identify potential first and second dose vaccination events (e.g. walk-up, drive-up/drive through) and potential locations (e.g., outdoor parking lots, community centers, Tribal building/centers, school gymnasiums, or home visits) following social distancing and mask wearing.

4. Communication

Development of a communications plan before and during the vaccination distribution will be critical to anticipate and respond to the needs of different groups. The purpose of the IHS communication plan will be to promote the risks and benefits of the vaccine, dismiss misinformation and address safety concerns. The communication plan will use culturally appropriate messages and materials based on the current influenza campaign model. The vaccine information distribution plan should include a variety of settings in coordination with influences from internal and external leaders (e.g., tribal leaders, tribal elders, traditional healers, public health practitioners, and health providers).

5. Data Management

The data management for COVID-19 vaccine administration will build on existing platforms and incorporate new platforms. CDC has identified required data elements for I/T facilities to comply, which is outlined in Appendix D of the plan.

CDC and Operation Warp Speed Data Platforms

- CDC Immunization Gateway (IZ Gateway) – facilitates secure electronic messaging of vaccination records.
- CDC Immunization Clearinghouse (IZ Clearinghouse) – a clearinghouse for centralized immunization data collection repository.
- CDC Data Lake – a catalogue of COVID-19 vaccine-related data sources to be used to assist in ordering, distribution, coverage, and uptake.
- CDC Vaccine Administration Management System (VAMS) – cloud-based application that provides an option to plan and fulfillment of mass vaccine administrations.
- CDC Vaccine Tracking System (VTrckS) – centralized vaccine ordering platform.
- Operation Warp Speed Tiberius – provides a COVID-19 vaccine distribution planning, tracking, modeling, and analysis.

I/T Facility Key Activities for Data Management of Vaccine Distribution

- Vaccine records must be maintained for at least 6 years following vaccination or longer if required by law.
- Report standard data practices for immunization data, including IHS reporting status.
- Report barriers to data IHS reporting.
- For Tribal Health Program facilities with HealthShare 2017, Certified Health IT (CHIT) 2015 and current immunization patches installed: (1) document vaccine administration in RPMS/EHR per usual process; and (2) report daily vaccine administration data via

Health Level Seven (HL7) version 2.5.1 to the National Data Warehouse (NDW), which will be transferred to the CDC Immunization Clearinghouse.

- For Tribal Health Programs *without* HealthShare 2017, Certified Health IT (CHIT) 2015 and current immunization patches installed: upgrade necessary software for data transmission to the IHS Aggregate services (Windows 2016, HealthShare 2017, RPMS/EHR 2015 CHIT software patches, immunization patches, and AIX version 7.2).
- For non-RPMS/EHR users: (1) document vaccine administration in health record; and (2) report daily vaccine administration via HL7 to the NDW. It is option for non-RPMS/EHR users to document vaccine administration in the CDC Vaccine Administration Management (VAMS) application.
- For vaccine documentation for employees, all I/Ts are required to report vaccine administration to CDC. Tribal Health Programs must document vaccine administration in VAMS for employees and document vaccine administration for employees in RPMS or COTS as appropriate.

6. Safety and Monitoring

The CDC COVID-19 Vaccination Program Provider Agreement requires vaccination providers to report adverse events following vaccination. Anyone can submit an adverse report to the Vaccine Adverse Events Reporting System (VAERS), which can identify "signals" of potential safety issues that will required additional investigation. The following should be reported in VAERS: vaccination administration errors (whether or not associated with an adverse event), severe COVID-19 illness, death, life-threatening adverse event, hospitalization, disruption of da-to-day functions, congenital anomaly/birth defect, and medical events that jeopardize the patient.

IHS COVID-19 Vaccine Task Force

The IHS COVID-19 Vaccine Task Force (VTF) is leading the Agency's COVID-19 activities under the Headquarters Incident Command Structure (ICS). The VTF will guide the development of action plans through six teams. The six teams are focused on vaccine administration, prioritization, distribution, data management, safety and monitoring, and communication. The role and scope of each of the IHS VTF teams are included below.

IHS COVID-19 Vaccine Task Force Teams

Task Force Team	Role and Scope
Vaccine Administration Team	• Develop resources and tools for I/Ts to utilize and tailor to their vaccine administration and documentation. • Provide event planning strategies for vaccination distribution, such as drive-up events.
Prioritization Team	• Engage I/Ts to compile priority population estimates for vaccine distribution based on federal guidance.

	• Provide guidance and technical assistance to I/Ts for plans to include equitable COVID-19 vaccine distribution.
Distribution and Allocation Team	• Identification of I/T facilities and their preferences for distribution for programs that choose to receive the vaccine distribution from IHS. • Promote transparency and open communication to ensure every I/T has a distribution source. • Identify and acquire resources for vaccine administration supplies, including storage and monitoring supplies and protective personal equipment (PPE). • Ensure along with CDC that I/T facilities can access tacking and ordering system for vaccine inventory.
Data Management Team	• Identify ways to track and document the COVID-19 vaccine, including administration data, reporting of inventory, and ordering processes. • Devote resources for I/T facilities to ensure export of the required data reporting elements to IHS and CDC. • Provide necessary IT support to I/Ts for upgrades and infrastructure to meet CDC reporting requirements.
Safety and Monitoring Team	• Provide education to I/T facilities regarding: adverse vaccine event (AVE) monitoring and reporting processes; clinical review and guidance for approved vaccines; and AVE active surveillance and passive surveillance via the Vaccine Adverse Event Reporting System (VAERS).
Communication	• Develop a strategic communication plan and culturally appropriate messages with internal IHS departments, tribes, and external partners. • Provide I/T facilities clinical information to make informed decisions on specific vaccine products.

Next Steps

We will continue to monitor the developments of new guidance, resources, and tools. As more information is available, we will include additions to this summary for I/T facilities. Please let us know if you have additional questions or comments, we would like to hear from expert tribal healthcare providers. Please contact Cyndi Ferguson, TSGAC ACA/IHCIA Project Lead at cyndif@senseinc.com.