

# COVID-19 Vaccination Plan

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MONTANA

DECEMBER V.5/01.06.2021



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## Record of Changes

Date of original version: October 16, 2020

Date of Change	Description of Change	Name of Author
11/6/20	Added table of Planning Group organizations with names of representatives; Section 5, E: edited and described verification of training; Adjusted Record of Changes page to DPHHS format; Created Record of Review and Record of Distribution per DPHHS preparedness planning format; Section 2, E :added sentence to describe how DPHHS shares data with LHJs	LWF
11/16/20	Included list of DPHHS preparedness plans already in play (pg. 7); added mention of Information and Intelligence Management Operations Guide; Moved pandemic population allocation tiers to Section 3; Incorporated Phase 1a and Phase 1b into plan; added CDC's pharmacy partnership strategies with long term care centers; Clarified background and approach to transient/cross-jurisdictional populations in Section 4; Updated strategies working with federal agencies, particularly IHS in Section 5; Added contents of ancillary supplies shipped with vaccine in Section 7; Clarified program information for monitoring and metrics (Sec. 15) for Provider Enrollment, Access to COVID-19 Vaccination Services, 2-Dose COVID-19 Vaccination Coverage, and Communication	LWF
11/20/20	Inserted updated information about ancillary kits for Pfizer vaccine; placed paragraph about equitable distribution of vaccine in Section 7; Wrote Purpose, Scope, and Assumptions into Section 1; Inserted Roles & Responsibilities table into Section 2; Updated to Version 3.	LWF
11/24/20	Developed and inserted draft Phase 1 vaccine distribution strategy; Created and inserted distribution strategy map as an attachment; Inserted updated list for the COVID-19 Vaccination Plan Coordination Team; Adjusted formatting.	LWF
11/30/20	Adjusted Phase 1 strategy based on new allocation information; Inserted reference to standing orders in regulatory considerations section; added brief paragraph for developing strategy to dispense to state staff in Phase 1; Began in-document reference linking	LWF
12/02/20	Created list of tables and figures in TOC.	LWF
12/15/20	Added note in Section 4 to acknowledge changing priorities in populations for vaccination; inserted Attachment 1: Record of Population Priority Adjustments on pg. 58; Removed distribution strategy tables from Phases 1A and 1B; Removed distribution map.	LWF
12/23/20	Adjusted phases to 1a, 1B, 1C and 2; inserted links to ACIP recommendations to replace target populations; Edits and related formatting.	LWF
12/24/20	Changed Attachment 1 to Proposed COVID-19 Vaccine Allocation and inserted the table; Updated plan version to 4.	LWF
12/28/20	Removed CDC pandemic tiers; staff reviewed for edits; adjusted TOC and figures list; republished as version 5.	
01/05/21	Updated Phase 1b and 1c	





## Section 1: COVID-19 Vaccination Preparedness Planning

### Purpose, Scope, Assumptions, and Situation

In the event of a public health emergency or crisis, the Montana Department of Public Health and Human Services (DPHHS) will initiate a state-level response in accordance with the Department's Emergency Operations Plan (EOP). Such an event might require active operations for Emergency Support Function #8 (Public Health and Medical Services).

This COVID-19 Vaccination Plan supports the DPHHS EOP and the Medical Supplies Management and Distribution (MSMD) Annex, and describes the response operations for supporting the introduction, ordering, allocating and coordinating shipment of COVID-19 disease vaccine to State and local ESF8 response partners. Both of these documents demonstrate DPHHS's operational readiness to respond to pandemic situations involving highly infectious diseases.

DPHHS's Public Health Emergency Preparedness (PHEP) and Healthcare Preparedness Program (HPP), Immunization Program, and Communicable Disease and Epidemiology Section (CDEpi) guide Montana's local and tribal jurisdictions in preparations through grant funding provided by the Centers for Disease Control and Prevention (CDC) for significant public health emergencies, such as this COVID-19 pandemic.

### Purpose

The purpose of this framework plan is to define the necessary activities to initiate and sustain a mass vaccination campaign, including

- Ensure development and execution of an appropriate public health emergency vaccination response
- Define roles and responsibilities
- Coordinate tracking, reporting, and ordering vaccine and ancillary supplies in Montana
- Ensure the timely and equitable distribution and dispensing of vaccine and ancillary supplies to providers in the State
- Communicate timely and accurate information about the COVID-19 vaccine including safety, availability, training, regulations, efficacy, and urgency

### Scope

This strategic framework is specific to the COVID-19 response efforts and limited to the extent of the Governor's declarations and directives. It is also limited to the specific operations of DPHHS. This framework only supplements the functions and operations of mass vaccination activities and does not replace day-to-day duties of any DPHHS staff or program.

DPHHS activities related to mass vaccination effort include

- Developing and implementing operational strategies for the distribution and dispensing COVID-19 vaccines to critical populations
- Collaboration and application of guidance and information from federal partners
- Coordination of available staff
- Recruitment, enrollment, and communication with vaccine and healthcare providers
- Defining and prioritizing critical populations for receiving vaccine

- Apportionment, ordering, distribution, and tracking, and ensuring appropriate storage of vaccine and ancillary supplies
- Development and implementation of vaccine specific just-in-time training for providers and healthcare personnel

## Assumptions

The following assumptions apply to this plan. These are the elements that must be in place to make mass vaccination in Montana successful.

- Emergency public health response operations for the COVID-19 pandemic in Montana will continue throughout the vaccination campaign
- DPHHS will enroll and train enough providers to administer COVID-19 vaccine throughout the entire operational time period
- Healthcare providers will continue to provide routine vaccines as well as those for seasonal influenza
- The federal government will authorize use and then distribute vaccines and ancillary supplies for COVID-19 disease in sufficient quantity to initiate a mass vaccination campaign
- Montana will receive an initial allocation of sufficient vaccine and ancillary supplies to begin vaccination of critical healthcare workers
- Federal allocation of vaccine to Montana will be based on population pro rata
- The Advisory Committee on Immunization Practices (ACIP) will recommend priority critical populations for COVID-19 vaccination by risk, current spread or prevalence of COVID-19, and vaccine production and availability
- The federal government will issue guidance on groups to prioritize for initial COVID-19 vaccination; populations of focus for initial COVID-19 vaccination will likely be: critical healthcare personnel, essential workforce that maintains crucial functions of society, and staff and residents in long-term care and assisted living facilities.
- Vaccine allocations to local jurisdictions might shift during the response based on supply, demand, CDC recommendations or guidance, and epidemiological assessments Relationships and partnerships, including Memorandums of Understanding (MOU) and Memorandums of Agreement (MOA), are established with local, state, and federal entities
- Trained staff and appropriate equipment are available to support a state-wide campaign
- The vaccine for COVID-19 disease will require 2 doses, separated by 21 to 28 days
- Unpredictable disturbances in the US political environment, due to an election year could impact the vaccination campaign causing adjustments in operational strategies
- Winter weather might occasionally slow distribution and dispensing of vaccine
- Some jurisdictions might need assistance acquiring equipment to maintain cold chain or ultra-cold chain storage of vaccine
- CDC will develop communication resources for Montana and tribal organizations to use with key audiences
- CDC will provide tools, software, assistance, communication materials, and guidance to all aspects of the COVID-19 vaccination program

## Situation/Background

DPHHS has exercised its mass vaccination and Medical Countermeasures (MCM) and Strategic National Stockpile (SNS) plans since the inception of the PHEP program with the help of the CDC Cooperative Agreement created by the US Congress passing the Pandemic and All Hazards Preparedness Act in December of 2006. These MCM and SNS plans include vaccine distribution.

DPHHS allocates a portion of its grant funding to local and tribal health jurisdictions (LHJ) in return for completing assigned deliverables. Part of the deliverable requirements include writing, exercising, and updating their own MCM plans and Point of Dispensing (POD) procedures.

Montana has a decentralized government, meaning local and tribal governments are responsible for distributing and dispensing vaccines within their own jurisdictions. PHEP reviews these plans as part of deliverable requirements for the LHJs.

Montana's role is to receive, stage, and ship medical assets to public health agencies and other healthcare related facilities. PHEP ensures each jurisdiction keeps their distribution plans current, and partners with the Immunization (IZ) program to ensure at least one vaccination clinic is conducted annually as an exercise of those plans. DPHHS does not conduct its own vaccinations. State facilities with resident populations work with local public health departments to conduct closed clinics for residents and staff.

The 2009 H1N1 response for distributing vaccine was the first time Montana activated its MCM plan. The after-action reports (AAR) and subsequent improvement plans (IP) allowed program staff to make changes to the gaps observed ten years ago. Since then, the PHEP cooperative agreement has cycled twice. The funding agreement requires jurisdictions to hold full-scale exercises to test SNS and MCM plans. Montana conducted Big Sky Push 2 in 2014 with participation from all local and tribal health jurisdictions and planning partners. The ARR and IP led to adjustments to several plans, as does any exercise.

DPHHS held its latest full-scale exercise, Operation Oro y Plata Armis, in October 2019. This exercise also included all local and tribal jurisdictions and planning partners.

Both of the full-scale exercises and the H1N1 response were predicated with planning and mutual agreements with multiple partners. These partners included federal agencies such as US Health and Human Services and the US Marshall Service and the United States Postal Service (quasi-governmental). State government agencies included the Montana Disaster and Emergency Services (DES) and the Montana Highway Patrol. Private enterprises also participated, such as transport companies United Parcel Service (UPS), FedEx, and Mergenthaler Transfer and Storage.

Planning partners for LHJs includes emergency managers, local law enforcement, pharmacies, hospitals and clinics, long term care centers, and private businesses, among others. Plans are supported by mutual aid agreements and memos of understanding (MOU).

DPHHS PHEP is currently working through its improvement plan developed from the 2019 full scale exercise that directly impacts distribution of medicine and medical material. Some of those gaps have

already been addressed through current operations for ordering and distribution of personal protective equipment (PPE) to Montana’s 58 county and tribal health jurisdictions.

In summary, the IP called for improvements in sharing essential elements of information (EEI) among partners, better verification of delivery points, more timely communication, information quality control, develop closer relationships with transport partners, and identifying back-up personnel for incident command positions.

**Anticipated gaps for immediate action:**

- Written operating procedures for ordering, delivery, and tracking of COVID-19 vaccine (most of which is accomplished within this document)
- Just in time training protocols for COVID-19 vaccine specific activities
- Developed and targeted public information campaign focused on the COVID-19 vaccine for Montanans
  - Vaccine hesitancy among the public
  - Misinformation and rumors about COVID-19 vaccine among the public
  - Importance of starting with critical populations
  - Follow-through with second dose of vaccine

**Shared challenges with local and tribal jurisdictions:**

- Healthcare systems and hospitals which will likely want closed PODs per their own emergency operations plans
- Lack of personnel in smaller jurisdictions to dispense vaccine
- Supporting local public health agencies in justifying prioritized selections of critical populations to their local governments

**Plan Exercises**

Upon implementation of Montana’s COVID-19 Vaccine Strategy, and prior to the first shipment of vaccine, PHEP will design and execute a tabletop exercise (TTX) with representative participants. Artificialities of the scenario will include an accelerated timeline to cover operational expectations. The resulting After-Action Report will drive an Improvement Plan (IP) and result in updates to the strategy document and refine procedural practices.

A TTX will precede each phase of the operation (see Section 3). The AAR and IP will ensure the continuity of quality improvement and mitigate gaps discovered in operational planning. Because the dates for the release of vaccine is uncertain, specific dates cannot be determined.

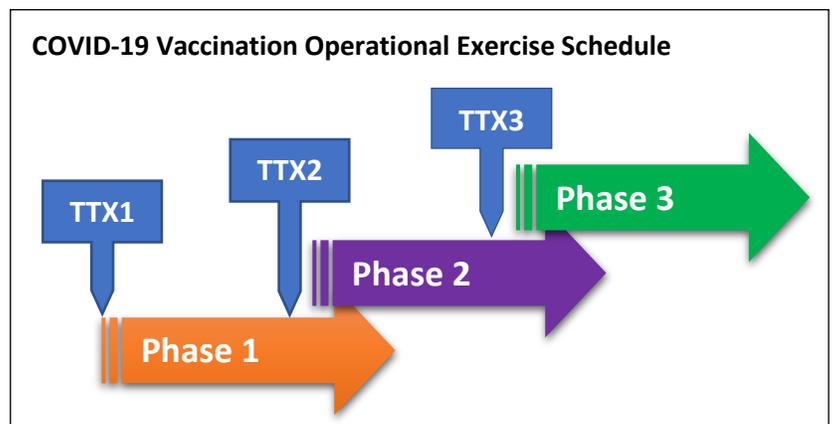


Figure 1.  
NOTE: Figure not scaled to actual dates.

In addition to the exercises, Incident Action Plans (IAP) for operational periods will address discovered issues and list improvement actions. This standard Incident Command Structure (ICS) practice is a built-in quality control method that meets the immediate needs of resolving issues throughout the campaign.

## Preparedness Plans

DPHHS PHEP has written and exercised specific annexes to its Emergency Operations Plan. DPHHS has activated the following planning documents along with their associated operational guides.

- Medical Supplies Management and Distribution Annex
- Medical Surge Annex
- Public Health Crisis and Emergency Risk Communications Annex
- Tactical Communications Annex
- Communicable Disease Epidemiology Annex
- Health Alert Network Operational Guide
- Incident Management Guide
- Duty Officer Manual
- Information and Intelligence Management Operations Guide

Response managers may activate other plans as needed.

## Section 2: COVID-19 Organizational Structure and Partner Involvement

### A. COVID-19 Vaccine Plan Management Structure

COVID-19 vaccinations require collaboration and communication across multiple agencies, programs and stakeholders. Montana recognizes the importance of a collaborative response and is establishing two key advisory groups that will guide the effective vaccination effort. DPHHS’s Immunization Section in the Communicable Disease Control and Prevention Bureau (CDCPB) is will conduct the operational implementation of the COVID-19 vaccination campaign. This work will be guided and assisted by both an internal Planning Advisory Group (reporting to the Governor’s Coronavirus Taskforce) as well as a Vaccination Plan Coordination Planning Team, comprised of key community stakeholders from across Montana representing multiple entities outlined below. The State of Montana is focused on ensuring representation, communication, and collaboration throughout this process. Therefore, this list may expand as the vaccination campaign progresses and more partners are identified.

### B. Roles and Responsibilities

Montana’s government is constitutionally decentralized, giving local governments much of the control within their jurisdictions for emergency planning. Creating a state-wide framework for a successful COVID-19 vaccination effort is dependent on equitable and mutually beneficial partnerships among the healthcare industry, local and state governments, and community partners.

Although the Governor’s emergency declaration helps DPHHS stretch its authority, the collaborative relationships already established by the communicable disease programs have made asserting such leverage unnecessary. Defining the roles and responsibilities between partners for this framework are already practiced and familiar.

The following entities have roles and responsibilities in a public health event requiring a mass vaccination campaign.

Table 1. Roles and responsibilities by response organization.

Organization	Roles & Responsibilities
<p><b>Department of Public Health &amp; Human Services</b></p>	<p><b>DPHHS is Lead Coordinating Agency in Montana for Emergency Support Function 8 – Public Health and Medical Services</b></p> <p><b>Immunization Program</b>                      The Immunization Section is responsible for the operational functions of this planning framework</p> <ul style="list-style-type: none"> <li>• Implementation of this plan</li> <li>• Enroll and train providers to dispense COVID-19 vaccine</li> <li>• Facilitating the internal COVID-19 Vaccination Plan Coordination Team and the COVID-19 Vaccination Planning Advisory Group</li> <li>• Provision of information and training to required personnel and partner providers</li> </ul>

	<ul style="list-style-type: none"> <li>• Track and order vaccines and supplies</li> <li>• Maintain information systems to collect data from providers</li> <li>• Conduct daily reports to CDC with updated information about orders, tracking, and administration of COVID-19 vaccine</li> <li>• Content development for communication activities</li> <li>• Support local and tribal health agency response activities</li> </ul>
	<p><b>Communicable Disease Epidemiology Section</b> Provides disease surveillance data to complete situation awareness to determine vaccination priorities.</p> <hr/> <p><b>Public Health and Emergency Preparedness Section</b> The Public Health and Emergency Preparedness (PHEP) section coordinates planning, logistics, risk communications, and other incident management functions. PHEP will implement other annexes and SOPs when appropriate.</p> <ul style="list-style-type: none"> <li>• Establish ICS</li> <li>• Augment Receipt Stage and Shipping (RSS) warehouse functions for auxiliary supplies</li> <li>• Provide operational planning expertise</li> <li>• Implement other emergency preparedness and response plans as needed</li> <li>• Maintain a 24-hour duty officer program to facilitate processing and responding to incoming incidents</li> <li>• Activate, operate, and maintain the Emergency Operations Center (EOC) to support response operations through planning, logistics, and other incident management functions</li> <li>• Provide emergency management expertise regarding public health and healthcare infrastructures</li> <li>• Liaise with other state and local agencies with overlapping areas of response</li> <li>• Arrange for healthcare personnel surge activities</li> </ul>
<p><b>Disaster &amp; Emergency Services (DES)</b></p>	<p><b>DES is the primary coordinating agency for all State disasters and emergencies.</b></p> <p>DES manages resources and support to local, State, and non-governmental organizations (NGO).</p> <ul style="list-style-type: none"> <li>• Activate and manage the State Emergency Coordination Center (SECC)</li> <li>• Coordinate other State ESF resources in response and recovery operations</li> <li>• Coordinate mutual aid and federal assistance, including Mutual Aid Agreements (MAA), Emergency Management Assistance Compact (EMAC), and federal assistance</li> </ul>

<b>Governor’s Coronavirus Task Force</b>	Provides the overall command and control for the COVID-19 pandemic response in Montana.
<b>Local &amp; Tribal Health Jurisdictions</b>	LHJs are responsible for identifying and investigating public health events and reporting these events to DPHHS. LHJs assist DPHHS in the administration of public health services and functions. <ul style="list-style-type: none"> <li>• Public health agencies will enroll as COVID-19 vaccine providers</li> <li>• Participate in disseminating public messages</li> <li>• Utilize HAN system to keep medical providers informed of current operations</li> <li>• Participate in online COVID-19 vaccine training</li> <li>• Utilize POD and MCM plans to conduct off-site immunization clinics</li> <li>• COVID-19 vaccine management: Receiving, dispensing, ordering, reporting, and disbursement to other providers</li> </ul>
<b>Montana Regional Healthcare Coalitions (HCC)</b>	Healthcare coalitions in Montana coordinate within their geographical boundaries for preparedness, response, and recovery issues. Although not response organizations themselves, the agreements amongst their member entities provide the framework for disaster and emergency response. <ul style="list-style-type: none"> <li>• Serve as a reference point for healthcare related resources</li> <li>• Advises local emergency managers regarding healthcare needs during disaster response operations</li> <li>• Maintains healthcare situational awareness during disaster and emergency responses</li> <li>• Coordinates information sharing with DPHHS</li> </ul> <b>Local Health Care Facilities</b> <ul style="list-style-type: none"> <li>• Maintain emergency operations plans as required of organizations that receive Medicaid funding</li> <li>• Enroll as COVID-19 vaccine providers</li> <li>• Coordinate the plans with their local disaster and emergency services representative</li> <li>• Maintain communication with State agencies and their Healthcare Coalition</li> </ul>
<b>Non-profit Organizations, and Private Businesses</b>	<ul style="list-style-type: none"> <li>• Facilitate communication with their constituents about vaccinating critical populations</li> <li>• Inform DPHHS of new or ongoing issues for situational awareness</li> </ul>
<b>Pharmacies</b>	DPHHS has regular engagement with pharmacies through both its Montana Health Programs and the Immunization Section <ul style="list-style-type: none"> <li>• Enroll with DPHHS as COVID-19 vaccine providers</li> <li>• Partake in online COVID-19 vaccine training</li> <li>• COVID-19 vaccine management: Receiving, dispensing, ordering, reporting, and disbursement to other providers</li> </ul>

<b>Other Montana State Agencies</b>	State agencies participate in emergency operations as needed and able.
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## Committees

### **COVID-19 Vaccination Planning Advisory Group**

The internal COVID-19 Vaccination Planning Advisory Group is comprised of subject matter experts in communicable disease, immunization, administrative direction, and public health emergency preparedness. This cross section of experts and Department leadership will be charged with advising strategic planning and framework for implementation of the vaccine campaign.

- State Medical Officer
- Medical Director, MT Department of Labor and Industry
- Deputy Director, DPHHS
- Public Information Officer, DPHHS
- Administrator, Communicable Disease & Laboratory Services Division
- Bureau Chief, CDCPB
- MT Disaster and Emergency Services/Governor’s Coronavirus Task Force
- DPHHS Immunization Program Supervisor
- Vaccine Manager, Montana Immunization Program
- Epidemiologists
- Public Health Emergency Preparedness Section Supervisor
- Healthcare Preparedness Program Supervisor

### **Vaccination Plan Coordination Team**

The broader external COVID-19 Vaccination Plan Coordination Team is comprised of stakeholders from various sectors across the state, many of whom are established key COVID-19 crisis response partners with the state government and in their communities. This committee will advocate for ensuring the equitable access to COVID-19 vaccination services, provide input on public communications, and participate in crisis and risk communication efforts if needed. Collaboration between the State of Montana and these partners can help solidify roles, responsibilities, and support among medical, non-medical, tribal council, and non-government organizations (NGO). Representation from at risk populations is especially essential as Montana defines its critical population throughout all phases of this plan.

Table 2. Members of the Vaccination Plan Coordination Team.

Sector	Organization
<b>Adult and child congregate group homes</b>	• AWARE, Inc.
<b>Behavioral health</b>	• Behavioral Health Alliance of Montana
<b>Business and occupational health organizations</b>	• Montana Chamber of Commerce

<b>Childcare and early childhood</b>	<ul style="list-style-type: none"> <li>• Montana Child Care Resource and Referral Network</li> <li>• DPHHS Early Childhood and Family Services Division/Child Care Licensing</li> </ul>
<b>Churches and religious leaders</b>	<ul style="list-style-type: none"> <li>• Our Redeemer’s Lutheran Church</li> <li>• Congregation Beth Aaron</li> </ul>
<b>Community representatives</b>	<ul style="list-style-type: none"> <li>• Montana Association of Counties</li> <li>• Montana Non-Profit Association</li> </ul>
<b>Correctional facilities</b>	<ul style="list-style-type: none"> <li>• Montana Department of Corrections</li> </ul>
<b>Educational agencies and providers</b>	<ul style="list-style-type: none"> <li>• Office of the Commissioner of Higher Education</li> <li>• Montana University System</li> <li>• School Administrators of Montana</li> </ul>
<b>Emergency Management Services</b>	<ul style="list-style-type: none"> <li>• Disaster and Emergency Services</li> <li>• Yellowstone County Disaster and Emergency Services</li> <li>• Fallon County Disaster and Emergency Services</li> </ul>
<b>Health insurance issuers and plans</b>	<ul style="list-style-type: none"> <li>• Blue Cross Blue Shield of Montana</li> <li>• Allegiance</li> <li>• Mountain Health CO-OP</li> <li>• Pacific Source Health Plans</li> </ul>
<b>Health systems and hospitals</b>	<ul style="list-style-type: none"> <li>• Montana Hospital Association</li> <li>• Montana Nurses Association</li> <li>• Providence Montana</li> </ul>
<b>Home health workers</b>	<ul style="list-style-type: none"> <li>• SEIU 775 Healthcare</li> <li>• Consumer Direct</li> </ul>
<b>Homeless shelters</b>	<ul style="list-style-type: none"> <li>• Poverello Center</li> </ul>
<b>Local health departments</b>	<ul style="list-style-type: none"> <li>• Association of Montana Public Health Officials</li> <li>• Montana Public Health Association</li> </ul>
<b>Long term care facilities</b>	<ul style="list-style-type: none"> <li>• Montana Health Care Association</li> </ul>
<b>Mental health representative</b>	<ul style="list-style-type: none"> <li>• National Alliance on Mental Illness-Montana</li> </ul>
<b>Organizations on aging</b>	<ul style="list-style-type: none"> <li>• AARP</li> <li>• Big Sky 55+</li> <li>• Montana Area Agencies on Aging Association</li> </ul>
<b>Organizations serving people with limited English proficiency</b>	<ul style="list-style-type: none"> <li>• Montana Migrant and Seasonal Farmworker Council</li> </ul>
<b>Organizations serving individuals with disabilities</b>	<ul style="list-style-type: none"> <li>• Disability Rights Montana</li> <li>• Statewide Independent Living Council</li> <li>• Summit Independent Living</li> <li>• Montana Independent Living Project</li> <li>• Montana Council on Developmental Disabilities</li> <li>• Montana Association of Community Disability Services</li> </ul>
<b>Organizations serving racial and ethnic minority groups</b>	<ul style="list-style-type: none"> <li>• DPHHS State Refugee Coordinator</li> <li>• Hopa Mountain</li> <li>• Montana Legal Services Association</li> <li>• The Montana Racial Equity Project</li> </ul>

<b>Pharmacies</b>	<ul style="list-style-type: none"> <li>• Montana Family Pharmacies</li> </ul>
<b>Rural health</b>	<ul style="list-style-type: none"> <li>• Montana Primary Care Association</li> </ul>
<b>Unions</b>	<ul style="list-style-type: none"> <li>• Montana Federation of Public Employees</li> </ul>

Note: This list may expand as vaccination operations progress and more partners are identified.

DPHHS fosters collaborative partnerships with counties, tribes, non-profit organizations, healthcare entities, and private businesses as standard operations. As a decentralized government, State agencies depend heavily on these partnerships to serve the people of Montana. Under the State constitution, all rights, privileges, or responsibilities assigned to the state government are given to local rule. Montana Code Annotated (MCA) [50-1-202](#) and [MCA 50-1-202](#), and Administrative Rules (ARM), Communicable Disease Chapter, [37.114.314](#), [37.114.204](#), and [37.114.315](#) address the State’s authorities regarding disease and vaccination.

Those partnerships not defined by law are governed mostly through contract. DPHHS engages county and tribal governments through contract riders, known as task orders, to disperse grant funds in return for participating in public health programs. This, in effect, makes local and tribal health agencies sub-awardees for funding from federal cooperative agreements. The networks of the collaborative relationships noted above come from the required activities for funding.

DPHHS will leverage these partnerships as part of the ongoing response to the COVID-19 pandemic. Key roles for DPHHS partners will be communication with their constituents and their partners. Engaging those partners as part of strategic involvement will encourage earlier participation of critical populations. Frequent communications for each phase of the plan will keep the partners engaged and is necessary to keep their organizations and patrons fully informed. An operational rhythm for meeting schedules and information exchange will be established initially on a weekly basis.

## E. Coordination with Local Governments

Each LHJ is engaged in their own emergency response to COVID-19 and will continue as vaccine operations are added. Montana DPHHS PHEP follows its written protocols found in the DPHHS **Information and Intelligence Management Operations Guide** to foster communication and data exchange. This is an operational function and is embedded with the phased operations described in Section 3.

## F. Coordination with Tribal Governments

Government-to-government relations and communications with tribal nations and health partners are important and critical throughout this process. A Virtual Tribal Consultation on the vaccine planning was held on October 8, 2020, and included tribal governments, urban Indian health centers, and Indian Health Service. The COVID-19 Vaccination Plan Coordination Team will include representation from each of the following tribal and health entities to ensure unique perspective and expertise is heard.

## COVID-19 Vaccination Plan Coordination Team Tribal Representation

Table 2a.

Nation/Organization	Representative
<b>Blackfeet Nation</b>	Laura Upham
<b>Chippewa Cree Tribe</b>	Lauren Corcoran
<b>Confederated Salish and Kootenai Tribes</b>	Chelsea Kleinmeyer
<b>Crow Nation</b>	Erin Birdinground-McCleary
<b>Fort Belknap Tribes</b>	Jennifer Show
<b>Indian Family Health Clinic</b>	Mary Lynn Billy
<b>Fort Peck Tribes</b>	Kaci Walette
<b>Little Shell Tribe</b>	Molly Wendland
<b>Northern Cheyenne Tribe</b>	Serena Wetherwelt
<b>All Nations Health Center</b>	Elizabeth Williams
<b>Billings Urban Indian Health and Wellness Center</b>	Kim Brown
<b>Helena Indian Alliance</b>	Todd Wilson
<b>Northern American Indian Alliance</b>	Shannon Parker
<b>Billings Area Indian Health Services</b>	Angela Troutt

### G. Partner Engagement

The Immunization Program and PHEP will establish an operational rhythm for communications and information exchange. The schedule will be established according to the partner, the need, and the role or responsibility. The schedule will also adjust accordingly as operations progress.

## Section 3: Concept of Operations

### Operational Response Strategy

The COVID-19 vaccination campaign is already underway with national planning and pharmaceutical trials nearing completion. The CDC’s COVID-19 Healthcare Resilience Task Force has provided models and information on expected release and delivery of the vaccine. Based on their planning, recommendations and guidance, DPHHS is adopting a phased approach for vaccine distribution operations. This strategic approach accounts for the overlap of work between phases.

**NOTE:** There are many dynamic factors on federal, state, and local levels that will impact the operations and delivery of the COVID-19 vaccine. The unforeseeable events that might impact this framework creates a cone of uncertainty, making planning difficult for future distribution of vaccine. This dynamic nature compels a framework approach that lends itself to shifting beyond currently defined timelines.

### COVID-19 Vaccination Operational Outlook

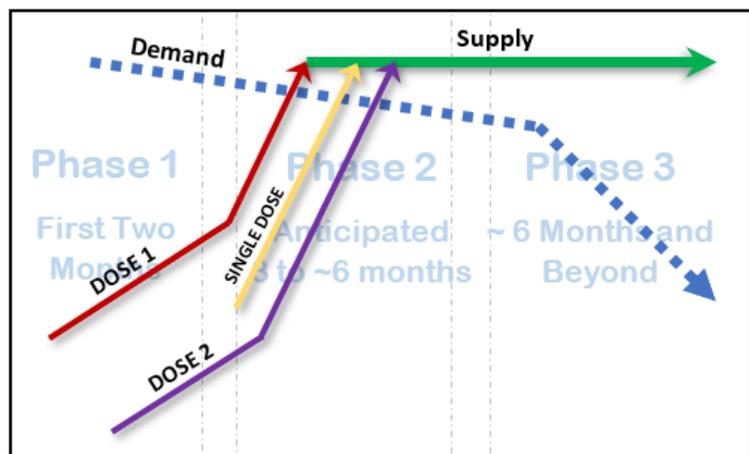


Figure 2.  
NOTE: Figure is not scaled to actual dates.

### Implementation

The ongoing pandemic of COVID-19 disease and the impending release of an FDA supported safe and effective vaccine prompts DPHHS and state authorities to implement this plan.

Implementation includes

- Assembling the COVID-19 Vaccination Planning Group
- Prompt notification to local and tribal health jurisdictions, health care centers, hospitals, pharmacies, and other vaccination partners
- Coordinating and briefing staff (including off-site employees) to perform prioritized activities
- Establishing and maintaining direct contact with the CDC
- Preparing vaccine reporting systems
- Identification of other emergency preparedness annexes and processes needed to support this framework.

Planning vaccine distribution encompasses several factors. The COVID-19 Vaccination Planning Advisory Group will use current local spread/prevalence of COVID-19, vaccine production and availability, and the recommendations of the Advisory Committee on Immunization Practices (ACIP) with input from the National Academy of Medicine (NAM).

## Access and Functional Need Populations

For the purpose of public health emergency preparedness in Montana, this population is defined as people having access or functional health (i.e., mental or medical) or physical (i.e., motor ability) needs beyond their capability to maintain on their own before, during, and after an incident. It also refers to the “at risk” or “special needs” populations described in the Pandemic and All-Hazards Preparedness Act.

DPHHS coordinates with its local, tribal, non-governmental organizations, and State agency partners to ensure the physical, programmatic, and communication access will address the requirements for access and functional need populations. A full statement and description of DPHHS’s emergency response activities regarding these critical populations is in the department’s EOP.

## Operational Phases

### Phase 1: Initial Distribution; Limited Vaccine Supply

#### First Two Months

The federal government will release stockpiled COVID-19 vaccines immediately after the FDA issues an EUA. The CDC has not indicated a specific amount of vaccine is allocated to Montana for the first phase.

#### COVID-19 Vaccine Staging Locations

CDC has notified states that it might stage manufactured vaccine closer to key administration sites after the FDA issues any EUAs but before ACIP makes recommendations to ensure rapid distribution. Because of this possibility, the agency has asked all states to identify 1 to 5 staging locations. This a one-time effort intended to shorten the timeline between EUA release and the initiation of vaccine administration (e.g., if initial prioritization focuses on administration of vaccine to healthcare providers). Instructions ask for jurisdictions to plan for this staging to focus on Vaccine A, a product that requires ultra-cold (-60°C to -80°C) storage, given the possible unique storage and handling considerations.

These potential sites are

- The most likely to serve the majority of priority groups for the initial doses of the vaccine
- Able to store, handle, and monitor ultra-cold temperature vaccine
- Not be dependent on dry ice or thermal containers for storage

The Immunization Program has indicated Montana’s preferred capable staging sites by using the CDC’s Ultra-Cold Temperature template.

**NOTE: Operation Warp Speed national planning has divided Phase 1 into A, B, and C.** Montana is adopting this approach to maintain consistency. Phase 1A and Phase 1B might concurrent, depending on the amount of vaccine the State receives in Phase 1.

The COVID-19 Vaccination Planning Advisory Group must allocate the COVID-19 Vaccine with priority and equity for these groups in Phase 1 as described in [Section 4](#), including populations defined ACIP interim recommendations for allocating COVID-19 vaccine ([The Advisory Committee on Immunization Practices’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020 | MMWR \(cdc.gov\)](#)). See Attachment 1: Proposed [COVID-19 Vaccine Allocation](#)

**Goal:** Maximize the limited supply of allocated vaccine to ensure essential response personnel and people at the highest risk of life-threatening infection receive at least the first dose within the first two months of initial distribution.

## Activities

1. Enroll vaccine providers and collect initial vital data (see [Section 5](#)).
2. Determine Phase 1A essential response personnel and define Phase 1B critical populations
3. Establish routine communication periods with providers.
4. Initiate vaccine orders to local and tribal health jurisdictions and their dispensing partners and engage tracking systems.
5. Begin routine reporting to CDC.
6. Initiate public information campaign.

## Phase 1A Distribution Strategy - Centralized Dispensing for HCWs

DPHHS will survey Montana's healthcare and long term care facilities and workers to determine who will qualify for Vaccine A. The survey will define the parameters of Phase 1 HCWs and all the respondents to provide the numbers within the categories of critical populations for prioritizing vaccination.

CDC has indicated staging ultra-cold vaccine at hospitals (must have ultra-cold -60°C to -80°C storage capabilities) when the FDA issues and EUA, but prior to ACIP recommendations. The size of critical HCW population determines the amount of COVID-19 vaccine distributed (staged).

### Primary Central Dispensing

Hospitals activate plans and set up their closed PODs to dispense vaccine to their own HCW and other first priority staff recommended by DPHHS and ACIP.

### Secondary Central Dispensing

Public Health takes over with partnering staging hospitals to host closed PODs for other essential 1A populations within approximately 1-hour travel distance. Strategically, DPHHS does not expect strict adherence to this travel limitation. It is for planning purposes only.

## Phase 1B and 1C Distribution Strategies - Hub and Spoke distribution of vaccine for HCWs

The CDC will ship more vaccine doses as the FDA approves more formulations and supply increases. DPHHS will encourage providers to continue targeting Medically vulnerable populations who are at higher risk for COVID-19 related complications.

**Goal:** Ensure access to COVID-19 vaccine for critical population members who were not vaccinated in Phase 1, provide second dosing for Phase 1 recipients (overlap), and expand availability to other prioritized groups.

## Activities

1. Expand vaccine provider enrollment.
2. Continue tracking vaccine to ensure administration to critical populations and essential personnel.
3. Continue regular communications with LHJs with COVID-19 vaccine distribution operations.
4. Continue daily reporting to CDC.
5. Troubleshoot and solve vaccine tracking, shipping, and storage issues as presented.

6. Begin measurement of uptake among critical populations for operational planning.
7. Work with Public Information to counter any misinformation, overcome vaccine hesitation, and to update the public about vaccine availability.

DPHHS anticipates EUA and distribution for cold storage COVID-19 vaccines approximately one to two weeks following approval of Vaccine A. McKesson delivers cold storage COVID-19 vaccines in 100-dose packs with matching ancillary supplies.

### **Distribution to Frontier Area HCWs**

Healthcare facilities in Montana's frontier areas have very few staff, volunteer EMS, and limited LTC patients. Ultra-cold storage and transport for Vaccine A is logistically difficult to maintain for distributing only a few vials at each location, leaving the short waiting time for Vaccine B necessary as a strategy in Montana.

Frontier areas are less likely to have enough HCWs to require 100 doses. A local public health department in a larger jurisdiction must divide a pack for transportation to outlying areas. Some facilities/areas might only need 1 or 2 vials. Distribution to outlying areas by couriers or other means will be necessary.

### **Hub & Spoke Distribution and Dispensing**

- Vaccine B direct shipped to hub hospitals or local public health
  - Hospitals conduct internal closed PODs if necessary
  - Public health conducts closed PODs for area HCW
- Public Health activates MCM plans and follows transport protocols
  - Distributes vials to surrounding areas

### **Dispensing Strategy for At-Risk Individuals**

Hospitals and other facilities with patients who fall into the qualifying Phase 1B and 1C at-risk categories recommended by ACIP and DPHHS may begin receiving Vaccine B. As enrolled providers, they must order the appropriate amounts and follow the processes defined in [Section 7](#).

Distribution to frontier areas for facilities with at-risk populations may have to adopt the hub and spoke strategy for Phase 1B. Frontier local public health departments will implement their MCM plans to dispense COVID-19 vaccine.

### **Pharmacy Partnership for Long-term Care Program**

Phase 1A will see the concurrent initiation of the federal partnership with Walgreens and CVS pharmacies to provide COVID-19 vaccine to at-risk long-term care residents and staff. See [Concurrent Phase Strategies with CDC and Pharmacies](#) description of this operation.

## Phase 2: Expand and Normalize Distribution for Public Dispensing; Adequate to Sufficient Vaccine Supply

### Three Months and Beyond

Focus for Phase 2 will shift to reaching the general population withing ACIP recommendations ([The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020 | MMWR \(cdc.gov\)](#)). Vaccine producers should have manufactured enough to make it widely available. At this point, distributing and dispensing should be routine. The COVID-19 vaccine may become part of routine immunizations along with influenza and scheduled or recommended preventative injections. Strategies for Phase 2 are highly dependent on event conditions and updated guidance and operational decisions from the CDC and FDA.

**Goal:** Make COVID-19 vaccine ordering and dispensing a routine process for providers and ensure equitable access across the entire population.

### Activities

1. Continue regular communications with LHJs and enrolled providers to share operational changes and messaging.
2. Continue daily reporting to CDC.
3. Continue working with Public Information
4. Troubleshoot and solve vaccine tracking, ordering, shipping, and storage issues as presented.
5. Continue measurement of uptake among all populations for operational planning and public communications
6. Transition operational activities into routine daily functions.

## Concurrent Phase Strategies with CDC and Pharmacies

Montana will participate in the Pharmacy Partnership for Long-term Care Program and the Federal Direct Allocation to Pharmacies, both coordinated by CDC. These programs will augment the State's strategies for vaccine coverage throughout Phases 1 and 2.

### Pharmacy Partnership for Long-term Care (LTC) Program:

The CDC has arranged a partnership with the corporate pharmacies of Walgreens and CVS to provide on-site COVID-19 vaccine clinics for residents of long-term care facilities (LTCFs) and any remaining LTCF staff who were not vaccinated in Phase 1A. The **Pharmacy Partnership for Long-term Care Program** provides end-to-end management of the COVID-19 vaccination process, including close coordination with jurisdictions, cold chain management, on-site vaccinations, and fulfillment of reporting requirements. The program will facilitate safe and effective vaccination of this prioritized patient population, while reducing burden on facilities and jurisdictional health departments. Reporting requirements with DPHHS still apply.

This program is free of charge to facilities.

**Phase 1A:** *Limited COVID-19 vaccine supply recommended for at-risk long-term care residents and staff*

The pharmacy will:

- Schedule and coordinate on-site clinic date(s) directly with each facility.

- Three visits over approximately two months are likely to be needed to administer both doses of vaccine and vaccinate any new residents and staff.
- Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
- Ensure cold chain management for vaccine.
- Provide on-site administration of vaccine.
- Report required vaccination data (approximately 20 data fields) to the local, state/territorial, and federal jurisdictions within 24 hours of administering each dose.

If interested in participating, each facility should sign up and indicate their preferred partner from the available pharmacies.

Skilled nursing facilities and assisted living facilities will indicate which pharmacy partner (one of two large retail pharmacies or existing LTC pharmacy) their facility prefers to have on-site (or opt out of the services) between October 19–October 30.

- SNFs will make their selection through NHSN beginning October 19.
- An “alert” will be incorporated into the NHSN LTCF COVID-19 module to guide users to the form.
  - ALFs will make their selection via online REDCap sign-up form.
  - The online sign-up information will be distributed through ALF and SNF partner communication channels (email, social media, web).
  - After November 1, 2020, no changes can be made via the online forms, and the facility will have to coordinate directly with the selected pharmacy provider to make any changes in requested vaccination supply and services.
  - Indicating interest in participating is non-binding and facilities may change their selection (opt-out) if needed.
  - CDC will communicate preferences to the pharmacy partners and will attempt to honor facility preferences but may reassign facilities depending on vaccine availability and distribution considerations, and to minimize vaccine wastage.

CDC expects the Pharmacy Partnership for Long-term Care Program services to continue on-site at participating facilities for approximately three months.

After the initial phase of vaccinations, the facility can choose to continue working with the pharmacy that provided its initial on-site clinics or can choose to work with a pharmacy provider of its choice.

### **Federal Direct Allocation to Pharmacy Partners**

CDC has agreed to provide several large corporate pharmacies with direct shipments of COVID-19 vaccine and ancillary supplies. These providers must still enroll with the State and complete the required training for that enrollment. The reporting and ordering requirements with DPHHS also still apply.

### ***Phase 1B and 1C: Adequate Vaccine Supply for Expanded Population Coverage***

Vaccine will be allocated and distributed directly to select pharmacy partners from the federal government. The CDC will share all contact information as well as distribution and administration data from each partner store with DPHHS.

- Direct allocation opportunities will be provided to retail chain pharmacies and networks of independent and community pharmacies (those with a minimum of 200 stores)
  - All partners must sign a pharmacy provider agreement with the federal government.
- Once the list of federal partners has been finalized, CDC will share the list with DPHHS.
- Pharmacy partners must report the following information about its supply of COVID-19 vaccine on a daily basis (every 24 hours) to CDC and DPHHS
  - Ordered by store location
  - Supply on hand in each store reported through VaccineFinder
  - Number of doses of vaccine administered to individuals in each location

## Section 4: Critical Populations

### A. Identifying Critical Populations

Defining critical personnel in Montana is primarily a local function. However, the State will define the critical populations for the COVID-19 vaccine in accordance with federal guidance and ACIP recommendations. The vaccine may be a limited resource and a successful strategic framework for a mass vaccination campaign should follow ethical, yet practical, principles for fair and equitable allocation decisions.

State agencies provide program services to specifically defined critical populations, but LHJs along with public and private providers provide the direct services within the communities. LHJs meet regularly with community partners for preparedness planning and exercises. They also collaborate to hold vaccination clinics within their jurisdictions. Because the populations of individual jurisdictions are so small, locating and estimating critical populations within communities is not a difficult task, is already part of preparedness through PHEP, and will only need updating for vaccine planning. The State will assist by providing tools and information to help local planning for POD/clinic planning and to COVID-19 vaccine enrolled providers.

Guidance from the COVID-19 Vaccination Planning Advisory Group using Montana data and ACIP recommendations will assist local operational strategies.

[The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020 | MMWR \(cdc.gov\)](https://www.cdc.gov/mmwr/preview/mmwrhtml/aa6010a1.htm)

Recommended populations might change to reflect adjustments in vaccine supply, shifting disease epidemiology, economic priorities, and success of other public health measures.

### B. Define and estimate numbers of persons in the critical infrastructure workforce

DPHHS works with datasets provided by the federal government and Montana's Department of Labor & Industry (DLI). The Federal Cybersecurity and Infrastructure Security Agency (CISA) provides definitions for critical infrastructure workforce and specific guidance for COVID-19. DLI provides workforce information by occupation across the state and by county.

- Federal Cybersecurity and Infrastructure Security Agency. <https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19>
- Montana Labor Market Information Dataset. <https://data.mt.gov/>

The healthcare systems workforce estimates can also be gathered through the Regional Healthcare Coalitions' situational awareness program, Juvare.

- Hospitals
- Public Health Departments
- Long-term care facilities (assisted living facilities & skilled nursing facilities)
- Outpatient (Clinics, Alternative Care, Urgent Care, etc.)
- Home health care
- EMS

## Determining subset groups of critical populations if there is insufficient vaccine supply

The COVID-19 Vaccination Planning Advisory Group, using the reference resources listed from above, will determine guidance for delineating subsets of priority critical populations. Current local spread/prevalence of COVID-19 and anticipated resupply of vaccine is also a likely factor for local planning strategies for distribution and dispensing.

### C. Points of Contact (POCs) Communication

LHJs and DES coordinators develop preparedness plans with community leaders and representatives. Representatives include those organizations that serve access and functional need populations, healthcare, community officials, and local emergency management. LHJs build this collaboration as preparedness activities through requirements of the PHEP cooperative agreement. Planning community members also include Local Emergency Planning Committees (LEPC), Tribal Emergency Response Councils (TERC), non-government organizations (NGO), faith-based organizations, and VOAD. DPHHS will serve as the contact for state-level partners and organizations.

### D. Transient/Cross-Jurisdictional Populations

The nature of Montana’s ratio of frontier to metropolitan areas requires many people to travel for major medical services. Local public health departments are in county seats, but many counties are geographically larger than some eastern states with populations well under 10,000. Residents of a jurisdiction might find services in another county closer or more abundant than their own. Accounting for these transient populations for purposes of vaccine allocation is very difficult. See Table 2 for comparison examples.

Table 3. Example comparison of cross-jurisdictional populations for healthcare services

Montana	4 <sup>th</sup> Largest State	Square Miles	Population
		147,164	1.08 million
Petroleum County	Least populated county in MT	1,674	513
	Distance to healthcare from Winnet, the County seat: 54 miles to Lewistown, Fergus Co.		
Yellowstone County	Most populated county in MT	2,649	161,953
	Billings, the largest city in MT, has 4 area hospitals and a wide variety of general and specialized healthcare services. <ul style="list-style-type: none"> <li>• Serves populations from 7 surrounding counties and the Crow Indian Reservation.</li> <li>• Most of these counties have their own healthcare services and public health agencies, but most are very general or LTC.</li> </ul>		
Rhode Island	Comparable for pop and size	1,212	1.06 million

<https://worldpopulationreview.com/states/montana-population>

The COVID-19 Vaccination Planning Advisory Group and the COVID-19 Vaccination Plan Coordination Team must rely on information gathered from local providers through imMTrax and other IIS tools to balance allocations with actual jurisdictional populations.

Of note are tribal reservations with boundaries that intersect state counties. Indigenous populations may seek services either in the county or from the tribal resources. The COVID-19 Vaccination Plan Coordination Team and DPHHS Director's Office will work with IHS and tribal governments to determine plans and develop public communications to equalize allocations to Native Americans.

Long-term congregate settings for consideration:

- College and university residence halls
- Prisons and jails
- Homeless shelters
- Organizations working with resident high-risk and functional need populations (e.g. youth camps)

## Section 5: COVID-19 Provider Recruitment and Enrollment

### A. Determining and Contacting Providers for Enrollment

The Immunization Program is obtaining primary contacts and emails for all potential Phase 1 COVID-19 vaccine providers identified as having the ability to reach Phase 1 critical populations. The Immunization Program will prioritize processing Phase 1 enrollments initially and progress to providers in other phases as the vaccination effort develops. The goal is to have providers enrolled and trained by the time vaccine is available to ship during that phase.

The Immunization Program will recruit potential providers by sending an email to the medical director or equivalent at the organization with the following attachments:

- COVID-19 Vaccine Program Provider Agreement and Profile
- Storage and Temperature Monitoring Addendum
- Redistribution Agreement
- imMTrax Memorandum of Agreement (MOA).

The Storage and Temperature Monitoring Addendum will describe the storage unit and temperature monitoring requirements for vaccine providers and a place to list the make and model of temperature monitoring equipment used for vaccine storage units at the location.

The body of the email will contain:

- A description of the program and request that they enroll as a COVID-19 vaccine provider
- The criteria for being a vaccine provider and how they meet that criteria
- Training and storage requirements
- Vaccine provider roles and responsibilities
- Critical populations for the current phase
- Instructions on how to enroll
- Instructions for submitting a mandatory imMTrax MOA, if not already an imMTrax participant
- A description of the Redistribution Agreement and how to become a vaccine redistributor
- Instructions to reply to the email with “Our organization is not interested in becoming a COVID-19 vaccine provider” if they are not interested in participating.

Program staff will attempt to call the point of contact at the organization if there is no response to the first email within one week. The goal is to receive either enrollment documents or an email or verbal confirmation that they are not interested within two weeks of initial contact.

### B. Collecting Enrollment Data; Verifying Credentials, Capabilities, & Capacities

The Immunization Program will distribute a COVID-19 Vaccine Program Provider Agreement and Profile, COVID-19 Vaccine Program Enrollment Addendum, and Redistribution Agreement to potential enrollees as fillable PDFs for them to complete using a computer and sign digitally. The completed and signed forms must be returned to the Immunization Program by email ([covidvax@mt.gov](mailto:covidvax@mt.gov)) either through the “Submit” button on the form or by attaching the form to an email. Enrollment forms cannot be scanned or faxed.

Enrollment of approved vaccine providers will be completed within three business days of receiving the enrollment forms by the Immunization Program.

Enrollment documents will be processed as follows:

- 1) The VFC Quality Specialist will:
  - a. Inspect documents for completeness and accuracy; contact the organization for clarification and missing information or forms.
  - b. Ensure organizations with multiple locations have a provider agreement for each location.
  - c. Complete all “For official use only” fields and assign unique COVID-19 organization and location IDs following the instructions on the provide agreement so that all locations can be associated with the right organization.
  - d. Verify the medical licenses of providers listed in the provider profile are active and valid by looking them up in the Montana Department of Labor and Industry’s License Lookup database. Remand issues with licenses back to the organization for resolution, when necessary.
  - e. Forward submitted imMTrax MOAs to IIS staff for processing and entry into imMTrax.
  - f. Save inspected and completed enrollment forms on the shared drive in a folder called “Incoming Enrollment Documents” in a folder with the facility name.
- 2) The Vaccine Manager will review facility folders in the “Incoming Enrollment Documents” folder to confirm the listed vaccine storage units and temperature monitoring equipment meet requirements for COVID-19 vaccine in accordance with the manufacturer’s guidance, Emergency Use Authorization (EUA), and *CDC’s Vaccine Storage and Handling Toolkit*.
  - a. If equipment does not meet minimum requirements, the enrollment documents will be returned to the organization with guidance on how to meet requirements and instructions on how to re-submit. The facility folder will be moved to a “Pending” file. Organizations that cannot meet minimum storage unit and temperature monitoring requirements will not be approved as COVID-19 vaccine providers.
  - b. If equipment meets minimum requirements, the facility folder will be moved to an “Approved” folder. Approved enrollment forms will be retained for at least 3 years and made available to the CDC upon request.
- 3) The Vaccine Manager will compile the vaccination capacity, populations served, and vaccine storage capacity/capability information from the provider profiles for each location to be used in allocating vaccine. See [Section 7](#).
- 4) The VFC Quality Specialist will enter approved facilities into imMTrax, the state immunization information system and the federal Vaccine Tracking System (VtrckS) marking them as COVID-19 vaccine providers where possible.
- 5) The VFC Quality Specialist will email the primary and backup vaccine coordinators, the medical director, and chief executive/fiduciary officer letting them know their enrollment is complete, what phase of the vaccination process they have been assigned, and what training requirements they must be complete before receiving vaccine.

Immunization staff evaluates this process after Phase 1 enrollment to determine if an online form should be developed to collect enrollment information for subsequent phases.

### Compiling and Reporting Enrollment Data

The Montana Immunization Program will extract data from completed, reviewed, and approved provider agreements collected on the fillable PDF provided by the CDC. The extracted data will be copied into a Provider Agreement Template Master CSV file, quality checked, and then uploaded to the Immunization Data Lake (IZDL) using the Partner Portal. Subsequent data extractions will be added to the master and the entire file will be uploaded to the IZDL twice a week Monday and Thursday by 1900 MST.

## C. Training COVID-19 Vaccine Providers

The Immunization Program is designing a Montana-specific online instruction course. All enrolled providers are required to complete this Montana COVID-19 Vaccinator Training Module to receive and administer COVID-19 vaccine. The primary contact at each site verifies completed training.

Upon completion of their enrollment, the provider location's primary and backup vaccine coordinators will receive an email detailing how to meet the training requirement. Anyone at the enrolled provider location can take the training course, but the primary and backup vaccine coordinator must complete the training and disseminate the information to relevant staff at their facility. Completion of the instruction by the primary contact at each site creates a verification record and confirms the Immunization Program's training requirement. The location cannot receive vaccine until the primary coordinators complete the training.

The Montana Immunization Program will train COVID-19 vaccination providers on the follow topics:

- ACIP COVID-19 vaccine recommendations, when available
- How to order and receive COVID-19 vaccine
- COVID-19 vaccine storage and handling (including transport requirements)
- How to administer vaccine, including reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
- How to document and report vaccine administration via the jurisdiction's IIS or other external system
- How to manage vaccine inventory, including accessing and managing product expiration dates
- How to report vaccine inventory
- How to manage temperature excursions
- How to document and report vaccine wastage/spoilage
- Procedures for reporting moderate and severe adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets or VISs to vaccine recipients
- How to submit facility information for COVID-19 vaccination clinics to CDC's VaccineFinder (particularly for pharmacies or other high-volume vaccination providers/settings)

An all-awardee email from CDC NCIRD on September 21, 2020, indicated they are developing training material on many of the COVID-19 vaccine training topics listed above and they will make these materials available to jurisdictions and enrolled providers. We will review the CDC-provided materials as they become available, incorporate them into our training curriculum as appropriate, and produce Montana-specific material to fill in any gaps. We will use the online learning platform Moodle to bring it all together into a comprehensive training program with the ability to track participation and completion. DPHHS requires the primary and backup vaccine coordinators at each location to complete the entire Moodle curriculum before they can receive vaccine at their location. See Table 1 for details on the Moodle curriculum.

Table 4. Montana COVID-19 Vaccine Provider Training in Moodle

Topic	Training Material	Author
<b>ACIP COVID-19 vaccine recommendations</b>	Webinar and slide deck summary	CDC
<b>Preparing and Administering COVID-19 Vaccine</b>	COVID-19 training module and product summary sheets	CDC
<b>Vaccine Storage, Handling, and Transport</b>	COVID-19 training module, CDC Vaccine Storage and Handling Toolkit, Summary Sheets,	CDC
<b>Determining BUD and Expiration Dates</b>	BUD and expiration date tracking tools	CDC
<b>Reporting Adverse Events and Administration Errors to VAERS</b>	Online Videos -VAERS: Overview and Demo; VAERS: Online Reporting Demo	CDC
<b>Providing and Managing EUAs and VISs</b>	Forthcoming from CDC	CDC
<b>Submitting COVID-19 Vaccination Clinic Information to CDC’s VaccineFinder</b>	Forthcoming from CDC	CDC
<b>Ordering and receiving COVID-19 vaccine</b>	Online video and quick reference guide	Montana IZ Program
<b>Managing and Reporting Temperature Excursions</b>	Online video and quick reference guide	Montana IZ Program
<b>Reporting Administered Doses</b>	Online video and quick reference guide	Montana IZ Program
<b>Managing and Reporting Vaccine Inventory</b>	Online video and quick reference guide	Montana IZ Program
<b>Documenting and Reporting Vaccine Wastage</b>	Online video and quick reference guide	Montana IZ Program

In addition to the Moodle course, we will develop a “COVID-19 Vaccinator Resource” page to serve as a central location for COVID-19 vaccine training and information. It will have links to current CDC- and Montana-produced materials as well as a portal to our Moodle training module.

## D. Approving Vaccine Redistribution with Equity

All potential COVID-19 vaccinators will receive a Redistribution Agreement upon initial contact, and any provider can apply to become a vaccine redistributor. However, the Vaccine Manager will review submitted redistribution agreements and, under guidance from the COVID-19 Vaccination Planning Group, only approve those that meet the following criteria:

- High-volume storage capacity

- Ability to comply with cold chain requirements for storage and transport as defined by the manufacturer, the EUA, and *CDC Storage and Handling Toolkit*
- Ability to reach other locations in their organization or clinics needing smaller quantities of vaccine within an 8-hour day
- Willingness to assume financial responsibility for redistribution
- Ability to ensure locations receiving redistributed vaccine have an approved CDC COVID-19 Vaccination Program Provider Agreement

The Vaccine Manager will notify providers approved as redistributors and will keep a list of redistributors for use in allocating vaccines. See Section 7.

## E. Federally Enrolled Pharmacies

Some multijurisdictional vaccination providers (e.g., select large drugstore chains, some IHS locations, clinics and hospitals, and other healthcare facilities) will enroll directly with CDC to order and receive COVID-19 vaccine in Phase 2 operations. CDC will notify DPHHS of any entities receiving direct allocations. These direct partners are required to report vaccine supply and uptake information to the Immunization Program (See Section 9). See Section 3 for operational strategy.

## F. Direct Allocations to Federal Entities

The CDC will provide COVID-19 vaccine directly to qualifying federal entities with residential populations in Montana. While there are several of these organizations that have operations in Montana, there are only three with critical populations that are affected by this strategy.

**IHS** is one of these qualifying entities and will work with DPHHS Director's Office, the COVID-19 Vaccination Planning Group, and the COVID-19 Vaccination Coordination Team to collaborate with CDC provisions of the vaccine to each of the eight tribal nations.

Six of the eight have elected to work directly with CDC to receive federal resources. The Confederated Salish Kootenai Tribe and Little Shell Tribe will work with DPHHS and its surrounding partners with COVID-19 vaccine distribution and administration. DPHHS will assist as needed with the Blackfeet, Crow, Fort Belknap, Fort Peck, Rocky Boy, and Northern Cheyenne reservations..

The **Veterans Administration Hospital**, located in Helena will receive vaccine for administration to its staff, volunteers, and veterans under its care.

**Malmstrom Air Force Base**, as an entity of the Department of Defense, will receive COVID-19 vaccine for all its military personnel and their dependents.

*Note:* At the time of this current plan version, military National Guard and Reservists are not part of direct allocation. Montana and its local jurisdictions will consider these personnel among the other populations in which they belong.

## Section 6: COVID-19 Vaccine Administration Capacity

**A.** Montana’s 2016 model study for pandemic influenza vaccination capacity suggested that it may take approximately 11 weeks for non-pharmacy providers and pharmacies to administer vaccines to 80% of the adult population in the state during a pandemic, assuming an optimum number of providers would enroll as pandemic vaccine providers. (Modeling Pandemic Influenza Vaccination Capacity for Adults - Montana Report, 2016) The study measured only capacity for adult vaccinations and social distancing protocol will impact throughput.

This model study for Montana encompassed the following assumptions, among others.

1. The vaccination campaign would take place during a severe pandemic, where public demand for vaccination would be extremely high and remain so throughout the vaccination campaign.
2. All providers described in the model inputs would actually enroll, be eligible, and agree to participate in the pandemic vaccination program.
3. Enrollment rate of 100% of health departments and hospitals, and 65% of doctor offices; 90% of chain pharmacies; 75% of supermarket and mass merchant pharmacies; and 50% of independent pharmacies.
4. The rate of vaccine administration by all providers would be constant throughout the weeks of the vaccination campaign.
5. 30 million vaccine doses could be distributed weekly with a pro rata allocation of doses by the Federal government to states.
6. Linear ramp up time of 5 weeks for full vaccine administration capacity in the state.
7. A lead time of 5.4 days between allocation and shipment of vaccines, based on historical data from the 2009 H1N1 Pandemic.

**B.** Immunization staff will enhance the basic modeling from this study in several ways. Accurate collection of data from provider enrollment forms can narrow the vaccine administration capacities and inform allocations. More specific information coupled with new technology and web-based calculating tools will also assist creating more accurate estimates. The Immunization Program will use these tools with guidance from the CDC.

Broader outreach to providers in Montana is already underway in an effort to maximize enrollment. Coupled with information about the population each provider serves, the staffing available, potential throughput (already estimated through LHJ preparedness planning) and other ongoing routing vaccinations, the Immunization Program staff can estimate the administration capacity for the COVID-19 vaccine.

## Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

The federal government will determine the amount of COVID-19 vaccine designated for Montana. CDC has indicated that the allocation will be pro rata by population. DPHHS's Immunization Program is responsible for managing and approving orders from enrolled providers (see part A below) using this allotment. Each order will draw down from Montana's allocation.

The amount allotted could change over time, which may be based on critical populations recommended for vaccination by ACIP (with input from NASEM), COVID-19 vaccine production and availability.

Federal agencies and additional commercial partners will also receive allocations directly from CDC (see Section 5-I).

### A. Allocating Vaccine

The COVID-19 Vaccination Planning Group, assisted by the COVID-19 Vaccination Coordination Team, will allocate vaccine to enrolled providers using the information from Sections 4, 5, and 6 of this document.

The Immunization Program's Vaccine Manager will maintain a database of the following information for each COVID-19 vaccine location and make it available to help with allocation decisions.

#### *Vaccination Capacity*

- Number of patients/clients seen weekly: <18 years, 19–64 years, >65 years
- Number of unique patients seen per week on average
- Number of influenza vaccine doses administered during peak week of the 2019-2020 flu season
- Populations served

#### *Storage Capability and Capacity*

- Storage temperature range capabilities
- Number of multi-dose vials that can be stored

The VFC Quality Specialist will provide current inventory, doses administered, and wastage information for each location. Locations will reconcile vaccine inventory weekly to keep information as up to date as possible.

Federal and commercial partners receiving vaccine directly from the CDC will also provide information on current inventory and vaccine administration to inform allocation decisions.

#### **Cold Chain Capability**

Provider locations must meet the requirements listed in the Storage and Temperature Monitoring Addendum before the Immunization Program allows them to store COVID-19 vaccine.

As part of the enrollment process, the Vaccine Manager will review the make and model of vaccine storage and temperature monitoring equipment listed in the enrollment documents to ensure they are:

- CDC-recommended storage unit types

- Capable of holding proper vaccine storage temperatures
- Equipped with continuous monitoring digital thermometers with the following features:
  - Continuous recording devices that take readings at least every 30 minutes
  - Reads temperatures from a buffered probe
  - Displays current, minimum, and maximum temperatures
  - Generates temperature data that is reviewable, archivable, and able to be sent to the Immunization Program for review
  - Alarms to indicate temperatures outside proper vaccine storage temperatures

Providers who cannot meet these vaccine storage standards will not be allowed to enroll as COVID-19 vaccine providers.

## C. Ordering Vaccine

During Phases 1 and 2 when vaccine supply is limited, COVID-19 vaccine providers will not directly order vaccines. The Immunization Program will hand-key orders into VtrckS for them following the process below.

1. Each week, the Planning Advisory Group with input from the Plan Coordination Team will review the vaccine available and apportion it between enrolled providers.
2. The Group will communicate to the VFC Quality Specialist the number of doses to be shipped to each location.
3. The VFC Quality Specialist will hand-key the orders into VtrckS.
4. Immediately after the order is placed, the VFC Quality Specialist will email the primary and backup vaccine coordinator at the receiving location to let them know a COVID-19 vaccine order has been placed and an estimated arrival date.
5. When the VFC Quality Specialist is notified by the CDC that the vaccine has shipped, she will again email the primary and backup vaccine coordinators at the location that a shipment will arrive that day and hand-key the inventory into the appropriate location in imMTrax.

As required by the enrollment agreement, COVID-19 vaccine providers will immediately communicate changes in contact information and shipping data to the VFC Quality Specialist. Upon receipt of this information, the VFC Quality Specialist will update imMTrax, VtrckS, and all COVID-19 vaccine provider databases with the updated information. The Immunization Program will develop a checklist to facilitate this process.

### Equitable Distribution

The Plan Coordination Team and the Immunization Program will use the information from vaccine orders and information about critical populations across the state to ensure appropriate access to the vaccine during the current phase. This will influence the distribution of vaccine to providers. Access to health services is widely variable across the state due to the vast geography. Uptake in the more urban centers in the state will include a large number of surrounding rural jurisdictions. Public health agencies in cities such as Billings, Great Falls, and Missoula often conduct off-site clinics or PODs for vaccination operations to reach underserved populations. DPHHS will recommend that local and tribal jurisdictions conduct Phase 1 vaccinations to critical populations (e.g. healthcare workers and high-risk patients) on-site in closed PODs. See Section 3 for distribution strategies.

## D. COVID-19 Vaccine and Ancillary Supplies

As announced by HHS on August 14, 2020, McKesson is collaborating with the CDC for [vaccine distribution \[hhs.gov\]](#). As the central distributor of future COVID-19 vaccines and related supplies, McKesson will work under CDC's guidance to ship COVID-19 vaccines and accompanying supplies to administration sites. Critical to the nation's COVID-19 vaccination strategy, these matching vaccination kits will be automatically ordered in amounts to match vaccine orders and shipped with the vaccine once it is available.

McKesson is working with the Strategic National Stockpile (SNS) to assemble, package, and label individual vaccine ancillary supply kits at various McKesson distribution facilities throughout the United States. Each kit contains supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
  - 25-gauge, 1" (if vaccination indicated for pediatric population)
  - 22–25-gauge, 1-1.5" (adult)
- Syringes, 105 per kit (ranging from 1–3 mL)
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit
- Vaccine [needle guide \(https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf\)](https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf) detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)

Other supplies, such as sharps containers, gloves, bandages, and other standard equipment will not be included. DPHHS will work with LHJs who will require additional PPE through its current resource supplement ordering program.

### Vaccine A Ancillary Supplies

The Pfizer COVID-19 vaccine is the exception to the McKesson plan. This product requires ultra-cold transport and storage, will be shipped directly from the manufacturer along with its own ancillary kit. The kits will contain both Administration Kits, Mixing Kits, and vials of diluent to prepare the vaccine for use.

Each combined kit weighs 40 pounds and consists of enough material to mix and administer one tray of the Pfizer vaccine, or 975 doses. Vaccine A requires pelletized dry ice to maintain the ultra-cold temperature (-60°C to -80°C).

## E. Vaccine Transfers

The Immunization Program may occasionally allow local transport of vaccines from one location to another, outside of established Redistribution Agreements, as long as cold chain requirements are maintained. Staff will train providers on how to submit transfers for approval and maintain cold chain during transport in the Montana COVID-19 Vaccine Provider Training in Moodle.

- Locations can only transfer vaccine between currently enrolled COVID-19 vaccine providers.
- Locations cannot transfer opened, multi-dose vials.

- Locations must follow the current guidance for cold chain management during transport of COVID-19 vaccine as described in the manufacturer’s prescribing information, the EUA for the vaccine, and the *CDC Vaccine Storage and Handling Toolkit*.
- Transfers must be limited to those that can be personally carried and where the vaccine can reach an approved storage unit within eight hours or a regular business day.
- Vaccine transfers must be approved by the Immunization Program prior to physically exchanging the vaccine.
- Provider must submit all transfer requests in imMTrax and notify the VFC Quality Specialist by email that a transfer request has been submitted.
- The VFC Quality Specialist will review transfers for compliance with the requirements listed above, and if approved, will email the submitting and receiving location saying the vaccine is approved for transfer and provide transport guidance for the vaccine beginning moved.

## F. Monitoring Vaccine Inventory and Wastage

DPHHS will require COVID-19 vaccine providers to manage their inventory in imMTrax. Providers will learn inventory management in the Montana COVID-19 Vaccine Provider Training in Moodle.

- The VFC Quality Specialist enters the doses of vaccine shipped to each location into their imMTrax inventory
- Vaccine providers are required to reconcile their inventory each Friday by removing doses administered from their current inventory. Weekly reconciliation is necessary to provide current stocking levels to the Planning and Coordination Team for making allocation decisions
- The VFC Quality Specialist will submit current inventory for all COVID-19 vaccine providers in VtrcKS weekly each Monday
- Vaccines distributed under an EUA will not have an accurate expiration date in imMTrax, but will have a “placeholder” date of 12/31/9999 instead; Current guidance in the EUA and BUD tracking tools from the CDC should be used to determine expiration dates

Providers will report vaccine wastage to the Immunization Program by submitting a Wasted and Expired form to the VFC Quality Specialist. The Montana Immunization Program will track wastage by location. The Immunization Program will develop a process for recovering (returning) COVID-19 vaccine when the CDC communicates detailed guidance.

## Section 8: COVID-19 Vaccine Storage and Handling

### A. Assessing Cold Chain Capabilities

As part of the enrollment process, providers must submit a Storage and Temperature Monitoring Addendum. The Addendum describes the equipment requirements for storing COVID-19 vaccine and a place to list the make and model of their storage units and temperature monitoring equipment at each location.

The Vaccine Manager will review information provided on the Addendum to ensure:

1. Equipment meets vaccine manufacturer, EUA, and CDC-requirements for the vaccines of interest
2. Storage units are capable of holding proper vaccine storage temperatures for the vaccines
3. Storage units are equipped with a continuous monitoring digital thermometer with the following features
  - a. Continuous recording device that take readings at least every 30 minutes
  - b. Reads temperatures from a buffered probe
  - c. Displays current, minimum, and maximum temperatures
  - d. Generates temperature data that is reviewable, archivable, and able to be sent to the Immunization Program for review
  - e. Alarms to indicate temperatures outside proper vaccine storage temperatures

If equipment does not meet minimum requirements, the Vaccine Manager will return the enrollment documents to the organization with guidance on how to meet resolve the issues and instructions on how to re-submit. Providers who cannot meet these vaccine storage standards will not be allowed to enroll as COVID-19 vaccine providers.

If equipment meets minimum requirements, the Vaccine Manager will approve facility to store the vaccines within their capabilities and the enrollment will proceed.

All COVID-19 vaccine provider locations must enroll through the Immunization Program as described in this plan and have their storage and temperature monitoring capability approved by the Vaccine Manager, including those approved to redistribute vaccine and locations that will receive vaccine from a redistributor.

The Vaccine Manager will track storage and temperature monitoring capabilities of each enrolled location and make it available to the Planning and Coordination Team for use in making allocation decisions.

### B. Ensuring Adherence to Cold Chain Requirements

All providers must complete the COVID-19 Vaccine Provider Training course in Moodle, which will include general storage and temperature monitoring guidance and vaccine-specific requirements based on forthcoming guidance from the manufacturers, EUA, and *CDC Vaccine Storage and Handling Toolkit*.

In addition to any vaccine-specific cold chain requirements (yet to be determined), providers will be required to:

- Document minimum and maximum temperature every morning their facility is open and prior to any major vaccination event
- Immediately report temperature excursions to the Immunization Program by submitting an online Vaccine Incident Report and not using vaccine affected by the excursion until the Immunization Program clears it for use
- Archive electronic temperature data and minimum/maximum temperature documentation for all COVID-19 storage units for three years and make it available to the Immunization Program upon request

### **Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations**

Satellite, temporary, or off-site clinics that require vaccine transport from a central location need enhanced storage and handling practices. The DPHHS COVID-19 Vaccine Provider Training Course in Moodle will train providers on proper vaccine transport procedures based on the COVID-19 addendum to CDC’s *Vaccine Storage and Handling Toolkit*.

The Storage and Temperature Monitoring Addendum collected during enrollment will describe the requirements for COVID-19 vaccine transport and have a place to list the transport capability of the provider location. The Vaccine Manager will review the equipment to ensure it meets requirements and either approve or deny the location as a COVID-19 vaccine transporter.

In addition to any vaccine-specific requirements, providers holding satellite, temporary, or off-site clinics will be required to:

- Limit the amount of COVID-19 vaccine transported to the location based on the anticipated number of vaccine recipients
- Transport vaccine using proper equipment and procedures outlined in the COVID-19 Addendum to CDC’s *Vaccine Storage and Handling Toolkit*
- Store vaccine at the appropriate temperature throughout the day of the clinic
- Review and document temperatures according to the COVID-19 addendum to CDC’s *Vaccine Storage and Handling Toolkit*
- Assess temperature data at the end of the day before returning vaccine to fixed storage
- Immediately report temperature excursions to the Immunization Program by submitting an online Vaccine Incident Report and not using or discarding the affected vaccine until receiving instructions

### **C. COVID-19 Vaccine Handling**

CDC will provide vaccine product information as it becomes available from each manufacturer and is granted an EUA from the FDA. The Immunization Program will keep this information on file and on-line for reference and to provide guidance to enrolled providers. This information includes dosage amounts, mixing directions, storage needs, and other standard instructions provided with all vaccines.

## Vaccine A (Pfizer) Ultra-Cold

Pfizer’s product is the first COVID-19 vaccine submitted to the FDA for an EUA and ready for distribution. This vaccine requires ultra-cold storage and handling until it is ready to be administered.

### Ultra-Cold Shipping

Pfizer, working with CDC and DPHHS’s Immunization Program, will fulfill authorized orders through VtrcKS and send vaccines directly to providers (see Section 7-C) along with ancillary supplies (Section 7-D). Pfizer will ship its vaccine directly ( ) in an Aerosafe Thermal Shipper. This box is insulated and

### Overview of Direct Shipments to Points of Vaccination

#### Direct Shipments\* to Vaccination Center by Transport Courier

- Pfizer has designed a distribution model which is built on a flexible just in time system to ship the vaccine from manufacturing site and/or storage facility directly to the points of vaccination.

#### Temperature & Location Tracking During Transportation

- Each thermal shipper has reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.
- Shipments will be executed under the management of Pfizer Quality processes and controls to ensure that upon ownership transfer, product has arrived under acceptable conditions.
- Temperature records of the shipments can be shared with upon request.

COVID Vaccine supply chain model is a drop ship direct from Pfizer manufacturing sites to the designated locations by the governments. \*Markets with no Pfizer commercial legal entity: Product ownership transfer at port of entry for governmental customer importation and in-market distribution

Figure 3. Ultra-Cold shipping

### Ultra Low Temperature Thermal Shipper – Overview of Pack Out

ITEM	DESCRIPTION
1	DRY ICE POD
2	PAYLOAD (VIAL TRAYS)
3	INNER LID
4	PAYLOAD SLEEVE
5	OUTER CARTON

Weights and Dimensions	
Tare Weight (Inc. Dry-Ice)	8.5kg (31.5kg)
Volumetric Weight	15.0kg
Payload Space L x W x H	245x245x241mm
Shipper Dimensions L x W x H	400x400x560mm

Figure 4. Ultra-Cold thermal shipping container

filled with pelletized dry ice. Each shipper will contain a Geospatial Positioning System (GPS) enabled device that monitors the temperature of the vaccine to ensure it arrives at its destination with no excursions.

Pfizer packs its COVID-19 vaccine in single trays, each holding 195 vials. The vials are 2 ml. type 1 glass multi-dose (MVD) holding 0.45 ml of frozen vaccine. Each vial will yield 5 doses after mixing with the diluent provided by Pfizer (Section 7-D). A single tray will provide 975 doses.

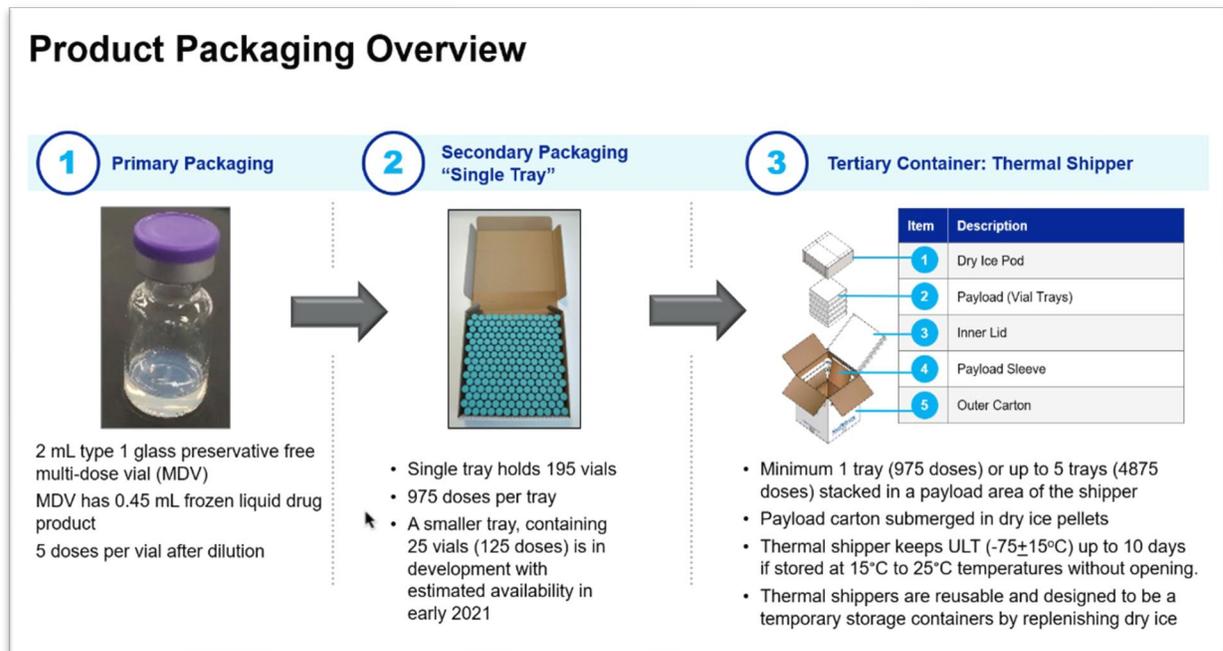


Figure 5. Ultra-Cold packing tray

### On-Site Ultra-Cold Vaccine Storage

As described in Section 5, enrolled recipients for ultra-cold vaccines must demonstrate the capability to handle the requirements for storage. CDC issued the following guidance.

#### Ultra-Cold Temp Frozen (-60°C to -80°C)

- Freezer units capable of ultra-cold temperatures (UCTs)
- The shipping container (thermal shipper) may be used to store vaccines:
  - Once received (day 1), the thermal shipper should be replenished with pelletized dry ice within 24 hours.
  - Shippers should be replenished with dry ice every 5 days thereafter to maintain required temperature.
  - Total amount of dry ice needed per thermal shipper “recharge” is ~23 kg.
  - On day 15, transfer the vaccine to refrigerated temperatures (2°C to 8°C). Use within 5 days (120 hours).
  - Shippers may only be opened two times a day.
- Temperature monitoring must be in alignment with CDC guidance, irrespective of re-icing.

- Thermal shipper may be monitored using a temperature probe on the container, in alignment with guidance provided by CDC and information provided by the manufacturer.
- Direct handling of dry ice needed for re-icing the containers will require the use of appropriate PPE.

### *Thawed but NOT diluted (2°C to 8°C)*

- Product may be removed from the ultra-cold storage or thermal shipper, thawed, and stored at 2°C to 8°C for up to 5 days (discard unused doses after 5 days).
- Cannot return to ultra-cold storage or thermal shipper once thawed

### *Diluted (room temperature)*

- If removed directly from ultra-cold storage, vaccine must be thawed ~30 minutes at room temperature before dilution.
- Once vaccine is thawed, it must be diluted within 2 hours. If unable to dilute within 2 hours, store at 2°C–8°C.
- Must use diluted vaccine within 6 hours (discard any unused diluted vaccine after 6 hours)

## **Vaccine B**

Enrolled participants must meet the standards described in parts A and B above for vaccine storage. CDC has not indicated that any other COVID-19 vaccines under development will require ultra-cold handling and storage. CDC has contracted with McKesson as a central distributor for vaccines and ancillary supplies (see Section 7-D). [vaccine distribution \[hhs.gov\]](https://www.mckesson.com/vaccine-distribution). McKesson will fulfill authorized orders (see Section 7-C) and send vaccines directly to providers.

### **On-Site Vaccine Storage (Vaccine B Products)**

The following is the storage guidance provided by CDC

#### *Frozen (-25°C to 15°C until ready for use)*

Note: This is a narrower range than for varicella-containing vaccines.

#### *Refrigerated (2°C to 8°C)*

- Must use within 7 days if the vial has not been entered.
  - Thaw before use:
  - Thaw in refrigerated conditions between 2°C to 8°C for 2 hours. Let vial stand at room temperature for 15 minutes before administering.
  - Alternatively, thaw at room temperature between 20°C to 25°C for 1 hour.
  - After thawing, do not return vial to the freezer.

#### *Room temperature*

- The total time before administration and after removal from the refrigerator should be no more than 12 hours.
- Once the vial has been entered, it must be used within 6 hours (discard any unused vaccine after 6 hours).

## Section 9: COVID-19 Vaccine Administration Documentation and Reporting

### A. Data Collection

Montana DPHHS offers several systems and methods for data collection to vaccine providers. Immunization staff will determine which to use based on the unique facility needs and capabilities.

- IIS – direct entry, HL7 submissions
- Vaccine Administration Management System (VAMS) – provided by CDC, is available for direct entry, reporting to the IZ Gateway, and subsequently to the IIS
- External Web Application – PrepMod (pending), available for direct entry reporting to the IIS
- Flat file submission (where direct entry or HL7 submission is not feasible) based on provided template with required data elements; Files submitted would be validated and uploaded into the IIS
- Paper administration record received via fax based on provided template with required data elements; This method is for emergency use and only appropriate where internet or computer access becomes unavailable, such as a prolonged power outage

### B. IZ Gateway

COVID-19 required vaccine information will be collected through the IIS and sent to the CDC via the IZ Gateway. If this method is not available, we will compile a CSV file of the required data elements and send it to CDC via an approved, secure method.

### C. Documenting and Reporting Vaccine Administration

Each facility administering COVID-19 vaccine that is required to report every 24 hours will be contacted by Immunization Program staff to establish primary and back-up methods for data submission. Regardless of methods identified, Immunization Staff will provide each facility instructions and resources for flat file (Excel) and paper record submission in case of emergency or failed primary or back-up reporting method. Immunization staff will document the methods identified and maintain them for reference.

- Immunization Program staff will contact all facilities to determine if the providers will be, or expect to be, administering COVID-19 vaccine at a satellite, temporary, or off-site clinic setting. If yes, the facility will provide the primary and back-up method for data submission in that setting.
- Facilities submitting data via direct data entry or HL7 into the IIS or PrepMod will be provided instructional resources and documents created by IIS staff.
- Facilities submitting data via direct data entry into the IIS or PrepMod will be offered individual and group web-based training to review functionality and requirements by IIS staff.
- Immunization staff will encourage all facilities to establish and familiarize themselves with their respective reporting method prior to use, along with basic troubleshooting information available and phone/email contacts for help desk services based on reporting method used.

## D. Reporting for Off-Site Clinics

Part of the communication with facilities will determine which will, or expect to, administer COVID-19 vaccine at a satellite, temporary, or off-site clinic setting. If yes, the facility will provide the primary and back-up method for data submission in that setting.

Immunization staff will encourage all satellite, temporary, or off-site clinic settings to establish and familiarize themselves with their respective reporting method prior to use, along with basic troubleshooting information available, and phone/email contacts for help desk services based on reporting method used.

## E. Verify Reports

Immunization Program staff will compare doses reported as administered to doses reported to the IIS in the same evaluation period. The staff will contact facilities directly to request investigation and resolution when they find discrepancies. Staff will directly contact facilities not reporting any vaccination data for 2 consecutive business days to determine any gaps in reporting.

## F. COVID-19 Data Dashboard

The State of Montana expects to obtain access to an IIS connected COVID-19 Data Dashboard, currently under development with Scientific Technologies Corporation (STC). This vendor estimates making a dashboard available by early November. While the specifications are not yet available, the dashboard is expected to display vaccination administration and coverage assessment data by county and defined population groups. Numerators and denominators will be available. All data will be exportable.

Immunization Program staff will utilize the Coverage Rate Report tool within the IIS to review vaccination series completion coverage for persons receiving COVID-19 vaccine, by type.

## Section 10: COVID-19 Vaccination Second-Dose Reminders

Montana’s Immunization Information System (IIS) has a Reminder/Recall module available to all users with permissions higher than read-only. The Immunization Program will provide instructional materials specific to COVID-19 reminder and recall functions in the IIS to all participating facilities.

Montana’s IIS Coverage Rate Report includes an option to export patient lists based on vaccine selected. The tool can be used to obtain a list of patients who have received the first dose and includes basic information such as primary phone number.

Immunization Program staff will encourage VAMS users to familiarize and utilize any reminder and recall functionality available in that system.

## Section 11: COVID-19 Requirements for IISs or Other External Systems

### A. Mitigation for IIS High Use Issues

Montana's IIS has a mass immunization data entry module which facilitates rapid information input. The module requires inventory and lot management within the IIS. All administering facilities will have access to the module. The module is contained within the IIS and requires computer, internet access, and current credentials.

### B. Montana's IIS Personal Identifying Information (PII) Gathering

- Date of Birth
- Sex
- Race
- Ethnicity
- Address
- Phone Number
- Email

### C. Capacity for Data Exchange

Montana uses STC's IWEB, PHC-Hub, and VOMS applications to comprise the cloud hosted IIS. PHC-Hub is the interoperability tool and can receive VXU messages and return QBP messages, including forecasting (Z44) where requested.

The IIS has several report and output capabilities available, including doses administered. The State of Montana expects to obtain access to an IIS connected COVID-19 Data Dashboard, currently under development. The STC dashboard will display vaccination administration and coverage assessment data by county and defined population groups. Numerators and denominators will be available. All data will be exportable.

### D. On-Boarding Enrolled Facilities to IIS

The DPHHS Immunization Section is currently contacting pharmacies, long-term care centers, and nursing homes not currently submitting data to the IIS to offer enrollment to establish their locations and respective users as COVID-19 vaccine providers.

### E. IZ Gateway Connect and Share

CONNECT - Credentials have been provided to the American Immunization Registry Association (AIRA) for the Production and Staging environments. Connectivity for VXU submissions has been established and confirmed in both environments.

SHARE - STC is currently coordinating needed certificate updates to facilitate the CONNECT options and expected to be in place by 10/16/2020. Pending legal approval APHL and Interjurisdictional Agreements (below).

## F. Data Sharing Agreements

Montana has completed the Association of Public Health Laboratories (APHL) Data Use Agreement for the CONNECT component of the IZ Gateway. Montana is in the process of amending the APHL agreement to include the SHARE component.

Per CDC, this data use agreement is not yet finalized or available for legal review.

The Memorandum of Understanding is in legal review

## G. Mitigation for IIS Access Issues

In case of internal network outages, the Immunization Program staff will provide all facilities with a PDF file complete with required fields to use for data collection. Vaccine providers will print an adequate number of copies of the document and store as an emergency method.

Immunization Program staff will distribute an Excel spreadsheet complete with required fields to use for data entry and submission to all COVID-19 vaccine providers. Instructions for using these spreadsheets include saving copies to the internal drive of any computer or device they use for data collection to ensure it is available if needed.

## H. Data Quality Assurance

DPHHS Immunization Program staff will provide specific information on data entry expectations and requirements to all submitting facilities. Staff will compare administration dates with insertion dates into the IIS for all providers. Deviations outside 24 hours will be evaluated to determine outreach and improvements.

Staff will evaluate facilities or organizations administering COVID-19 vaccines and submitting via HL7, including the IZ Gateway, VAMS, and PrepMod, to ensure adherence to CDC-provided required fields. Evaluations of these various compliance reports are used for analysis and individualized follow up.

Immunization Section staff monitor all submitting organization interfaces daily for errors to prevent data not being applied to the IIS. Communication between IIS staff and the submitting facility will ensure correction and resubmission. Facilities entering data manually through the IIS must complete the required fields.

IIS staff will run Provider Error and Warning Reports weekly to evaluate completion or validity of data elements submitted. Facilities found to be submitting patient/vaccination data at a threshold less than 97% for required fields will receive individual follow-up by IIS staff.

Staff will also directly contact facilities who fail to report any vaccination data for two consecutive business days to determine any gaps in reporting.

IIS and contract staff will manage and process any outstanding records held for duplicate review for all COVID-19 administering locations daily.

## Section 12: COVID-19 Vaccination Program Communication

The Immunization Section will develop communications for guidance and information intended for COVID-19 vaccine providers. DPHHS public messaging is coordinated through the department's Public Information Officer (PIO) with IZ SME guidance. All communications are subject to the DPHHS Communications Policy in addition to the Governor's Coronavirus Task Force Joint Information Center.

The thirteen tribal health and government agencies represented on the COVID-19 Vaccination Plan Coordination Team will work with the DPHHS Director's Office to ensure the consistency and accuracy of all messages about vaccine safety and efficacy.

DPHHS recognizes there are consistencies to public messaging concepts throughout all three phases of the COVID-19 vaccine program. Several of the elements will not change or will only change minimally. These static items are the audiences, modes of communication, and information sources.

### Audiences:

- Critical infrastructure workforce (includes Healthcare Personnel)
- People at increased risk for severe COVID-19 illness and acquiring or transmitting Covid-19
- Educators
- Employers
- Local and Tribal governments
- General Population

### Information resources:

- CDC guidance and information
- DPHHS Subject Matter Experts
- DPHHS Communications Policy
- COVID-19 One-Stop Shop Toolkits (in anticipation that COVID-19 vaccine informational materials will be added. <https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/index.html>)
- World Health Organization Vaccine Safety Events: Managing the Communications Response [https://www.euro.who.int/\\_data/assets/pdf\\_file/0007/187171/Vaccine-Safety-Events-managing-the-communications-response-final.pdf](https://www.euro.who.int/_data/assets/pdf_file/0007/187171/Vaccine-Safety-Events-managing-the-communications-response-final.pdf)
- Enrolled COVID-19 vaccine Providers
- Local and Tribal Health Jurisdictions
- Pharmaceutical COVID-19 vaccine producers
- Other Federal sources

### Modes of Communication

- Web and Social Media
- Hotline
- Public meetings
- Fact Sheets
- Radio and TV Broadcast

- Print publications
- Letters

Messaging might shift or take a different direction as the campaign progresses. This creates a cone of uncertainty for anticipated messages, and DPHHS acknowledges any variety of factors can re-prioritize message purpose and goals. Thus, the following objectives are current as of the creation of this document and remain only as general concepts. More key messages will develop as the PIO and subject matter experts continue to meet and discuss options with leadership. Tactical and strategic public information development will focus on the identified critical populations of each phase.

## **Phase 1: Medically Vulnerable Populations and Targeted Critical Workforce; Limited Vaccine Supply**

*Objective:* Notify the public of the arrival of vaccine into the state and introduce the plan for distribution and the reasons supporting it.

### *Key Messages:*

1. Montana has received its first shipment of vaccine.
2. A defined sector of vulnerable people and critical workforce will be the first to receive vaccinations
3. Limited supply of the vaccine at this time requires Montana to take a prioritized and planned approach to distributing and dispensing the vaccine.
4. Continue to social distance, wear masks, and wash hands.
5. Counter any misinformation about the safety or efficacy of the vaccine

## **Phase 2: Total Remaining Population Aged 16 and Over**

### **Risk Communications**

DPHHS PHEP maintains a Public Health Crisis and Emergency Risk Communications Annex as part of the department's EOP. The Annex encompasses guides and procedures based on the CDC's CERC and its principles. A toolbox document contains templates and instructions for rapid situational analysis, message development, audience identification, and delivery modes. Accompanying the toolbox is an immediate response template to quickly plan and execute a response to emergency situations.

Emergency communications are led by the DPHHS Public Information Officer. Two staff trained in Advanced Public Information Officer: Health & Hospital Emergencies course at the Center for Domestic Preparedness.

The expedited process for emergency response, in brief, includes

1. Rapid situation assessment
2. Identify the audiences
3. Determine the communication methods
4. Develop immediate key messages
5. Focus on message integrity

A schedule of updates for the emergency is developed after the initial response. Even if no new information is available, the update event occurs to reinforce previous messaging or to add detail to the current information, which will demonstrate transparency.

All crisis and emergency messages are subject to the DPHHS Communications Policy.

## Section 13: Regulatory Considerations for COVID-19 Vaccination

### Emergency Use Authorizations

The Immunization Program nurse consultant will review the EUAs and Vaccination Information Statements (VIS) for use in Montana. The nurse will use information from training provided by CDC and the ACIP to develop instructional modules for the mandatory Moodle training for COVID-19 Vaccine Providers on how to locate, understand, and distribute EUA fact sheets and VISs.

The confirmed EUA fact sheets are available on the FDA and CDC websites.

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

The mandatory online training, as described in [Section 5-E](#), will inform providers where to find the EUA and VIS documents for each COVID-19 vaccine, and we will link to these documents from our Montana COVID-19 Vaccinator Resource webpage.

### Standing Orders

The local Medical Officer is authorized to issue standing orders and protocols for dispensing sites. However, if a local order is not in place, the State Medical Officer has developed a standing order to prescribe medications for individuals at a Point of Dispensing (POD) site during a mass prophylaxis event. This order will include only those jurisdictions that do not have orders in place.

More information about legal authorities regarding mass vaccinations may be found in DPHHS's MSMD Annex.

## Section 14: COVID-19 Vaccine Safety Monitoring

### *Instructions:*

- A.** The Montana Immunization Program nurse consultant is the main point of contact for vaccine safety and VAERS reporting questions. The nurse consultant will develop a section in the mandatory Moodle training, as described in Section 5-E, on the requirements and process for reporting adverse events following any COVID-19 vaccination to VAERS.

## Section 15: COVID-19 Vaccination Program Monitoring

### Monitoring Progress in COVID-19 Vaccination Program implementation

Montana will utilize CDC's data compilation program, Tiberius, and its dashboard tools for comprehensive information management.

#### *Provider enrollment*

This is measured by the number of providers, categorized by type, engaged and the number of providers enrolled to participate in the vaccination program. Numbers will be compared as percentages of providers enrolled and those not enrolled.

#### *Access to COVID-19 vaccination services*

Throughout all phases of the vaccination effort, enrolled providers administering COVID-19 vaccine will submit all required information about individuals to the State's data gathering systems. Among this information is data indicating the population category to which the vaccine recipient belongs. As stated above, DPHHS's Immunization Program will use Tiberius to access the collective information from the State's data gathering systems identifying which populations are accessing COVID-19 vaccine administration and location among other information.

#### *IIS Performance*

The IIS manager, located in the Montana Immunization Program, will monitor IIS performance and enrollment by ensuring that systems are working properly. IIS Staff will monitor submissions daily and work with COVID-19 providers if errors in data submissions are found.

#### *Data reporting to CDC*

This will be measured by meeting the required daily uploads to the CDC's data clearinghouse. Daily uploads contain patient-level information on COVID-19 vaccines reported as administered in imMTrax.

#### *Provider-level data reporting*

This will be measured by comparing the percentage of enrolled providers meeting reporting expectations and the percentage of follow-up contacts made to facilities or organizations for not meeting acceptable frequency or not providing required information.

#### *Vaccine ordering and distribution*

This will be measured by tracking the orders and distribution of COVID-19 vaccine to enrolled providers.

#### *2-dose COVID-19 vaccination coverage*

This will be measured by tracking the percentage of targeted populations who received a 2<sup>nd</sup> dose within 1, 2, and 3+ months after the 1<sup>st</sup> dose

#### *Budget, Staffing, and Supplies*

The Immunization Section Supervisor along with the PHEP section supervisor will monitor budget, staffing and supplies associated with the COVID-19 vaccination response. Any deficiencies in any of these categories will be reported to leadership during internal planning meetings.

## *Communication*

All public communications must comply with the DPHHS Communications Policy. DPHHS does not maintain current mechanisms, resources, or sufficient staffing to dedicate to properly maintain effective monitoring of public information activity impacts or responses.

## *Local-level situational awareness*

DPHHS Immunization Section, PHEP, and CDEpi conduct regularly teleconference meetings with local and tribal jurisdictions regarding their COVID-19 pandemic response operations. A specific meeting dedicated to vaccine distribution is held every two weeks. Agendas include exchange of information and discussions of operational updates. As a decentralized state, these meetings are voluntary and collaborative in nature.

- The number of participants at virtual meetings is recorded
- Specific inquiries for guidance from providers are recorded

## *COVID-19 Vaccination Program metrics*

COVID-19 vaccination program metrics, including provider enrollment, doses distributed and administered, and vaccine coverage by jurisdiction will be calculated using the state's IIS. Relevant data will be shared using the Department's Coronavirus page located at <https://dphhs.mt.gov/publichealth/cdepi/diseases/coronavirusmt>.

## Section 16: Supplements

### References & Authorities, Acronyms, & Initializations

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- National response framework. (2019). Washington, DC: Department of Homeland Security.
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- Public health emergency preparedness and response capabilities: National standards for state, local, tribal, and territorial public health. (2019). Atlanta, GA: Centers for Disease Control and Prevention, Center for Preparedness and Response.
- Roadmap to Implementing Pandemic Influenza Vaccination of ... (n.d.). Retrieved October 13, 2020, from [https://www.cdc.gov/flu/pandemic-resources/pdf/roadmap\\_panflu.pdf](https://www.cdc.gov/flu/pandemic-resources/pdf/roadmap_panflu.pdf)
- United States, Centers for Disease Control and Prevention, Immunization Services Division. (2020). *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* (Vol. 1). Washington, DC: Centers for Disease Control and Prevention.

# Attachment 1: Proposed COVID-19 Vaccine Allocation – Montana

Time frames and target populations are based on current estimates of vaccine availability and current recommendations of [The Advisory Committee on Immunization Practices’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine – United States, 2020 | MMWR \(cdc.gov\)](#). (ACIP).

Timeframes and populations may be adjusted as resources and recommendations are reviewed.

Phase and Recipients	Administration Sites
<p><b><u>1A: Approximately 60,000 Montanans</u></b></p> <ul style="list-style-type: none"> <li>➤ <b>Frontline healthcare workers</b></li> <li>➤ <b>Long-term care facilities</b></li> <li>➤ <b>Healthcare workers with direct patient contact or virus exposure</b></li> </ul>	<ul style="list-style-type: none"> <li>➤ Hospitals</li> <li>➤ Critical Access Hospitals</li> <li>➤ Community Health Centers</li> <li>➤ Local Health Departments</li> <li>➤ IHS and Tribal Health</li> <li>➤ Pharmacies</li> </ul>
<p><b><u>1B: Approximately 290,000 Montanans</u></b></p> <ul style="list-style-type: none"> <li>➤ <b>Persons aged 70 years and older</b></li> <li>➤ <b>Persons aged 16-69 with high-risk medical conditions</b> <ul style="list-style-type: none"> <li>➤ <b>Qualifying medical conditions include:</b> <ul style="list-style-type: none"> <li>▪ Cancer</li> <li>▪ Chronic kidney disease</li> <li>▪ COPD (chronic obstructive pulmonary disease)</li> <li>▪ Down Syndrome</li> <li>▪ Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies</li> <li>▪ Immunocompromised state (weakened immune system) from solid organ transplant</li> <li>▪ Severe Obesity (BMI ≥ 40 kg/m<sup>2</sup>)</li> <li>▪ Sickle cell disease</li> <li>▪ Type 1 and 2 Diabetes mellitus</li> <li>▪ <b>On a case by case basis, medical providers may include individuals with other conditions that place them at elevated risk for COVID-19 related complications.</b></li> </ul> </li> </ul> </li> <li>➤ <b>Special populations at higher risk:</b> <ul style="list-style-type: none"> <li>➤ <b>American Indians and people of color who may be at elevated risk for COVID-19 complications</b></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>➤ Hospitals</li> <li>➤ Critical Access Hospitals</li> <li>➤ Community Health Centers</li> <li>➤ Local Health Departments</li> <li>➤ IHS and Tribal Health</li> <li>➤ Pharmacies</li> </ul>
<p><b><u>1C: Population number to be determined</u></b></p> <ul style="list-style-type: none"> <li>➤ <b>Frontline Essential Workers</b></li> <li>➤ <b>Persons aged 60 years and older</b></li> <li>➤ <b>Persons aged 16-59 with certain medical conditions</b> <ul style="list-style-type: none"> <li>▪ <b>Asthma (moderate to severe)</b></li> <li>▪ <b>Cerebrovascular disease</b></li> <li>▪ <b>Cystic Fibrosis</b></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>➤ Hospitals</li> <li>➤ Critical Access Hospitals</li> <li>➤ Community Health Centers</li> <li>➤ Local Health Departments</li> <li>➤ IHS and Tribal Health</li> <li>➤ Pharmacies</li> </ul>

<ul style="list-style-type: none"> <li>▪ Hypertension or high blood pressure</li> <li>▪ Immunocompromised state due to blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids or other immune weakening medications.</li> <li>▪ Neurologic conditions such as dementia</li> <li>▪ Liver disease</li> <li>▪ Overweight (BMI &gt;25 but &lt;40)</li> <li>▪ Pulmonary Fibrosis</li> <li>▪ Thalassemia</li> </ul> <p>➤ Individuals residing in congregate care and correctional facilities</p>	
<p><b><i>Phase 2</i></b></p> <p>➤ All remaining Montanans aged 16 or older</p>	<ul style="list-style-type: none"> <li>➤ Hospitals</li> <li>➤ Critical Access Hospitals</li> <li>➤ Community Health Centers</li> <li>➤ Local Health Departments</li> <li>➤ IHS and Tribal Health</li> <li>➤ Pharmacies</li> </ul>
<p><b>**Timeline based on current allocation and 100% vaccine uptake</b></p>	

## Attachment 2: Acronyms & Initializations

### A

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<b>AAR/IP</b>	After Action Report/Improvement Plan
<b>ACIP</b>	Advisory Committee on Immunization Practices
<b>ASTHO</b>	Association of State and Territorial Health Officials

### C

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<b>CDC</b>	Centers for Disease Control and Prevention
<b>CDEpi</b>	Communicable Disease Epidemiology Section (DPHHS)
<b>CISA</b>	Cybersecurity & Infrastructure Security Agency
<b>COVID-19</b>	Coronavirus disease 2019 or SARS-CoV-2

### D

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<b>DES</b>	Disaster and Emergency Services Division of Montana
<b>DID</b>	De-Identified Data
<b>DLI</b>	Montana Department of Labor and Industry
<b>DPHHS</b>	Montana Department of Public Health and Human Services
<b>DUA</b>	Data Use Agreement

### E

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<b>EOC</b>	Emergency Operations Center
<b>EOP</b>	Emergency Operations Plan
<b>EMS</b>	Emergency Medical Service
<b>ESF8</b>	Emergency Support Function Public Health and Medical Services
<b>EUA</b>	Emergency Use Authorization

### F

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<b>FDA</b>	U.S. Food and Drug Administration
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### H

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<b>HCP</b>	Healthcare Personnel
<b>HHS</b>	U.S. Department of Health and Human Services
<b>HPP</b>	Healthcare Preparedness Program
<b>HRSA</b>	Health Resources & Services Administration

### I

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<b>ICS</b>	Incident Command Structure
<b>IIS</b>	Immunization Information Systems
<b>imMTrax</b>	Montana's IIS

**IZ** Immunization

**IZDL** Immunization Data Lake

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**J**

**JITT** Just in Time Training

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**L**

**LEPC** Local Emergency Planning Committee

**LHJ** Local Health Jurisdiction

**LTCF** Long Term Care Facility

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**M**

**MACo** Montana Association of Counties

**MCM** Medical Countermeasures

**MCMD** Medical Countermeasures and Distribution

**MMWR** CDC Morbidity and Mortality Weekly Reports

**MOA** Memorandum of Agreement

**MOU** Memorandum of Understanding

**MUAFind** Web based program hosted by HHS for locating Medically Underserved Areas/Populations

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**N**

**NAM** National Academies of Medicine

**NCIRD** National Center for Immunization and Respiratory Diseases

**NPI** Non-Pharmaceutical Intervention

**NRF** National Response Framework

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**O**

**OWS** Operation Warp Speed

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**P**

**PAHPA** Pandemic and All Hazards Preparedness Act

**PAHPRA** Pandemic and All Hazards Preparedness Reauthorization Act

**PHEP** Public Health Emergency Preparedness

**PHL** Public Health Laboratory

**PIO** Public Information Officer

**POD** Point of Dispensing

**PPRI** Privacy-Preserving Record Linkage

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**R**

**RHCC** Regional Healthcare Coalition

**RSS** Receipt, Stage, Shipping – warehouse functions for SNS or other medical materiel

## **S**

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**SME** Subject Matter Expert

**SNS** Strategic National Stockpile

## **T**

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**TERC** Tribal Emergency Response Council

## **V**

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**VAERS** Vaccine Adverse Event Reporting System

**VAMS** Vaccine Administration Management System

**VFC** Vaccines for Children

**VOAD** Voluntary Organizations Active in Disasters

**VTrckS** Vaccine Tracking System