

COVID-19 Vaccination Plan

STATE OF MISSOURI

Interagency COVID-19 Vaccination Planning Team
November 11, 2020

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Record of Changes

Date of the original version: October 1, 2020

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Introduction

We are in an unprecedented season during this COVID-19 pandemic. While it's been challenging to tackle these unforeseen circumstances, it's also showed us that our best solutions come by working collaboratively and collectively to serve our citizens. We are better together. We continue to be resilient, resourceful, and re-energized as we proactively work on this next critical phase of our pandemic plan—COVID-19 vaccinations.

Missouri has established the Missouri Interagency COVID-19 Vaccination Planning Team to find a "Show Me Strong" solution to designing and implementing a statewide COVID-19 vaccination plan. While this next phase has some challenges to overcome, including frequently changing national guidance, timeline uncertainties, and unprecedented scope of work, we have worked to build a team of solution starters to overcome the hurdles we see ahead. The Missouri Department of Health and Senior Services' Bureau of Immunizations convened a broad group of state and local government, healthcare and social work professionals, industry partners, community advocacy groups, and military logisticians to start this process. This plan represents a combination of innovation and preparation. It also builds upon successful emergency-management strategies refined over years of use and exercise while using the strength of Missouri's citizens and communities to respond locally to help their neighbors and communities.

With the strong likelihood of limited vaccine availability in the initial phase of this COVID-19 vaccination effort, this plan initially focuses those limited doses toward reducing or stopping death and disability by lessening the stress on our healthcare system caring for our impacted citizens. This is a vital first step to protecting those delivering critical care to protect our most vulnerable. As vaccine availability expands, we will strategically target vaccination efforts to those residents most at risk—our elderly and those with medical conditions, placing them at high risk for poor outcomes. Simultaneously, we will also begin efforts to accelerate Missouri's economic recovery by protecting our schools and critical businesses. As vaccine availability continues to increase, the plan ensures every Missourian who wants a vaccination, regardless of who they are or where they live, will be able to obtain one at no cost.

The unique aspect of the Missouri COVID-19 Vaccination Plan is the primary and essential role of our local communities, including the collaboration with the State to assist and be a vital resource for their efforts. While a State Implementation Team (SIT) is responsible for coordinating with federal agencies, our plan empowers local Regional Implementation Teams (RIT) with additional financial and technical support from the State to convene local community leaders, citizen advocates, and local healthcare providers. Our plan builds on the existing network of immunizing providers across Missouri, including augmenting their efforts in areas of provider shortages to ensure a safe and effective vaccine is distributed equitably and efficiently in Missouri.

Executive Summary

The Centers for Disease Control and Prevention (CDC) and federal Operation Warp Speed have established a framework for effective State planning to distribute the forthcoming COVID-19 vaccination. This Missouri COVID-19 Vaccination Implementation Plan represents the culmination of planning by a cross-sectional coalition of stakeholders, the Missouri Department of Health and Senior Services, and the Missouri National Guard to successfully provide the CDC with a state framework vaccinating willing residents to ensure safe and healthy Missourians. This is a guiding document outlining the overall strategy and will be followed closely with additional plans, tactics, and measurements for successful implementation.

The plan's specific objectives include:

1. Identifying key stakeholders and partnerships necessary for effective implementation.
2. Identifying necessary infrastructure and resources and preparing for deployment.
3. Setting the stage for gap analysis and the developing countermeasures necessary for success.
4. Establishing systems for ensuring ongoing planning.

Stakeholders involved in the development and review of this document include:

- Missouri Health Care Association
- Missouri State Board of Nursing
- BJC HealthCare
- Missouri Department of Corrections
- Missouri Department of Health and Senior Services' Bureau of Emergency Medical Services

The Missouri COVID-19 Vaccination Implementation Plan leverages local expertise and resources with state government support to accomplish three key objectives:

1. Arrest the morbidity and mortality of COVID-19 while reducing the stress on critical healthcare infrastructures.
2. Protect those at most significant risk of adverse events from COVID-19 and those critical to accelerating economic recovery.
3. Provide vaccination at no cost to every Missourian desiring one.

We developed regional **Vaccination Support Teams** (VST) in each of the State's nine State Emergency Management Agency (SEMA) regions to achieve these objectives. These five-person teams contract with the State to provide direct support and oversight of COVID-19 vaccination efforts within their contracted region. **Regional Implementation Teams** (RIT), made up of local healthcare and community leaders, coordinate the local deployments of vaccinations with the support and guidance of the **State implementation Team** (SIT). Made up of representatives from the RITs and leadership from the Bureau of Immunizations, the SIT serves as a central coordinating group for information dissemination, problem-solving, sharing of best practices, and ensuring local voices are at the forefront of the statewide plan. Day-to-day oversight operations of the vaccination program lie with the Chief of the Bureau of Immunizations and an executive planning team able to rapidly and flexibly respond to changing pandemic environments while complying with federal and state guidelines.

Section 1: COVID-9 Vaccination Preparedness Planning

Program Planning Activities

Upon receipt of August 4, 2020, COVID-19 Vaccination Planning August Letter to Health Departments:

- The Missouri Department of Health and Senior Services (DHSS) charged Bureau of Immunizations Chief Jennifer VanBooven, MPH, MA, to develop a statewide vaccination plan.
- DHSS established the Missouri Interagency COVID-19 Vaccination Planning Team to support VanBooven's leadership efforts and broaden collaboration, including ideas and strategies, to develop the plan. The team includes representatives from state and local government and community and professional organization representatives selected to provide emergency planning, social work, public health, and healthcare experience.
- To supplement the team's administrative support, SEMA requested military and medical planners from the Missouri National Guard to assist with initial planning for a phased deployment of COVID-19 vaccinations across Missouri.

COVID Vaccine Microcell State Participation

- DHSS
- DSS
- DPS/MONG
- DPS/SEMA
- DESE
- DHEWD
- OA

External partners involved in the process (not exhaustive)		
LPHAs	HHS Region 7	MPCA
MO Health Net	MHA	Med Res. Corps
MO Council of Public Health Excellence	MO Health Connection	MSMA
MHCA	St. Louis Regional COVID Task Force	BJC Healthcare

The Interagency COVID-19 Vaccination Planning Team began meeting weekly in-person on August 26 with a conference call option to allow partners across Missouri to participate. To effectively address the myriad of planning issues, the team was divided into six "**Lines of Effort (LoE)**" for more in-depth discussions, idea generation, and planning. Each LoE comprises a team lead, a military planner, and engaged government and industry stakeholders.

The LoE teams met each week separately to conduct in-depth dives into their topical areas while holding weekly "Synchronization and Action" meetings to facilitate inter-LoE sharing and alignment efforts.

The groups' earliest tasks included reviewing a combination of existing emergency preparedness plans, after-action reports of previous outbreaks (notably a Hepatitis A outbreak in September 2019 that required a mass vaccination deployment), and engaging individuals previously participated in the planning and delivery of past emergency services. In addition to reviewing state influenza vaccination and biologic agent terrorism plans, the teams coordinated with local and county public health agencies to verify resources and capabilities. The groups also confirmed local knowledge of

"the situation on the ground" could be integrated into statewide plans, guaranteeing a flexible organizational approach. This early recognition of the situation as a complex adaptive system facilitated the development of executive intent to guide future decision-making.

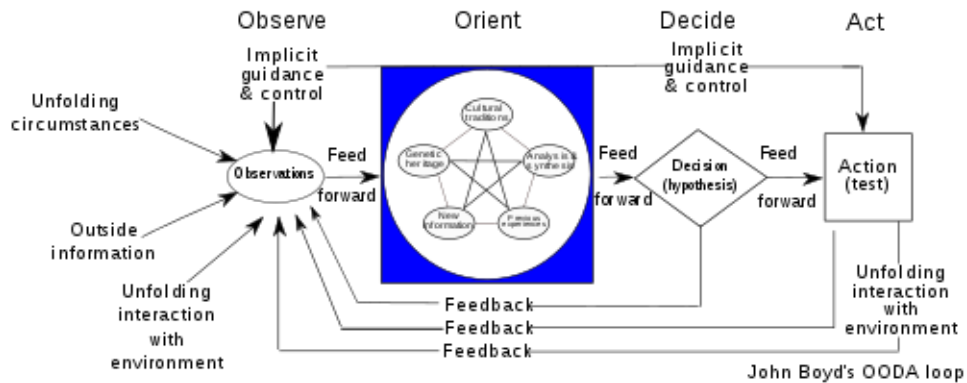
Continuous Quality Improvement Efforts

At each phase of plan development, the teams used constraint-based scenarios to refine traditional vaccination and response plans. As planning became more concrete, the planning team conducted weekly failure point analyses discussions, using an Observe-Orient-Decide-Act loop analytic process to identify critical nodes, decision points, and data requirements. This helped define decision-making authorities and establish working relationships to facilitate actions, including pivoting quickly in a changing environment. For example, Missouri originally planned to use the Vaccine

H1N1 Lessons and their COVID Vaccine Application

- **H1N1 Issue:** Poor quality ancillary supplies shipped with vaccine
 - **COVID Mitigation Strategy:** State is purchasing ancillary supplies (and PPE) to send to health care providers so that the vaccine campaign will not be slowed down.
- **H1N1 Issue:** Messaging and information flow to local partners was hampered by state leaders trying to craft perfect messages.
 - **COVID Mitigation Strategy:** State teams already made contact with 20+ external partners, including LPHAs, and are convening an External Advisory Committee comprising community leaders with ties in the neighborhoods most in need
- **H1N1 Issue:** Initial distribution of antiviral medications done by using a standard "Pull Method" Receive, Stage and Store site (RSS).
 - **COVID Mitigation Strategy:** Given centralized distribution, logistical issue will lessen. Nonetheless, community tabletops will help troubleshoot the process.
- **H1N1 Issue:** Various issues and certain procedures caused gaps and access to care barriers that prevent individuals from receiving the recommended vaccines.
 - **COVID Mitigation Strategy:** DHSS Bureau of Immunization Assessment and Assurance (BIAA) staff will utilize survey information developed by the State Epidemiologist that is designed to determine gaps and access to care barriers that prevent individuals from receiving the recommended vaccines. Following completion of the survey, DHSS will host a gathering of LPHAs and other public health stakeholders to discuss the results of the survey and develop a plan of action to address the gaps identified.

Administration Management Systems (VAMS) for vaccination efforts in Phase 1. After working through the onboarding process, the teams identified this would cause providers to onboard two systems (one system for Phase 1 and another system for Phase 2 and 3). Therefore, we chose to use Missouri's immunization information system (IIS).



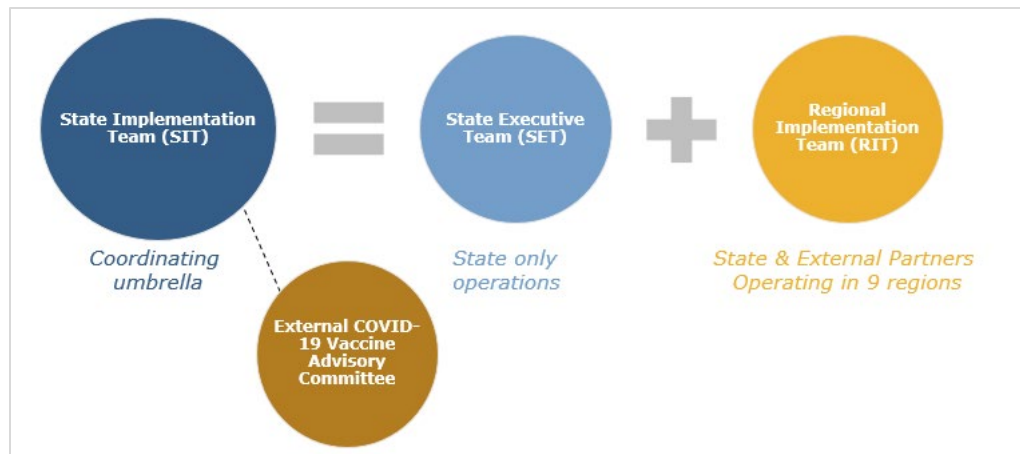
Upon finalizing the initial statewide COVID-19 vaccination plan, the implementation team will continue to "stress test" the plan, expanding to include real-time involvement of vaccinators, logistical partners, and technical interfaces. DHSS will execute conducting a comprehensive real-time exercise on Thursday, December 3rd.

Section 2: COVID-19 Organizational Structure and Partner Involvement

Organizational Structure and Teammates- From Planning to Implementation

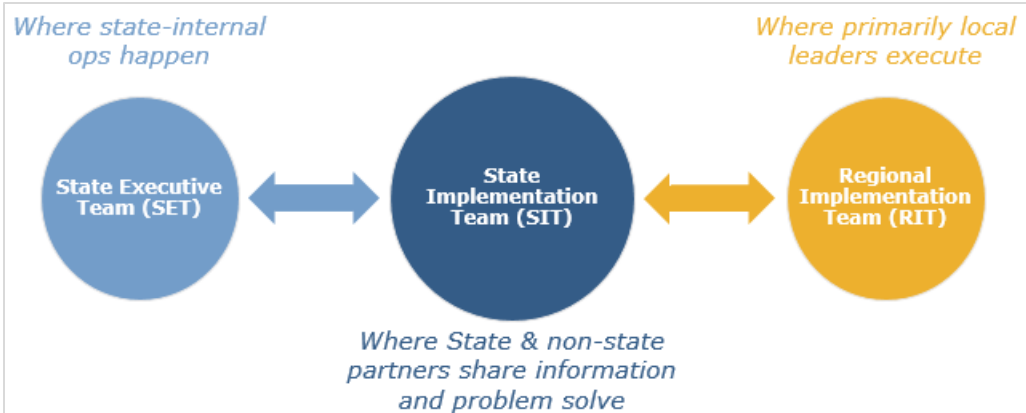
While the Interagency COVID-19 Vaccination Planning Team's initial organization and the structure were discussed in Section 1, it is essential to highlight the transition of the majority efforts from initial planning to implementation. This transitions from the current collaborative planning effort to a need for full-time staff dedicated to the phased- execution of Missouri's COVID-19 vaccination program. The recent planning effort relies on the part-time attention of six teams composed of 75+ state employees, 10 Missouri National Guard planners, and 50+ external non-state partners. An executive planning team (EPT), State Implementation Team (SIT), Regional Implementation Teams (RIT), and Vaccination Support Teams (VST) will guide future efforts.

The State takes a regionally-empowered model, supported by a team of State experts, and advised by the communities most vulnerable to COVID

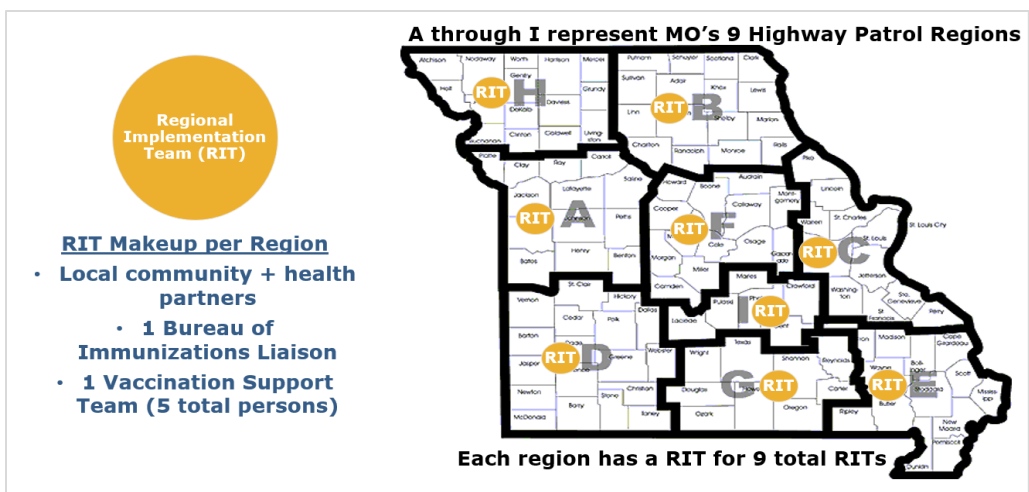


Success on the ground requires behind-the-scenes work—SET fulfills this role

Those on the ground know best, so RIT will operate within the community in each region
Coordination of external and internal efforts occurs regularly under the unified SIT



The RITs team of experts will cover the entire State—serving alongside those that know the communities best



The EPT ensures that significant operational adaptations to the state COVID-19 vaccination plan occur within a continually changing environment. Led by the Chief of the Bureau of Immunizations, it includes both state COVID-19 response leadership and topical leads from each of the implementation LoEs:

1. Vaccine Providers.
2. Populations to be Vaccinated.
3. Process and Logistics of Vaccination.
4. Information Technology/Interfacing.

An expanded team, including the EPT, makes up the **State Implementation Team (SIT)**. SIT is responsible for overseeing and implementing the effective deployment of Missouri's COVID-19 vaccination plan and providing critical services, such as IT support, vaccine distribution planning, and sharing of best practices between Regional Implementation Teams (RIT).

Early in the planning process, the Bureau of Immunizations recognized the strength of local healthcare and public health communities. The COVID-19 vaccination plan supports this local empowerment by establishing and supporting **Regional Implementation Teams (RIT)**. Within each of the nine SEMA regions, the RIT comprises a state Bureau of Immunizations liaison, local healthcare providers, local community organizations, and a contracted regional COVID-19 **Vaccination Support Team (VST)**.

Regional VSTs are composed of a contracted executive, registered nurse, two licensed practical nurses, and a communicable disease/public health specialist. VSTs will be established through an open competitive bid process, allowing each region to propose the partners most able to support local success, whether a local public health agency, a healthcare system, existing quality improvement organizations, or private contractors. This regional support structure facilitates a useful span of control for state actions while empowering local authorities and ensuring the personal relationships needed during an emergency response can be maintained and nurtured. It also provides trusted community leader involvement in local vaccination rollout planning.

Initial participants within the planning process who will be transitioning to the EPT, SIT, or RITs include the following:

Recruiting /Engaging Diverse Partners

The State of Missouri actively engaged various organizations from the public, private, and nonprofit sectors during the planning process. This emphasis continued within the RITs, which will continue to outreach to obtain the broadest insights actively. Regional stakeholders are a crucial component of the RIT, including patient/population/community advocates, healthcare/social work providers, public health experts, emergency management directors, and industry representatives. This represents an inclusive and diverse group of stakeholder engagement and participation in the State's efforts to provide COVID-19 vaccination to all citizens. DHSS will also pay close attention to historically underrepresented populations and those at the most significant risk of morbidity and mortality from COVID-19 infection across regions.

RITs will organize their efforts around five revised LoEs:

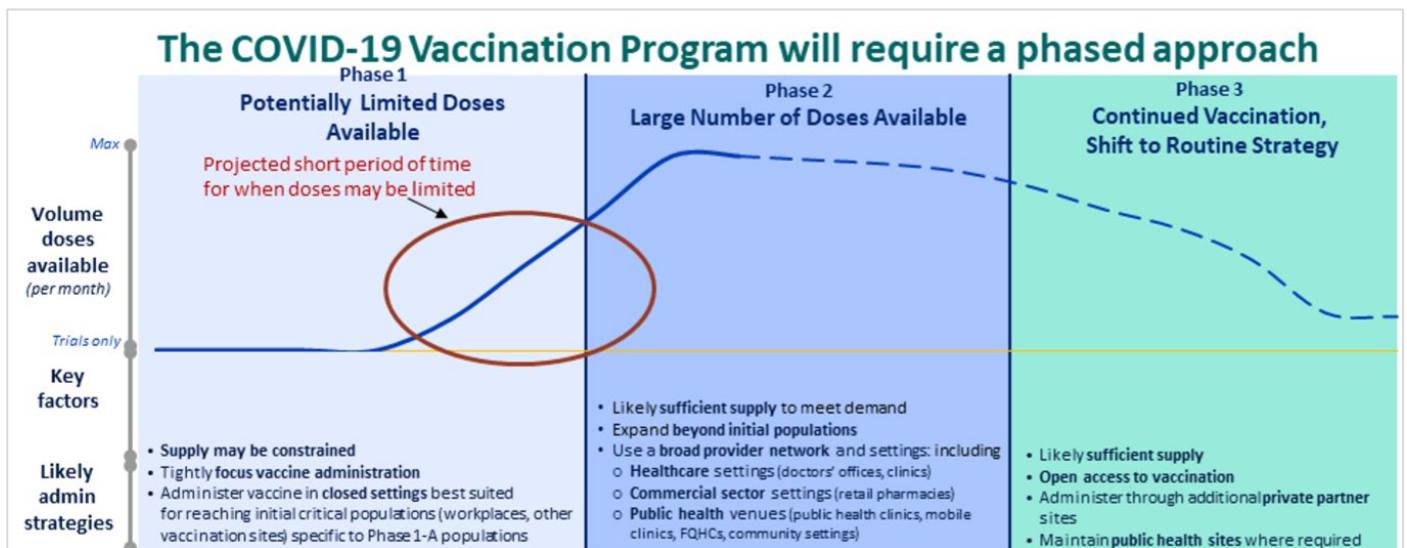
1. Vaccine Providers.
2. Populations to be Vaccinated.
3. Process and Logistics of Vaccination.
4. Information Technology/Interfacing.
5. Communications.

These LoEs facilitate problem-solving and work on continued outreach within each of these five critical areas. Using the RIT model, each region can customize its outreach to reflect its unique circumstances and guarantee local experience inclusion into implementation efforts. Initial additional participant targets include the following:

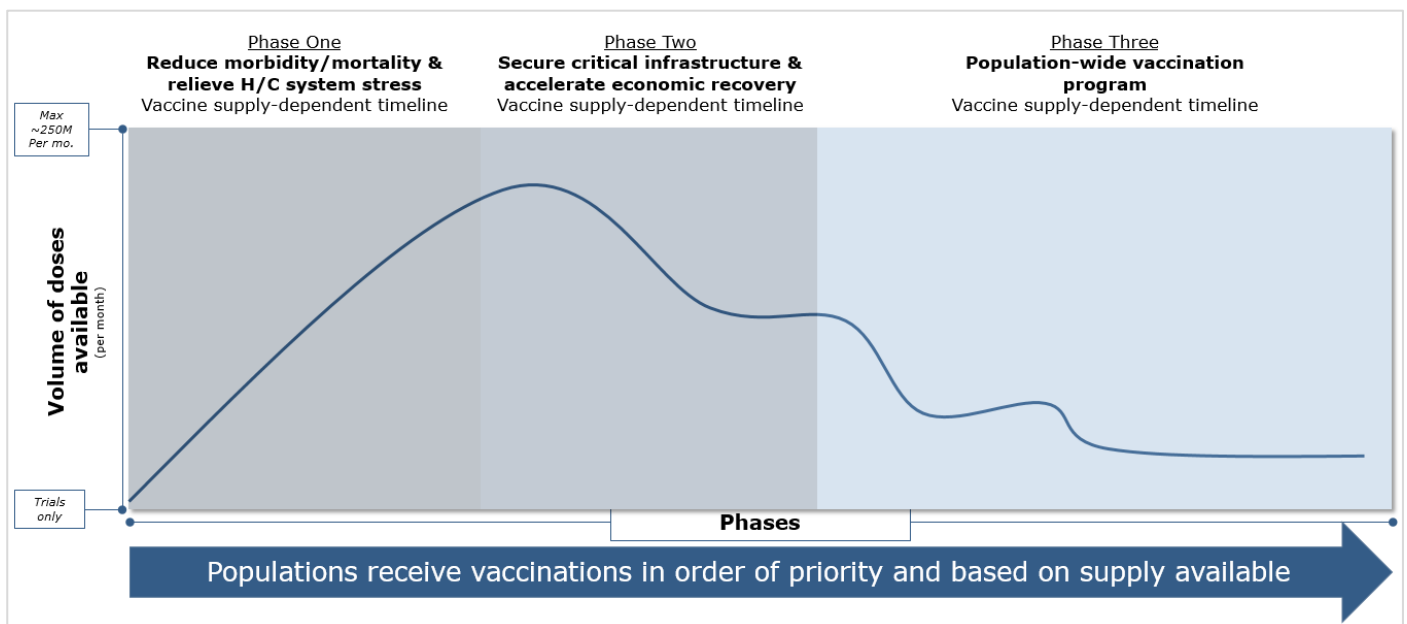
LoE Focus Areas				
LoE 1 Vaccine Providers	LoE 2 Vaccinated Populations	LoE 3 Process/Logistics	LoE 4 IT/Interface	LoE 5 Communications
Nursing Schools	Area Agencies on Aging	Pharmacies	Electronic Health Record Companies	Local Community Leaders
Dental Association	Homeless Advocates	UPS	Health Information Exchanges	Clergy
Medical Schools	Clergy	Medical Vendors		Organizations Serving Minority Populations
EMS Agencies	Local Community Leaders			
Home Health Agencies	NAACP			
Note: The above lists are NOT exhaustive.				

Section 3: Phased Approach to COVID-19 Vaccination

Missouri's planning efforts are based upon CDC guidance to anticipate a phased availability of vaccines within the State. The planning team delved deeper into the tiered-vaccination priorities currently published by those organizations, including the mismatch of early vaccine availability to the number of individuals needing to be vaccinated, the demands of ultra-cold storage the numbers of affected Missourians in each tier of prioritization. These challenges make the sequencing of vaccine distribution critical to our State's early success. Recognizing the continually changing situation and the need to provide flexible guidance for decision-making, the Governor's office has provided an executive intent around each phase of vaccine availability. The plan expands on the application of these principles in Section 4.



CDC's original guidance (figure above)



How the State translated the guidance (figure above)

Phase 1

Missouri's Executive Intent is to "Reduce the morbidity and mortality of COVID-19 within Missouri while reducing healthcare system stress." To achieve this, Missouri plans to follow the CDC, Advisory Committee on Immunization Practices (ACIP), National Academies of Sciences, Engineering, and Medicine (NASEM) guidance and begin the vaccination efforts by targeting unpaid and paid healthcare workers in Phase 1A.¹ Missouri plans to collaborate with healthcare systems, pharmacies, and community partners to vaccinate long-term care facility staff and other healthcare workers. If the need arises to break this group further down, Missouri plans to start with healthcare staff at long-term care facilities.² Again, if vaccine supply forces prioritization, the next step is healthcare workers who self-identify recognized CDC established comorbidities for COVID-19, starting with inpatient healthcare workers expanding out to outpatient healthcare workers. These vaccinations will take place in closed **Points of Dispensing (PODS)**. NOTE: This is still all occurring in Phase 1A.

Missouri will then move into phase 1B, working with local and community partners to begin vaccinating critical infrastructure workers and Missourians at higher risk for COVID-19 disease identified by the CDC established comorbidities for COVID-19 (details are in Section 4 Critical Populations). Missouri will collaborate with a RIT to work with community partners to vaccinate those in Phase 1B. Local healthcare providers, community organizations, their partners, and local public health agencies will perform these vaccination efforts in PODs where possible.

Phase 1B: Potentially limited supply of COVID-19 vaccine doses available AND long-term care residents recommended to receive vaccine.

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

Missouri plans to participate in the pharmacy partnership for Long-term Care Program coordinated by CDC.

- Partner through CDC's Pharmacy Partnership for LTC Program for COVID-19 Vaccine to provide on-site vaccine clinics for residents of long-term care facilities (LTCFs) and any remaining LTCF staff who were not vaccinated in Phase 1-A. 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.
 - This program is free of charge to facilities. 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.

¹ Phase 1A Definition: *Paid and unpaid people serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials and cannot work from home*

² Missouri Long Term Care Facilities encompass Skilled Nursing Facilities, Intermediate Care Facilities, Assisted Living Facilities, Residential Care Facilities, Immediate Care Facilities for Individuals with Intellectual Disabilities, and Adult Day Care

- Report required vaccination data (approximately 20 data fields) to the local, state/territorial, and federal jurisdictions within 24 hours of administering each dose.
- Adhere to all applicable CMS requirements for COVID-19 testing for LTCF staff.
- 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 two 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.

Phase 2

Missouri's Executive Intent is to "Secure the critical infrastructure of Missouri and accelerate economic recovery within the state." To accomplish this, Missouri will use the RITs to collaborate with local community partners to vaccinate those in Phase 1 who could not be vaccinated. We will also vaccinate populations at increased risk of acquiring or transmitting COVID-19. These populations of consideration include racial and ethnic minority groups, housing-insecure individuals, people living and working in congregate settings, and other groups and other communities at higher risk of severe outcomes from COVID-19. The staff of manufacturing facilities identified as critical infrastructure or critical to national security is, by definition, essential to the economy and safety of the State as part of Phase 2.

Missouri compiled information about these critical populations through the Pandemic Influenza Preparedness Tier Worksheet. The RIT will be working with local and regional partners to promote equitable and efficient uptake of the COVID-19 vaccine to reach these populations. The RIT will use onsite PODs and mass vaccination clinics as needed. Missouri will also prepare to vaccinate the general public depending on vaccine quantities and continue providing a regional approach to vaccinating the rest of its population.

Federal Direct Allocation to Pharmacy Partners:

Missouri plans to participate in the federal direct allocation to pharmacy partner strategy coordinated by CDC.

- Vaccine will be allocated and distributed directly to select pharmacy partners from the federal government.
 - Direct allocation opportunities will be provided to retail chain pharmacies and networks of independent and community pharmacies³ (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 jurisdictions.
 - On a daily basis, pharmacy partners must report to CDC, the number of doses of COVID-19 vaccine a) ordered by store location; b) supply on hand in each store reported through VaccineFinder, and c) number of doses of vaccine administered to individuals in each state, locality, and territory.
- Pharmacy providers will be required to report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC will provide information on these data elements and methods to report if stores are not able to directly provide data to jurisdiction IISs.
- All jurisdictions participating in this program will have visibility on number of doses distributed to and administered by each partner store.
- Jurisdictions will be given contact information for each partner participating in this program if they have any questions or concerns related to distribution of vaccine to stores in their jurisdiction.

Provider enrollment will continue to be a priority in Phase 2.

³Pharmacy services administrative organizations, or PSAOs

Phase 3

Missouri plans to continue vaccination efforts in this phase with individuals identified in Phases 1 and 2. The State of Missouri will focus on making sure every Missourian who qualifies and needs or wants a COVID-19 vaccine receives the requested vaccine at no cost.

The intention is federally qualified health centers, rural health clinics, private providers, and pharmacies take on the majority of the vaccination effort for most adults in their areas. Local public health authorities and the state health authority will target vaccination efforts toward the most vulnerable populations, such as homeless populations with limited access to care and local incarcerated individuals, and assist with college and university vaccination efforts.

For this effort, Missouri plans to use a state mobile medical unit, as needed or requested, staffed with a DHSS team dedicated to that mobile vaccination unit. The mobile unit will devote days and times in various locations to provide the COVID-19 vaccine to at-risk populations. State health authorities will work with local health authorities and community organizations to identify vaccination sites and communicate available vaccination days to the population. Community partners will need to identify other resources for vaccinating hard-to-reach populations. This will also help local and State health authorities to provide vaccinations to outbreaks in these communities.

Missouri will continue to support private providers, federally qualified health centers, rural health clinics, and pharmacies in their vaccination efforts. Vaccination supplies, vaccines, and appropriate PPE will be available, so cost is not a barrier to patient vaccination. Additionally, during this phase, Missouri will work toward routine annual vaccination for the qualifying population. Missouri also will continue to require all COVID-19 vaccine providers to register with Vaccine Finder.

Missouri's Bureau of Immunizations (BI) will continue to educate providers on the importance of working with providers on presumptive recommendations for COVID-19 vaccine, on notifying adverse events in VAERS, and continuing to recruit additional providers, especially in specialty clinics, such as geriatrics, endocrine, cardiac, pulmonary and kidney clinics, rural health, and independent pharmacies. BI will continue to monitor COVID-19 vaccine orders by assessing monthly ordering reports supplied by the vaccine ordering manager. BI will also consider monthly vaccine wastage reports provided by the vaccine-ordering manager to assure minimal waste. Finally, BI will provide COVID-19 vaccine administration reports to CDC as requested. BI will continue with a centralized reminder/recall for the second dose and annual COVID-19 vaccine.

Section 4: Critical Populations

Identification & Quantification of Critical Populations

Early in the COVID-19 vaccination program, the Bureau of Immunizations anticipates the supply of the COVID-19 vaccine will be limited. The planning team reviewed information from the CDC's Advisory Committee on Immunization Practices (ACIP), the National Institutes of Health (NIH), and the National Academies of Sciences, Engineering, and Medicine (NASEM) to provide recommendations for priority vaccination. The intent informed the planning team's guidance of the COVID-19 Vaccination Program, assumptions for vaccine delivery and storage, and knowledge of Missouri's population and critical infrastructure.

Research from COVID-19 data collected to date has shown that obesity (BMI ≥ 30), chronic kidney disease, chronic obstructive pulmonary disease (COPD), diabetes, hypertension, and chronic heart disease are associated with a higher risk of severe COVID-19 illness.^{1 2} Nearly 90% of hospitalized adults had at least one high-risk medical condition, and more than 60% had three or more.¹ Furthermore, adults ≥ 65 years old represent 80% of COVID-19 deaths and have the highest cumulative rate of COVID-19 associated hospitalizations. Older age is the most potent independent risk factor for in-hospital death.^{1 3} Statistics have also revealed racial and ethnic minority groups account for 60% of COVID-19 cases and 50% of COVID-19 deaths, although racial and ethnic minority groups only represent 40% of the total US population.⁴ ACIP identified factors—e.g., lack of healthcare access, working in higher-risk occupations, education, income gaps, and living in crowded housing areas—that may increase the risk of contracting COVID-19.⁴

ACIP has not yet provided formal recommendations for vaccine prioritization. However, current guidance discusses the inclusion of ethics and equity as part of the process.⁵ ACIP reviewed three frameworks for early COVID-19 vaccine allocations that incorporate ethics and equity in the process, which the planning team also reviewed. All identify frontline healthcare personnel in the initial phase of vaccine allocation and those at significantly higher risk (≥ 2 underlying medical conditions) and ≥ 65 years of age.⁵ The frameworks were less consistent with the placement of essential workers. For example, the National Academies placed police and fire workers in Phase 1A, and Johns Hopkins placed them in Tier 2.

The most recent CDC guidelines for prioritization follows:

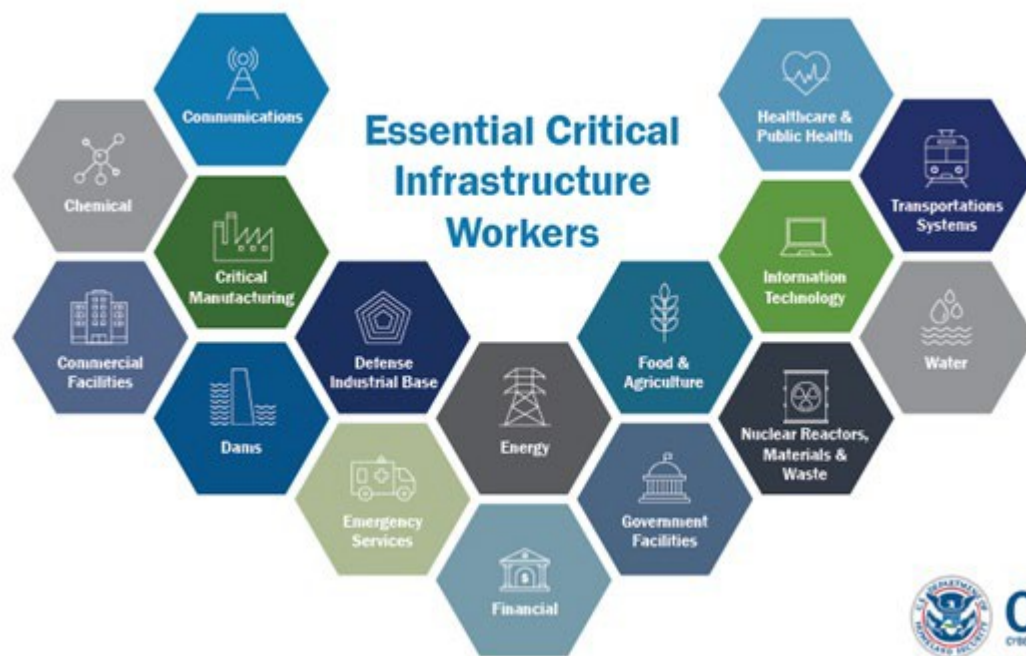
- Phase 1A "Paid and unpaid people serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and cannot work from home."
- Phase 1B "People who play a key role in keeping the essential functions of society running and cannot socially distance in the workplace (emergency and law enforcement personnel, food packaging and distribution workers, teachers/staff, childcare providers, etc.) and people at increased risk for severe COVID-19 illness, including people 65 years of age or older."

After reviewing all prior information described above, the COVID-19 planning team has identified the following population as priority groups for vaccination in Missouri:

- Phase 1A: All healthcare personnel and staff who have the potential for direct or indirect exposure to COVID-19 and are unable to work from home.

- Phase 1B: Those at increased risk for severe COVID-19 illness, including those ≥ 65 years of age, those with chronic illness, and those workers who are vital to keeping the essential functions of society running.

Essential workers were identified using the **Critical Infrastructure Sectors**.⁶ The Cybersecurity and Infrastructure Agency (CISA) defines Critical Infrastructure Sectors as "sectors whose assets, systems, and networks, whether physical or virtual are considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof." ⁶ The Occupational Safety and Health Administration (OSHA) further classifies each job as low risk to very high risk of COVID-19 exposure based on the type of duties and the need to contact within 6 feet of people known to be suspected of being diagnosed with COVID-19. A majority of jobs that fall in the high-risk to very high-risk exposure category are also considered critical infrastructure jobs. *Note: Education is not currently shown on the graph below but is regarded as a critical infrastructure sector.*



Source: CISA

DHSS obtained estimated numbers of priority groups for COVID-19 vaccination using data from the Bureau of Labor and Statistics, DHSS, CDC mapping tools, Missouri Economic Research and Information Center (MERIC), and Missouri Department of Economic Development. DHSS sent county-level tier sheets to each Local Public Health Agency (LPHA) for completion, with 14% of LPHAs not returning tier sheets. Many of the produced sheets had missing or apparent inaccurate data. Members of the planning team have reached out to those who did not return the document or had missing data. State-level data are included below. The maps in Appendix D will consist of locations of priority groups by county

Estimated Number of Missouri Priority Population for Vaccination				
Healthcare	First Responders	Adults ≥ 65	Adults w/high-risk conditions	Childcare workers
~425,000	~31,000	~1,075,000	~1,295,000	~16,750
Teachers/ Staff	Water/ Wastewater	Energy	Manufacturing	Food/Ag Plant
~250,000	~1,300	~2,250	~150,000	~50,000
<small>*Critical Manufacturing includes electrical equipment, appliance, and component manufacturing, fabricated metal product manufacturing, furniture, and related product manufacturing, machinery manufacturing, primary metal manufacturing, transportation equipment manufacturing; Source: EMSI 2020 Obtained from Missouri Department of Economic Research * Adults with high-risk conditions estimated by taking the population of 18-64 year-olds, 3,704,931 x 35%, the ~ average who have an underlying health condition.</small>				

Subset Sequencing Strategy

Using information described in Section 4A, the Missouri Interagency COVID-19 Planning Team has determined the following priority groups for vaccination sequencing. If insufficient vaccine supply requires further tiering, this will be done by limiting the described populations to those who are ≥ 65 years old who are known to increase poor outcomes with COVID-19.

Tier 1A Populations

- **How the CDC defines 1A:** "Paid and unpaid people serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and cannot work from home."
- **How Missouri defines 1A:** All healthcare personnel and staff who have potential for direct or indirect exposure to COVID-19 and are unable to work from home.

1A Priority Population Subset	Rationale
<p>Skilled Nursing Long Term Care Assisted Living Residential Care Facility Staff</p> <p>Population estimate: ~60K</p>	<p>The highest risk population for mortality from COVID-19 is nursing home residents, with 75% of the MO COVID-19 deaths occurring within these facilities. Visitor restrictions and new resident quarantine protocols have limited the exposure route to staff unaware of early infection. The addition of vaccination to the team, PPE, and screening protocols has been modeled by the CDC to result in the most significant reduction in COVID-19 deaths by reducing/eliminating the introduction of infection into these congregate living facilities.</p>
<p>Patient-facing Inpatient and Outpatient Healthcare Personnel with Underlying Health Conditions</p> <p>(Examples: Hospital-based Physicians, Nurses, Aides, Therapists, Clinical Area Janitorial Staff, Patient Reception Clerks, etc.)</p> <p>Population estimate: ~85K</p>	<p>Healthcare workers with asthma, chronic obstructive pulmonary disease (COPD), diabetes, BMI ≥ 30, hypertension (HTN), chronic kidney disease (CKD), and chronic heart disease (CHD) are more susceptible to COVID infection, early asymptomatic spread to patients, and more significant morbidity of infection. Vaccination of these individuals will serve a dual purpose of reducing the potential for infectious spread from medical staff to patients and eliminate/reduce their duration of illness, ensuring critical healthcare staffing availability, and returning them to care activities more rapidly.</p>
<p>ALL REMAINING Patient-Facing Healthcare Workers</p> <p>(Examples: Inpatient and Outpatient Physicians, Nurses, Aides, Therapists, Clinical Area Janitorial Staff, Patient Reception Clerks, etc.)</p> <p>Population estimate: ~125K</p>	<p>The remaining healthcare critical infrastructure personnel are equally at risk for infection and are essential for ongoing healthcare capacity.</p>
<p><i>Note: All examples provided are not exhaustive. Moreover, they are not mentioned explicitly in the order they will receive the vaccine. Vaccine administration within these prioritized populations will take into account numerous variables. The vaccination process will be as transparent as possible and directly involve the populations above.</i></p>	

Tier 1B Populations

- **How the CDC defines 1B:** "People who play a key role in keeping the essential functions of society running and cannot socially distance in the workplace (emergency and law enforcement personnel, food packaging and distribution workers, teachers/staff, childcare providers, etc.) and people at increased risk for severe COVID-19 illness, including people 65 years of age or older."
- **How Missouri defines 1B:** Those at increased risk for severe COVID-19 illness including those ≥ 65 years of age, and those workers who are vital to keeping the essential functions of society running.

1B Priority Population Subset	Rationale
Public-Facing Public Health Workers	These individuals are critical to implementing the State's COVID-19 response while directly engaging the public.
First Responders (Examples: non-hospital EMS, Law Enforcement Officers, Fire and Correction personnel)	<p>Personnel within this category provide essential emergency services that mostly cannot be performed virtually. As a result of these duties, they have unavoidable potential exposures that threaten both their well-being and the community they cannot serve during illness. Accelerated economic recovery and the provision of essential government services require the performance of these duties.</p> <p>Additionally, inmates' confined nature has been amenable to procedural controls to reduce the likelihood of correctional facility outbreaks. As a result, staff now represent the most likely source of a facility outbreak. Vaccination of corrections staff can vastly reduce this source of potential attacks.</p>
High-Risk Individuals including those 65 Years of Age and Older	Individuals with comorbid health conditions retain an elevated risk for mortality and morbidity due to their condition's nature. Those not covered by previous categories should receive priority for vaccination before general population vaccination in a limited vaccine environment. They have a more significant potential impact on vaccination.
Childcare Workers	Childcare workers represent a crucial enabler of economic activity while having similar exposure risk to that identified for teaching staff. Their immunization serves the dual role of personal protection and allowing Missouri residents to return to work.
Teachers/Staff	Society has highlighted the critical role of the public school system during the COVID-19 pandemic. School personnel, regardless of duties, are at a higher risk of exposure due to significant social distancing challenges in minority populations. Disease within this population has the dual impact of personal and societal impact due to the lack of suitable alternative educational options in their absence. The inability to conduct in-person schooling has a recognized secondary effect on parental employment capabilities, making the ability to reopen schools a necessary prerequisite to accelerated economic recovery.

Select State Emergency Management & Emergency Public Work Employees	Critical to the State's response in times of emergency—e.g., hazardous weather conditions like flash floods and severe snow effects—this select subset of the State's workforce runs the State's Emergency Management infrastructure and keeps vital public utilities and services operational.
Drinking Water-Wastewater Facilities	Water purification and wastewater treatment facilities and the staff necessary to run them are critical for residents' safety, well-being, and a significant economy.
Energy	The personnel who provide our residents and businesses with uninterrupted electrical power and restoration capabilities following damage are a necessary prerequisite for Missouri's accelerated economic recovery.
Critical Manufacturing	The staff of manufacturing facilities identified as critical infrastructure or critical to national security is, by definition, essential in the economy and safety of Missouri and the nation.
Food/Ag Plants	Mass facilities for the production or processing of food represent a critical economic component that has accounted for significant COVID outbreaks and the potential for food insecurity.
Employer-defined "Essential Employees"	Employees identified by their employers as "essential employees" (typically applied during weather emergencies) are essential to their employers' effective operations and the role that company plays within our communities and economy.
<p><i>Note: All examples provided are not exhaustive. Moreover, they are not mentioned explicitly in the order they will receive the vaccine. Vaccine administration within these prioritized populations will take into account numerous variables. The vaccination process will be as transparent as possible and directly involve the populations above.</i></p>	

The Bureau of Immunizations determined our earliest population (long-term care facility workers) to includes a majority female population with non-Hispanic Black employees at a higher rate than in the general populace. Remaining healthcare personnel has ~40% of individuals with either a high-risk healthcare condition (beyond occupational risk) or age ≥ 65 .

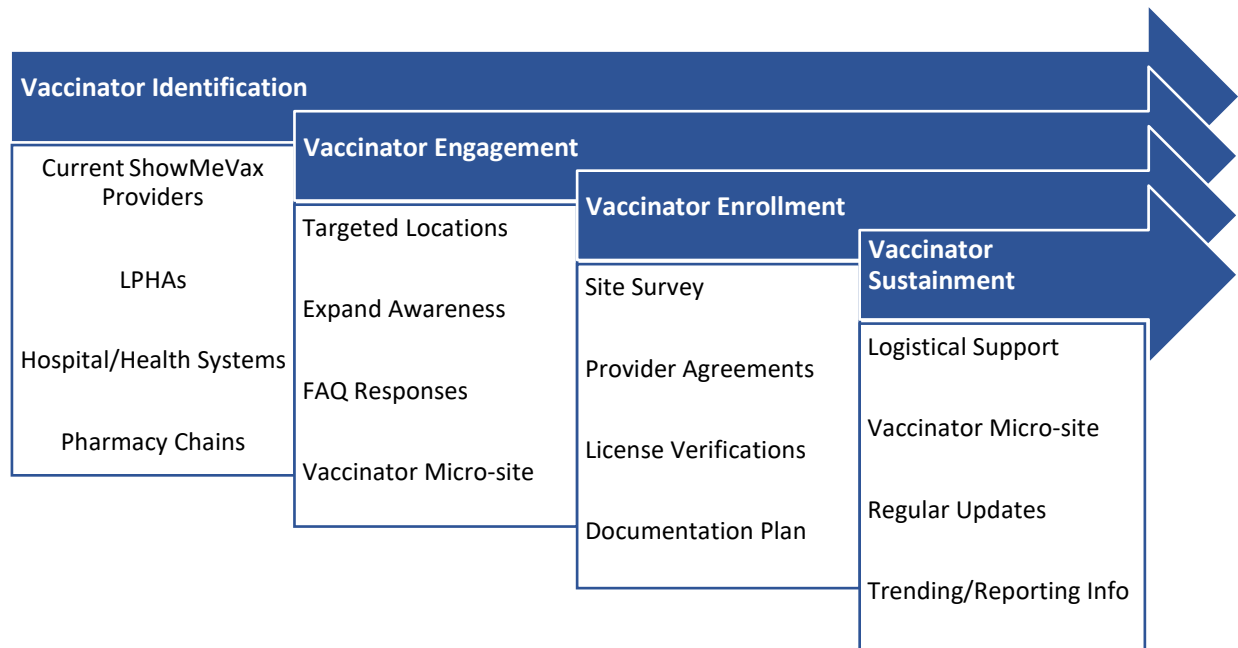
Engaging Critical Populations

As discussed in Section 2, the COVID-19 Vaccination Program SIT/RITs will continue equitable access to vaccinations, obtaining further information about populations within Missouri's counties, and informing future logistical requirements for providing access to COVID-19 vaccination services. Section 15 describes the monitoring efforts used to make sure SIT/RIT members proactively recognize populations that may not be adequately engaged or reached throughout the implementation.

For additional information: Appendices include Population Targeting Maps

Section 5: COVID-19 Provider Recruitment and Enrollment

As part of its initial efforts, the planning team identified potential vaccinators through a multi-step process. These key steps were to identify potential providers, effectively engage them, effectively and rapidly enroll them into the program, and sustain their ongoing participation within COVID vaccination efforts.



DHSS first identified providers already participating within state vaccination programs and with validated interfaces with the state IIS (minimizing technology challenges or delays in initial phases). Concurrently, the planning team developed a provider education FAQ. This was paired with an electronic site survey designed to prescreen potential vaccinators through self-identification of interest while providing state planners with real-time information about potential vaccinators' locations and capabilities. Those targeted professionals included hospital systems, primary care providers, volunteer organizations, occupational health programs, Department of Corrections, and local public health departments. Within the first 96 hours of the survey deployment, the planning team received more than 400 responses, which will continue to guide planning and implementation efforts.

The development and deployment of an electronic provider agreement allow for a simple collection and reporting of enrolled-provider data, delivered in various formats. Additionally, initial vaccinators will mainly come from institutions with established vaccination programs and verified state IIS interfaces. By pursuing this strategy, early monitoring and reporting capabilities can use standard dashboards and reporting modules within the ShowMeVax system (CSV reports can be pulled and sent to the CDC twice weekly). As additional providers are brought on board, those providing COVID vaccinations will receive prioritization for interfacing verification within ShowMeVax and immediately identify within the electronic provider agreement system.

Provider Validation

As efforts transition from planning to implementation, identified providers will complete an online version of the provider agreement, which will then undergo a three-stage validation process within DHSS to validate licensure and disciplinary history. As part of the provider agreement, the Chief Medical Officer (CMO) and Chief Executive Officer (CEO) will provide a list of all prescribers involved with the vaccine administration. The CMO and all prescribers will have their licensures verified by the Bureau of Immunization staff using the information provided by the Board of Healing Arts, Board of Pharmacy, Board of Nursing, and DHSS Bureau of Emergency Medical Services (EMS) as applicable. The CMO and CEO/CFO signing the provider document are responsible for confirming those administering the vaccine have received appropriate training and have relevant and current credentials/privileges to administer the vaccine. Any MOUs required for the healthcare professionals administering the vaccine must be in place before using any healthcare professionals who would need an MOU.

Initial Vaccine Providers/Location for Critical Populations

Once the details of initial vaccine receipt are known (vaccine type, potential arrival date, number of doses, etc.), the SIT will use the population sequencing tiers in Section 4 and the notification details to determine initial delivery sites. In preparation for this notification, the SIT will conduct several tabletop exercises before November 2020. To continue to refine the vaccine-allocation decision-support tool, the team will facilitate the rapid determination of appropriate allocations. While all Phase 1 vaccinator sites are expected to be prepared for delivery of vaccine within 24 hours of notification, the first potential delivery of vaccines will be additionally validated via phone to guarantee no circumstance changes might place the delivery in jeopardy.

Provider Training

A vital component of the provider-facing website discussed in Section 12 is the ability to provide a "one-stop-shop" for Missouri COVID-19 vaccination providers. Missouri will set up a provider-dedicated webpage with real-time updates and links to becoming a COVID-19 vaccine provider, downloadable vaccination consent, VAERS reporting information, just-in-time CDC vaccination training, and CDC COVID-19 vaccine materials, including storage and handling information. Also, Missouri will provide vaccine administration materials to avoid vaccine errors and ensure proper vaccination technique with CDC established materials. Finally, the website will be augmented by active outreach mail and other materials to ensure awareness and drive vaccinators to necessary training.

Vaccine Redistribution Strategy/ Principles

The planning team wants to minimize vaccine redistribution and reduce waste associated with temperature variations during transport. To accomplish this, the team is currently planning to distribute an ultra-cold vaccine only within major metropolitan areas (unless otherwise

recommended by CDC). Additionally, the team will provide only to organizations that sign an agreement to give vaccination to all-qualified-comers, including employees of other healthcare systems within their geographic region. Additionally, the team expects mobile vaccination teams within the nine Missouri regions to limit the need for redistribution beyond the original recipient of vaccines.

Should redistribution be requested or felt necessary, the provider will communicate the request to the Bureau of Immunizations, determining such a redistribution's acceptability. If determined appropriate, the Bureau of Immunizations will validate the *Supplemental COVID-19 Vaccine Redistribution Agreement* and transfer the vaccine under positive control, maintaining temperature data-logging throughout the process. The Bureau of Immunizations will determine on a case-by-case basis whether vaccines are directly transferred between providers or transferred from one site to another by Bureau of Immunizations personnel.

Equitable Access to Vaccines

The planning team has compiled an extensive collection of maps identifying a wide variety of demographic and social risk factor distributions across the State of Missouri. While many of the distributions mirror the general population distribution across Missouri, it is imperative unrecognized or historically underserved populations at elevated risk be identified and served appropriately. In addition to the population-based demographic information, the survey deployed by the planning team included efforts to identify underserved populations for prioritization, as appropriate, guaranteeing equity in vaccine distribution. Missouri's RITs will develop further plans to reach at-risk populations and people of color in their identified regions. The RITs will supply the Bureau of Immunizations with the plans to assure equity is achieved. The RITs will also partner with medical schools in both the Kansas City and St. Louis metropolitan areas to leverage existing outreach clinics into the homeless, minority, and underserved populations to deliver the vaccine via existing, trusted entities. To effectively monitor these impacts, it is imperative demographic information be available and included in ongoing programmatic dashboards shared with the implementation team.

Community-based (non-chain) Pharmacies

While federal discussions about the potential deployment of vaccines via large pharmacy chains are ongoing, it is unclear to what extent this will penetrate many rural areas within Missouri. To clarify this impact, the Missouri Pharmacy Association distributed the planning team's survey, which included questions about the association of local pharmacies with national chains or associations that might be involved in federal efforts. Upon receiving this information, the implementation team will actively outreach to those local pharmacies for potential inclusion as vaccinator sites to augment rural vaccination capacity through its existing relationship with the Missouri Pharmacy Association. Additionally, members of the Interagency COVID-19 Vaccine Planning Team have been part of webinars for the Missouri Pharmacy Association and Missouri Board of Pharmacy to encourage pharmacies to become vaccinators.

Section 6: COVID-19 Vaccine Administration Capacity

Theoretical Approaches to Vaccination Capacity

CDC's Playbook defines vaccine administration capacity as "the maximum achievable vaccination throughput regardless of public demand for vaccination." Our planning team conducted time-motion analyses of multiple vaccine delivery strategies and settled on three primary approaches to use in capacity modeling: 1) Single Vaccinator, 2) Expandable Drive-Thru Lane, and 3) Gymnasium Mass Vaccination Event. These strategies took into account expanded infection control requirements/hygiene, vaccination preparation and delivery, documentation, and post-vaccination patient observation periods. The potential throughput of each process presented below:

	Single Vaccinator	Drive-Thru	Gymnasium
Description	A single individual dedicated to providing vaccinations. May be accomplished parallel to physician office visits or as a dedicated onsite vaccinator	An available 14' x 85' drive-thru lane performs all aspects of screening/ vaccination/observation without leaving the vehicle. Assumes one vaccinated per car (# in a vehicle has minimal impact on time, but dramatically increases throughput). Additional lanes are additive to volume.	A 94' x 50' basketball court allows 16 vaccination lanes while maintaining 6' social distancing. The limiting factor is likely to be parking availability and safely keeping social distancing outside the facility's controlled area.
Throughput	Max = 10 doses/hour Avg = 48 doses/8 hr day	Max = 12 doses/hour Avg = 94 doses/8 hr day	Max = 160 doses/hour Avg = 1,280 doses/8 hr
Required Staffing	1 Clinical FTE	4 Clinical FTE 3 Non-Clinical FTE	20 Clinical FTE 30 Non-Clinical FTE

The three strategies' development provides future planners with the option to target vaccination efforts and respond to environmental drivers of methodology (such as severe weather in Missouri in winter and spring).

Practical Application to Vaccine Availability Scenarios

Using the above Vaccination Capacity Modeling, the planning team has calculated the "Days to Complete Vaccination" for each county in Missouri. This calculation is currently based upon the premise that each eligible Primary Care Physician in the county would devote one individual in their office to full-time vaccination duties. This throughput is then compared to the county's total population, providing a rough estimate of the days of work required to vaccinate the county fully. This calculation is based on assumptions and has apparent challenges. Still, it has allowed the planning team to identify those counties and communities within the State who **WILL NOT** have the ability to likely self-vaccinate with

their local healthcare resources. As a result, the State knows the areas that likely require augmentation with external vaccinator resources. We will use this knowledge to estimate what help is necessary within these communities before moving to the next.

The storage, handling, and administration requirements of ultra-cold vaccines have presented a logistical challenge to the planning team. As a result of these challenges, those ultra-cold doses will likely need to be targeted within Kansas City and St. Louis (unless otherwise recommended by CDC). Although vaccination capacity exists to use the 975-dose minimum orders and complicated storage requirements, extended availability of ONLY ultra-cold vaccine could undermine the tiered sequencing currently planned to guarantee equitable vaccine distribution across rural and urban populations.

Vaccination Capacity Modeling demonstrates it would take a minimum of 331 days of gymnasium events to vaccinate all Tier 1A healthcare workers statewide. This model's apparent failure demonstrates the crucial role of concurrent efforts across Missouri and the importance of decentralized execution.

Impact of Vaccination Capacity Modeling on Provider Recruitment

The planning team is in the process of combining the results of the days-to-completion vaccination capacity modeling and the initial survey results identifying potential willing vaccinators to create a real-time map of vaccination capacity across Missouri. As mentioned above, this map will show planners where to deploy augmentative vaccination teams and where to focus recruitment efforts for additional local vaccinators.

For additional information: Appendices include Satellite and Curbside Vaccination Site Info

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

Vaccine Allocation Strategy

The primary factors driving vaccine allocation in the vaccination plan's initial phases are the vaccine's type and volume. Even with additional sequencing to reduce initial populations, Tier 1A vaccinations are expected to require multiple vaccine supply months. The potential need to limit ultra-cold vaccinations to major metropolitan areas would likely require much of the initial doses to be allocated to those geographic areas, and vaccinations are provided onsite at large medical centers. As vaccine availability increases, the ability to deploy regional immunization teams and leverage LPHA vaccination clinics will expand geographic allocation. However, tiered delivery to populations is expected to continue for up to six months after vaccinations initiation (depending upon availability). The Bureau of Immunizations will monitor vaccine allocation in real-time and regularly report to the implementation team to ensure the allocation process's transparency and provide feedback on potential next steps. DHSS will use the ongoing evaluation of the vaccination program against the Governor's Executive Intent to drive decision-making.

Cold-chain Storage Assessment/ Planning Impacts

As discussed previously, the deployed site survey of potential vaccinators included site-specific information about vaccine storage and monitoring capabilities at potential sites the State will use when placing orders into VTrckS. While the initial impression is that much of the ultra-cold capacity is confined to major metropolitan areas, the team will continue to assess this factor as results become available. This requirement potentially will result in a significant variable impact on geographic vaccine distribution, particularly during Phase 1, limited availability operations. The Bureau of Immunizations will also apply the critical patient population information to ensure the vaccine is allocated to the areas defined in Section 4.

Vaccination Ordering Process

The Bureau of Immunizations will maintain oversight for all aspects of the ordering of the COVID-19 vaccine and ensure the state allocation strategy is upheld. Using existing infrastructure, approved providers will place orders for the COVID-19 vaccine. The Bureau of Immunizations checks approved provider locations are entered into VTrckS. After receiving and approving an order, the Bureau enters the order into VTrckS, allowing shipment to the approved sites.

Unplanned Vaccine Redistribution

As discussed previously, Missouri intends to limit the need for vaccine redistribution. However, recognizing the potential for an unforeseen need, the Bureau of Immunizations will use the existing emergency vaccine distribution plan. As part of this previously deployed plan, the Bureau of Immunization personnel will take custody of the vaccine and reposition the vaccine as necessary.

The Bureau's responsibility is to ensure the appropriate protections are taken to maintain the proper temperature levels and that any ancillary products supplied with the vaccine are also repositioned simultaneously. The Missouri State Highway Patrol can assist with security detail if the need arises.

Vaccine Wastage Monitoring

Missouri's Bureau of Immunization integrated an established wastage process within the immunization registry, ShowMeVax (SMV). This process will notify the Bureau of Immunizations of vaccine wastage and monitor these reports for potential challenges to specific vaccinators or sites indicating the need for additional scrutiny. Pending further direction from CDC, providers may apply current recapture procedures to return vaccine doses that have either experienced a temperature excursion or are otherwise suspect for wastage to the Bureau of Immunizations.

Section 8: COVID-19 Vaccine Storage and Handling

Site-specific Issues

Individual Provider Location

Individual provider locations will use the CDC Vaccine Storage and Handling toolkit until receiving the updated CDC toolkit with specific COVID-19 vaccine handling. Any temperature excursions will be managed following the state Vaccines for Children (VFC) program guidance and any additional supplementation provided by the CDC.

Satellite, temporary, or off-site settings

For mobile, satellite, or temporary sites to receive the vaccine, the sites must assure cold storage. The Bureau of Immunizations will require the onsite point of dispensing manager to record temperatures every 30 minutes using a digital data logger and the off-site vaccination clinic checklist. SEMA currently has more than four mobile vaccine transport coolers used to transfer vaccine but has only four digital-data loggers.

Planned redistribution from depots to individual locations and from larger to smaller locations

At this time, Missouri is not planning to have vaccine depots. If this changes, Missouri will contract with commercial shipping platforms to transport vaccines from storage depots to providers when redistribution requirements exceed provider capabilities. The Bureau of Immunizations may use additional public transportation methods if an emergency redistribution situation arises. The commercial shipping platform needs to verify it can maintain a cold-chain.

Unplanned repositioning among provider locations

Before the movement of any vaccine, providers must submit a request to the Bureau of Immunizations at which time the Bureau of Immunizations will provide the CDC redistribution form to the site. Before the approval of the movement of vaccines, cold-chain management must be secured.

Assessment of Provider/Depot Storage and Temperature Monitoring

DHSS sent a preliminary site survey to providers before onboarding to assess the ability to sustain cold-chain management. The formal provider agreement will follow. Providers need to provide refrigeration/freezer certificates to the Bureau of Immunizations. Additionally, providers must review data-logging equipment logs regularly and upload them to SMV to validate compliance. Providers must record the minimum/maximum in the morning and the temperature once in the morning and once in the afternoon. Providers must upload the temperature logs into SMV the first day of the month for the previous month. DHSS will only allow sites to order vaccines if they can guarantee the appropriate temperature is maintained.

For additional Information: Appendices include Refrigerated / Frozen Vaccine Storage/Monitoring Info

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Existing Infrastructure

While recognizing the appropriateness of both the state IIS and VAMS, early efforts within Missouri focused on recruiting providers with demonstrated data exchange with the state IIS, ShowMeVax (SMV). Using this strategy for initial recruitment allows the State to prioritize future vaccinators' enrollment not yet in the system without switching between documentation software. The contractor that provides ShowMeVax, Envision, is currently adding additional IZ Gateway (SMV) data feeds into the CDC's WebIZ interface, allowing Missouri to submit following the (IAW) CDC guidelines.

Provider Readiness / Documentation

Signing and submitting the provider agreement obligates the organization's chief medical officer/chief financial officer to validate the provider's readiness and compliance with reporting dose administration to the state's immunization information system, ShowMeVax, within 24 hours. There are several options available to providers for documenting the required data elements of the COVID-19 vaccination to ShowMeVax:

- HL7 Interface
- HL7 Batch Upload
- Manual Entry

For consideration, if a provider isn't documenting priority population administration in their electronic health record or hub, an HL7 batch upload or manual entry are the options for populating ShowMeVax. If a provider is not utilizing an electronic health record or hub, manual entry is the only option for populating ShowMeVax.

Providers must contact the DHSS Reporting Team (immunizationhl7onboarding@health.mo.gov) to register their preferred method of populating ShowMeVax with COVID vaccine doses both for priority populations as well as clients prior to enrolling as a COVID vaccinator. Once registered, the Reporting Team will provide the appropriate implementation guides and how-to procedures.

Vaccination Delivery Monitoring

The Bureau of Immunizations will regularly pull reports from SMV identifying how many vaccines have been administered and how much vaccine is on hand, as well as vaccination administration versus documentation entry timestamps. This will provide insight into accurate and complete documentation. If providers are non-compliant with the provider agreement, the Bureau of Immunization will send a provider's reminder. Failure to comply with the provider agreement may result in termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 USC § 3729 *et seq.*, and other related federal regulations, 18 USC §§ 1001, 1035, 1347, 1349.

Section 10: COVID-19 Vaccination Second-Dose Reminders

The complexity of multiple second-dose timing represents a potential confounder for both system design and public education. The Bureau of Immunizations has been using this strategy to ensure the infant/toddler vaccine series is complete. Missouri has extensive experience conducting a centralized reminder recall program. In addition to the centralized reminder/recall, Missouri will incorporate various other strategies outlined below.

Missouri will use a centralized reminder/recall system from SMV. To identify patients needing a second dose in the series, the Bureau will weekly run a list of patients with set parameters uniformly applied at 28 days. It will send reminders via postcard, email, or phone call to the vaccine recipient one week before the vaccination is needed. The Bureau of Immunizations will conduct follow-up reports twice a month to confirm two-dose compliance. Dedicated staff members will conduct a centralized reminder/recall.

Missouri will also encourage all clinics to schedule the next appointment before the patient leaves the clinic. This is an evidence-based strategy for achieving series completion. Missouri will also enable clinics and health systems to implement its patient reminder system or centralized reminders/recall.

For mobile mass clinic sites, Missouri will work with off-site providers, establishing a set schedule for communities using this service. The Bureau of Immunizations will ensure the centralized reminder system works in conjunction with this mobile mass clinic effort.

Additionally, providers will make sure each person will receive documentation at the time of vaccination. This will include the manufacturer name, lot number, dose, site, and date of vaccination for the patient's records and the date when the second dose is due.

Combining these evidence-based methods will help guarantee a two-dose completion.

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

WebIZ/DUA

Missouri has executed a data use agreement with the Association of Public Health Laboratories to participate in the Connect component of IZ Gateway. Missouri currently has a Memorandum of Understanding with Kansas to share immunization data between those two jurisdictions outside of the IZ Gateway. Missouri is now in the preliminary phases of having conversations with neighboring states about entering into Memorandums of Understanding to share immunization data in a means other than the IZ Gateway Share component. As the CDC releases its Data Use Agreement, Missouri will evaluate the DUA for compliance with Missouri legal requirements.

Data Exchange/Interface/Quality Monitoring

In addition to a direct provider entry portal and the ability to ingest flat files, SMV has an established data exchange that currently accepts HL7v2.5.1 immunization messages from provider electronic health records (EHR). In coordination with both providers and the leading four EHR manufacturers in Missouri, standardized discrete data elements were identified to facilitate data exchange. This discrete data element structure enables the generation of standardized and ad hoc reporting of vaccinations recorded within the IIS and data warehouse.

New SMV providers are initially placed in a quality assurance (QA) environment until the Bureau of Immunization verifies their data accuracy. Once verified, the provider is migrated into SMV production via an HL7 message or a flat-file. SMV currently validates data against the federal data standard, which exceeds the CDC's requirements. In addition to the data's technical quality, the Bureau of Immunization staff conducts intermittent audits comparing vaccine inventory reporting against vaccine administration documentation. This can also be monitored at the provider level by comparing system timestamps of data entry versus reported administration times.

Provider Enrollment Strategy

Although providers can use either SMV or VAMS in Phase 1, our provider engagement team targeted potential vaccinators with existing relationships and interfaces within the SMV system. A statewide network of existing providers without the requirement for significant additional IT onboarding requirements allows the State to immediately get to work while providing a ramp-up time for providers requiring enrollment for Phase 3. In the event of an unplanned need for an alternate-site vaccination deployment, the flat file roster reporting capability of WebIZ provides an additional emergency capacity.

Data Collection

Missouri's ShowMeVax system collects specified demographic information during documentation capture. As required data fields are outlined by CDC guidance for immunization reporting, the

Bureau of Immunization will continue monitoring to ensure the correct information is being captured within SMV and reported as required.

High Volume/Contingency Documentation

The WebIZ software has a vaccination module that allows for a mass vaccine import. The Bureau of Immunization will use this tool, as required, although the preferred process is for vaccination administration to enter ShowMeVax in real-time. The Bureau recognizes the potential for network outages, cloud service failures, and their significant impact on documentation efforts. However, all server types (database, web, domain controllers) in our production Azure environments are configured in pairs to provide load balancing in the event of high-traffic events and redundancy in the event of Azure hardware and networking failures. Additionally, customer databases are frequently and regularly backed up to Azure storage using SQL Server-managed backup to Microsoft Azure. In the unlikely event that the Azure data centers experience a catastrophic outage, this would render the site unavailable. Contingency planning for this scenario aligns with that for general web unavailability at a mobile site. Providers use localized tracking (either electronic or manual) through WebIZ's roster import function as soon as connectivity is restored.

Section 12: COVID-19 Vaccination Program Communication

Comprehensive, Coordinated Campaign

DHSS submitted a formal request submitted to a state-approved marketing vendor to develop a multi-sourced media campaign encouraging Missourians to get the COVID-19 vaccination, explicitly focusing on stigma reduction and consistent messaging. Campaign media breakout can be found in the appendices.

This campaign will have four primary messaging objectives:

- 1) Protecting communities
- 2) Empowering families
- 3) Stopping myths by highlighting vaccine safety and privacy protection
- 4) Vaccinating so we can move beyond COVID-19

The campaign end state is Missourians are informed, understand what priority group they are in, and the associated timelines of when the vaccine is available to them. Providers and health departments are adequately trained and equipped to administer vaccines as soon as they are available.

Key Tasks:

1. Provide providers and health departments with education and training materials to safely and timely administer the COVID-19 vaccines and counter myths about the vaccine.
 - a. Included are instructions for the safe handling, storage, preparation, and administration of the vaccines along with educational material/talking points providers can use to educate Missourians.
2. Inform Missourians on the timeline of vaccine availability, who the targeted populations are, and why the vaccine is essential.
 - a. This is based on the concepts of protecting communities and empowering families. A multi-sourced media campaign will guarantee timely, accessible, and effective public health and safety messaging for Missouri communities.

The campaign will run from 10 days before vaccine delivery and continue six to eight months after the first vaccine delivery. The vaccine will be available and distributed based on a three-phase approach; however, Phase I and II will be the priority for education and messaging:

Phase One – Phase One intends to reduce morbidity and mortality and provide relief to critically stressed community healthcare resources while protecting those residents engaged in supporting critical infrastructure and economic reopening. This phase is expected to begin upon the vaccine delivery date through approximately 90 days. Vaccines are anticipated to be in limited amounts, with high-risk populations being the primary focus.

- **Priority Populations**

- Phase 1A: All healthcare personnel and staff who have the potential for direct or indirect exposure to COVID-19 and are unable to work from home

- Phase 1B: Those at increased risk for severe COVID-19 illness, including those ≥ 65 years of age, and those workers who are vital to keeping the essential functions of society running.

Phase Two –Phase Two's intent is to promote the vaccine's safety and the importance of being vaccinated so Missouri can continue to reopen safely. Transition in messaging is anticipated on or about vaccine delivery date plus approximately 90 to 180 days. Phase One messaging will continue through this time.

- Priority populations
 - Individuals who fall within Phase 1A and 1B but who could not be vaccinated in Phase 1.
 - General population

Phase Three –Phase Three's intent is to provide widespread vaccine availability to Missouri residents, with continued emphasis on those at high risk from a COVID-19 infection.

The campaign intends to reach all Missourians, but the priority populations focus on phase and vaccine availability, as described earlier in this report. The identified priority populations, urban, minorities, rural, and underserved communities will also be primary messaging recipients.

The campaign's activity plan includes educational material for the safe handling, storage, preparation, and administration of the actual vaccine. In conjunction with DHSS, the State's vendor will develop training videos with consistent messaging for training across Missouri. The training material will highlight the safe and appropriate steps taken to administer the vaccine. Additionally, educational material will specify this is a two-shot vaccine with 21 or 28 days between doses.

The COVID-19 vaccination plan is a new campaign concept and will account for transitions in messaging as the phases change. Consistent messaging and science-based evidence will be paramount.

Emergency/Crisis Communication, Timely Updates

As part of the media campaign, DHSS and the vendor will develop a website so messaging and design remains consistent. DHSS will also populate the information so it remains accurate and timely.

This website will be specific and only for information for the COVID-19 vaccination efforts in Missouri. The following sections will be available:

- General information/education for the public with vaccination locations
- Providers, vaccinators, and public health department education and training
 - Location for Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients and a place for vaccine information statements (VISs)
 - Tool kit for training and educational material
- Vaccine recipient testimonials/feedback with phone number/call center information and a frequently asked question section.

- Data repository allowing Missourians to stay informed with up-to-date statistics
- “Myth busters” will be a page dedicated to getting the facts about the vaccine.

In addition to the website, DHSS will use a funded, multi-sourced media campaign to reach the intended audiences positively. To use the budget most efficiently, DHSS will rely on research from a more general audience of Missourians and key influencers to reach and best connect with urban, rural, and culturally diverse audiences as much as possible. The marketing entity will develop various creative assets in digital and traditional ad placements, print collateral, etc.

The following additional tactics are planned to combat misinformation challenges:

- Digital billboards instead of traditional billboards – provide added flexibility to quickly adapt messaging in targeted areas as needed in population centers.
- Social media – target messaging tailored for communities and use these platforms for social listening.
- Influencer feedback – maintain a two-way conversation with minority influencers.
- Earned media – provide media availability to address frequently asked questions

Provider Resources: covidvaccine.mo.gov

The screenshot displays the Missouri Department of Health & Senior Services (DHSS) website. The header includes the DHSS logo, navigation links (MO.gov, Governor Parson, Find an Agency, Online Services), a search bar, and social media icons. A secondary navigation bar lists categories: Healthy Living, Senior & Disability Services, Licensing & Regulations, Disaster & Emergency Planning, and Data & Statistics.

The main content area is titled "COVID-19 Vaccine Information for Vaccinators". It includes a breadcrumb trail: DHSS Home » Healthy Living » Health Conditions & Diseases » Communicable Diseases » COVID-19 » vaccine. Below this is a "Select Language" dropdown and a "Powered by Google Translate" note. A prominent green button reads "COVID-19 Vaccine Provider Enrollment Open Now".

The "State of Missouri COVID-19 Vaccination Plan" section lists several resources:

- CDC guidance on PPE usage for vaccination sites
- CDC IIS Data Requirements for COVID-19 Vaccine Administration
- COVID-19 Vaccination Program Interim Playbook
- Legal Information
- PPE burn rate calculator

The "General Vaccine Information" section lists:

- Immunization Site Demographics Template (5 or more sites)
- Missouri Immunization Registry MOU
- PanFluVax Planning Tool
- PanVaxManual
- ShowMeVax Immunization System
- VFC form and guidance for temperature excursions

A green button at the bottom of this section says "Email us your questions".



A right-hand sidebar titled "COVID-19" contains a list of links:

- CARES Act Funding Toolkit for Local Governments
- Show Me Strong Recovery Plan
- Analytics
- CDC Situation Summary
- Face Covering Guidance
- Frequently Asked Questions and Answers
- Missouri News
- Plasma Donations
- Resource Toolkit
- State Testing Guidance
- Missouri Testing Sites
- COVID-19 Vaccine
- Statewide Orders
- Local Orders
- Waivers of Laws and Rules



At the bottom right, a purple button with a location pin icon reads "Free Community Testing Events".

COVID-19 Vaccinator Enrollment

DHSS Home » [Healthy Living](#) » [Health Conditions & Diseases](#) » [Communicable Diseases](#) » [COVID-19](#) » vaccine-enrollment






Select Language 
Powered by  Google Translate

The Missouri COVID-19 Vaccinator Enrollment program is now open! Providers will utilize Missouri's Immunization Information System, ShowMeVax, to complete the enrollment process. The Missouri Bureau of Immunizations has developed helpful tools to guide you through the COVID-19 Vaccinator Enrollment process, including provider enrollment FAQs, a provider enrollment checklist, and the provider enrollment training guide.

Providers who are new to ShowMeVax must submit a signed copy of the **Missouri Immunization Registry Memorandum of Agreement**  (MOA). If your organization does not have a signed MOA on file, please email the signed MOA to vfc-smvsupport@health.mo.gov with the subject line "COVID Vaccinator MOA." If your organization has multiple sites, please include the **Immunization Site Demographics Template**  along with the MOA. To request access to ShowMeVax, please visit <https://showmevax.health.mo.gov/smv/login.aspx>. Providers **CANNOT** use Internet Explorer to access ShowMeVax.

ShowMeVax training videos can be viewed [here](#). 

We are looking forward to working with you in the statewide COVID-19 vaccine effort and will assist you in any way we can. Please do not hesitate to contact us at c19vaxenroll@health.mo.gov, if you have any questions regarding the enrollment process.

- [SMV User-Account Roles](#) 
- [SMV Covid-19 Enrollment Training Guide](#) 
- [SMV Covid-19 Vaccine Enrollment FAQ](#) 
- [COVID-19 Vaccine Provider Enrollment Checklist](#) 
- [COVID-19 Vaccination Program Provider Agreement and Profile Form](#)  (also referred to as the *COVID-19 Provider Program Manual*)

Missouri Immunization
Registry MOA 

Immunization Site
Demographics Template 


COVID-19

[CARES Act Funding Toolkit for Local Governments](#)

[Show Me Strong Recovery Plan](#)

[Analytics](#)

[CDC Situation Summary](#)

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[Frequently Asked Questions and Answers](#)

[Missouri News](#)

[Plasma Donations](#)

[Resource Toolkit](#)

[State Testing Guidance](#) 

[Missouri Testing Sites](#)

[COVID-19 Vaccine](#)

[Statewide Orders](#)

[Local Orders](#)

[Waivers of Laws and Rules](#)

 **Free Community
Testing Events**

For additional information: Appendices include a Marketing/Communications Activity Plan

Section 13: Regulatory Considerations for COVID-19 Vaccination

EUA/VIS Availability

Due to the uncertain nature of whether vaccines will be released under an Emergency Use Authorization or FDA approval, Missouri will use a real-time COVID-19 Vaccination provider website. Also, to push notifications via email and text, this will give providers access to the most up-to-date information about the COVID-19 vaccination program. This site will include links to the FDA- and CDC-maintained website, where the agencies maintain EUAs and VISs for the COVID-19 vaccine. Missouri will also target the POCs listed on provider agreements with periodic email reminders on locating the most current and up-to-date EUAs and VISs. The Bureau of Immunizations will additionally disseminate this information through its traditional means of communication. Finally, upon order confirmation for a COVID-19 vaccine, the Bureau will include a link to the FDA- and CDC-maintained website with the message confirming the order.

EUA/VIS Delivery

The Bureau of Immunizations will provide signage and posters to vaccinators and mobile sites. The signage and posters will have a standardized QR code providing a link to the website where VIS or EUA information is located. Following the provider agreement, the Bureau of Immunizations expects all providers to make the EUA and VIS available before administering the vaccine, through whatever means necessary depending on the constraints of the population being served and the constraints of the location where the vaccine is administered.

For additional information: Appendices include a Legal/Regulatory FAQ

Section 14: COVID-19 Vaccine Safety Monitoring

Missouri's overall vaccine safety monitoring approach includes pre-administration communication with providers, a COVID-19 vaccine-specific informational website, links to reporting through the Missouri IIS, direct technical assistance provided by the Missouri vaccine safety coordinator/backup vaccine safety, and provider organization partnerships.

Missouri has a long history of provider education. Missouri intends to build on this foundation, which includes the importance of vaccine safety monitoring, a significant component in all annual Vaccines for Children (VFC) provider training pieces. Providers received an initial survey to assess vaccine implementation readiness and capacity. This survey and the accompanying FAQs emphasized the role and requirement of VAERS reporting following COVID vaccination. Through this communication, Missouri began making providers aware of the various vaccine safety monitoring requirements before administering vaccines. To create a hub of information, Missouri will have a dedicated website for the COVID vaccine. This site includes the VAERS provider fact sheet, a downloadable writable VAERS reporting form, and a link to the VAERS online reporting demonstration on the VAERS website.

Additionally, the contact information for Missouri's vaccine safety coordinator will be on Missouri's COVID-19 vaccination website. Missouri has a dedicated vaccine safety coordinator and a reliable backup safety coordinator, both in constant communication with the CDC's Immunization Safety Office (ISO) and participating in all vaccine safety calls. Missouri also linked the VAERS system on the Immunization Information System ShowMeVax for easier reporting by the provider.

The dedicated vaccine safety coordinator and the backup vaccine safety coordinator can assist any provider with questions on VAERS or help with reporting adverse events into the system. The vaccine safety office will be providing specific data on state-specific VAERS each week that have been entered into the system. Additionally, the vaccine safety coordinator or representative will assist with any provider follow-up on VAERS reports requested by the ISO.

To reach the providers who are not VFC providers, Missouri is working with the Missouri Academy of Family Physicians, the Missouri State Medical Association, and the Missouri Immunization Coalition to create educational awareness materials to be distributed to providers across the State, regardless of their involvement with the COVID-19 vaccination program. Again, Missouri's overall vaccine safety monitoring approach includes pre-administration communication with providers, a COVID-19 vaccine-specific informational website, links to reporting through the Missouri IIS, direct technical assistance provided by the Missouri vaccine safety coordinator/backup vaccine safety, and provider organization partnerships.

Missouri will not deploy a vaccine that has not passed safety and efficacy studies and has not been approved by the Food and Drug Administration (FDA) as fully licensed or released under an Emergency Use Authorization (EUA).

Section 15: COVID-19 Vaccination Program Monitoring

Provider enrollment

Our proactively deployed potential vaccinator survey provides our implementation with the earliest possible information on potential provider enrollment within the initial planning efforts. By comparing these results with existing SMV providers, the implementation team can reconcile and simultaneously monitor both vaccinator enrollment potential and onboarding status and their HL7 interface documentation capabilities. Using state GIS assets to deliver this information within a mapped format, RIT and SIT monitors recognize the individual vaccinator status and how their position affects regional capabilities.

Vaccination Delivery Demographics

The usage of SMV and the CDC-determined required vaccination data collection fields will guide the deployment of vaccination delivery demographic reporting. The Missouri COVID-19 Vaccination Plan specifically targets high-risk populations and actively encourages more significant health equity throughout the vaccine allocation process. The Bureau of Immunization will monitor this objective's success on an ongoing basis through weekly delivery of a comprehensive overview of the previous week's vaccination activity. Report variables will include race/ethnicity, rural/urban zip codes, age, etc.

IIS or other designated system performance

As discussed extensively in Section 11, the Bureau of Immunizations will use SMV and the CDC's WebIZ . SMV is vendor-hosted (Envision) with a 99% uptime agreement, monitored in real-time with automated outage reporting. Additionally, paired servers for load balancing allow for regular proactive review of data traffic patterns, particularly to model potential threats associated with future volume expansions. Finally, the traditional backup notifications via Azure storage provide the team with real-time monitoring and data protection assurance.

Provider-level data reporting/Dose Coverage

Once a vaccinator submits the administration information via SMV, the RITs/SIT can leverage the standard routine reporting functionality within SMV. Previously established reports provide initial information but are expected to be iteratively improved as DHSS identifies additional factors. Initial weekly status reports from SMV will include numbers of vaccinations delivered, raw immunization rates, and first-dose/second-dose percentages. The Bureau of Immunizations can review these reports at State, region, county, and zip code levels, providing VSTs and RITs immediately actionable information for their responsibility areas.

Vaccine ordering and distribution

SMV allows for a relatively optimized approach to vaccine ordering and distribution. As described elsewhere, the requesting of vaccine by vaccinators within SMV populates a daily ordering report,

which Bureau of Immunization staff will review and act upon by daily. The combined reporting capability of VTrckS and SMV allows the SIT to have daily insight into current and historical requests and how vaccine allocation decisions impact the State and regions.

Budgeting/Materiel Management

The combination of DHSS financial management systems and SEMA warehousing capabilities provides Missouri's COVID-19 vaccination plan with a well-tested and exercise program for the accountability of federal and State funds supporting these efforts as the awardee signatory for Missouri, the Chief of the Bureau of Immunizations has direct responsibility for the accountability and expenditure of awarded funds. This will be accomplished under existing state/federal laws and accounting policies. Recognizing the potential for frequent situational changes and the fundability of the awarded funds, the executive planning team will also serve in an advisory role to the Bureau of Immunizations' Chief in determining budgetary changes. As required by state policy, routine financial accountability reporting will be monitored by the Chief of the Bureau of Immunizations.

In addition to funds, the acquisition of expendable ancillary supplies required for the effective deployment of the COVID-19 vaccine presents an ongoing accountability challenge. While stores will be ordered in bulk, they are intended to be broken down into deployment units based on supporting 100 doses. The deployment of these supplies will occur in conjunction with the direct delivery of vaccines and is triggered by the SIT allocation of doses. The SEMA/SNS warehouse plans to ship out the needed ancillary supplies ahead of the vaccines to guarantee timely vaccine delivery to the patient. This duplicative reporting model of both the warehouse records of inventory and the vaccine allocation reports provides a ready-made audit capability. This reconciliation is expected to occur on at least a monthly basis.

Communications/Messaging

The appendices include information about the Elasticity Activity Plan. DHSS will provide the SIT with ongoing media monitoring and feedback via a comprehensive communication strategy. This includes monitoring and trending of traditional media and social media venues at the state and regional levels. While regularly shared in the ongoing communications meetings focused on shaping/refining our messaging approach, DHSS can also report information quickly in a significant development event. Complimenting this formal process, community leaders within the RIT model also provide the Missouri COVID-19 vaccination program with ears to the ground across the State, providing ongoing community sentiment barometers to each RIT.

Any/all reporting of program metrics within a public-facing website will require close coordination with state communications officials and the Governor's office. The identification of these potential measures, and the associated reporting thresholds, are still under consideration and will be additionally informed by Elasticity and RIT feedback.

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APPENDICES

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Table of Acronyms

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Acronym Definitions

AAA	Area Agencies on Aging
AARP	American Association of Retired Persons
ACIP	Advisory Committee on Immunization Practices
BI	Bureau of Immunizations
BMI	Body Mass Index
CDC	Centers for Disease Control and Prevention
CSV	Comma Separated Value
DHSS	Department of Health and Senior Services
DMAT	Disaster Medical Assistance Team
EHR	Electronic Health Record
EMS	Emergency Medical Services
EPT	Executive Planning Team
EUA	Emergency Use Authorization
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
HIE's	Health Information Exchange
IIS	Immunization Information System
IT	Information Technology
LoE	Line of Effort
LPHA	Local Public Health Agency
MERIC	Missouri Economic Research Information Center
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
MSHP	Missouri State Highway Patrol
NAACP	National Association for the Advancement of Colored People
OSHA	Occupational Safety and Health Administration
PPE	Personal Protective Equipment
RIT	Regional Implementation Teams
SEMA	State Emergency Management Agency

SIT State Implementation Team

SMV ShowMeVax

UPS United Parcel Service

VAMS Vaccine Administration Management System

VFC Vaccines for Children

VIS Vaccine Information Statement

VST Vaccination Support Team

VTckS Vaccine Tracking System

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Legal FAQs

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Legal Appendix of Frequently Asked Questions

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Vaccine Injury Compensation Program vs. Countermeasures Injury

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Emergency Use Authorization

1. *What is an Emergency Use Authorization (EUA)?*

An Emergency Use Authorization (EUA) is a legal mechanism that allows the Food & Drug Administration (FDA) to help strengthen the nation's public health protections by facilitating the availability of Medical CounterMeasures (MCMs) needed during public health emergencies. It allows the use of (a) *an unapproved medical product* (e.g., drug, vaccine, or diagnostic device) or (b) *an unapproved use of an approved medical product* during an emergency to diagnose, treat, or prevent a serious or life-threatening disease or condition. When scientific evidence is available to support such a use in an emergency, the issuance of an EUA enables response stakeholders to use, or prepare to use, an MCM without violating the Federal Food, Drug, and Cosmetic Act (FD&C Act).

2. *How long does an EUA last?*

An EUA terminates upon the earlier of (a) the determination that the circumstances justifying the EUA's issuance no longer exist or (b) a change in the approval status of the medical product such that an EUA is no longer needed.

3. *By what process is an EUA issued?*

The issuance of an EUA goes through a 3-step process.

1. A determination is made by either the Secretary of either the Department of Homeland Security, Department of Defense, or Department of Health and Human Services that an actual or potential emergency or threat exists.
2. The Secretary of Health and Human Services makes a declaration that circumstances exist to justify the issuance of an EUA based on the above-mentioned determination. Note: This determination is separate from any other declarations made concerning a public health emergency.
3. The FDA Commissioner issues an EUA after ensuring that the criteria for issuance of an EUA have been met.

4. *What criteria does the FDA Commissioner consider when issuing an EUA?*

The FDA Commissioner is required under section 564(c) of the FD&C Act to consider and make findings on following criteria prior to issuing an EUA.

- The Secretary of the Department of Health and Human Services declares the existence of a serious or life-threatening disease or condition
- The medical product may be effective in diagnosing, treating, or preventing such disease or condition
- The known and potential benefits of the use of the product outweigh its known and potential risks
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such a disease or condition

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FDA Approval Process

1. *Who is responsible for regulating and approving vaccines?*

The Center for Biologics Evaluation and Research (CBER) within the Food & Drug Administration (FDA) is responsible for regulating vaccines in the United States.

2. *What testing phases does a vaccine go through prior to approval?*

Prior to human clinical trials, a vaccine's safety and ability to elicit a protective immune response is done in animal testing. Once animal testing is concluded, a vaccine typically goes through three phases. Phase 1 focuses on safety and protective immune response in a small number of closely monitored subjects. Phase 2 focuses on the appropriate dosage at the time of administration. Phase 3 focuses on the critical documentation of effectiveness and additional safety data required for licensing.

3. *Who considers applications to approve vaccines for administration?*

All vaccine license applications are reviewed by a multidisciplinary team within the FDA that is made up of medical officers, microbiologists, chemists, biostatisticians, etc.

4. *What does the Multidisciplinary Team look for when reviewing applications?*

The multidisciplinary team evaluates all of the data collected from the clinical trial phases from an efficacy and safety perspective so as to make a risk/benefit assessment. This risk/benefit assessment looks at whether the benefits of the vaccine outweigh the known risks. During this evaluation process, the proposed manufacturing facility undergoes a pre-approval inspection.

5. *Does anyone not associated with the FDA look at the application?*

Either the sponsor of the vaccine or the FDA may present their findings to the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). VRBPAC reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines. This committee is made up of industry recognized experts in the fields such as immunology, biostatistics, epidemiology, vaccine safety, infectious disease, and vaccine development.

6. *Is there anything else required for vaccine approval?*

Vaccine approval also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public.

7. *Once the FDA approves a vaccine, does it continue to monitor the vaccine?*

After licensure, monitoring of the vaccine and its production continues as long as the manufacturer holds a license for the product. The FDA may request the manufacturer to provide lot samples for FDA testing or to report the results of the manufacturer's own tests for potency, safety, and purity. The FDA utilizes the Vaccine Adverse Event Reporting System (VAERS) to identify problems once the vaccine is on the market and administered to the general population.

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Fiscal Considerations

1. *Can money granted to the State of Missouri under the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) be utilized to supplement expenses necessary for vaccination? Further, can supplies purchased utilizing CARES Act funds for purposes of COVID-19 testing be repurposed for COVID-19 vaccination?*

Yes, funds from the CARES Act may be utilized to cover costs that are necessary expenditures incurred due to the COVID-19 public health emergency that were not accounted for in the state budget provided that the expenses are incurred between March 1, 2020 and December 30, 2020. As vaccination for the COVID-19 virus is a direct action taken to respond to the public health emergency any remaining CARES Act funds or supplies purchased through CARES Act funds may be utilized for purposes of vaccination.

It is important to note that performance of services or delivery of goods from CARES Act funds must occur during the covered period. The cost of services or goods are not CARES Act eligible if there is no need for receipt of said services or goods outside of the aforementioned covered period. However, the fact that a good may not be used during the covered period does negate its eligibility provided that in the case of bulk goods a portion of goods were used during the covered period and with durable goods if the acquisition was necessary due to the emergency.

2. *How will the COVID-19 vaccination be paid for?*

The COVID-19 vaccine will be procured and distributed to providers proportionately by the federal government at no cost to enrolled vaccination providers. Based on current information from the CDC ancillary products necessary for the administration of the vaccine will also be provided at no cost to enrolled vaccination providers.

3. *What happens if Federal money runs out prior to the completion of vaccination?*

In the event that Federal money is no longer available to complete vaccination or respond to the COVID-19 public health emergency questions concerning the utilization of state appropriate funds should be directed to the State Resource Office.

4. *Can National Guard Soldiers be utilized to support COVID-19 vaccination?*

The usage of National Guard Soldiers in support of COVID-19 vaccination is entirely fact dependent based on the specific task or project sought to be accomplished by the National Guard. As such it is not possible without specific details to determine whether it is permissible to utilize National Guard Soldiers in support of COVID-19 vaccination. As of the time of writing, there are no intentions to utilize the resources of the National Guard, including its soldiers, to support the logistical needs of the vaccination plan.

5. *How does the state appropriation process work?*

The legislative appropriations process is the process by which the Missouri General Assembly funds the operations of state government. Funds include “general revenue” and other revenues (including federal funds). The appropriations process differs from the legislative process used for ordinary legislative bills in that budget bills can only be introduced in the House of Representatives.

The appropriations process also utilizes different committee processes and conference committees to finalize appropriation bills versus ordinary legislative bills. Budget discussions begin before the session even starts. State departments submit their budget requests to the Office of Administration, which are reviewed by the Office of Budget and Planning, as well as the Governor’s Office.

At the beginning of the legislative session, the chairman of the Budget Committee introduces appropriation bills which are referred to the Budget Committee and various subcommittees to discuss the specific department requests. Once review is completed at the subcommittee level the full Budget Committee reviews the appropriations bill to either accept, amend or reject.

Typically in March, the entire budget made up of the various appropriation bills are presented to the entire House for amendment and passage. Upon passage the appropriation bills are forwarded to the Senate where the same process utilized in the House of Representatives is repeated. Once the Senate approves its versions of the appropriation bills, those bills which were amended by the Senate referred to a joint committee. This joint committee is composed of members from the House and Senate to reach a compromise between their respective versions of the budget.

Once the committee reaches an agreement on the budget it is sent back to both the House and Senate for passage of the Conference Committee budget. This process must be completed at least one week before the end of the session in May. In addition to the deadline for passage, the General Assembly is required under the Missouri Constitution to pass a balanced budget.

Once the budget is passed it is sent to the Governor who has until July to act on those budget bills. He is permitted to sign the budgets into law, completely veto a bill, or utilize a line-item veto on particular portions of a bill. The General Assembly reconvenes in September for its annual veto session to consider any override of the Governor’s vetoes and to finalize the budget.

Vaccine Administration Fees

1. *Can I charge a Vaccine Administration Fee?*

Yes. Per the terms of the CDC COVID-19 Vaccination Program Provider Agreement is permitted to charge an administration fee.

2. *How much can I charge for administering a COVID-19 vaccine?*

No maximum amount has been set at this time. It is anticipated that any administration charge set will not exceed the current maximum authorized under the VFC program. That current amount is \$21.53. It is important to note that when establishing an administration fee a provider is not permitted to seek reimbursement for the COVID-19 vaccine or any additional materials that are given to the provider at no cost by the Federal Government or State of Missouri.

3. *Can I require payment prior to administering a COVID-19 vaccine?*

No. While it is permissible to request a vaccine recipient to pay an administration fee a provider may not mandate payment. Per the terms of the Provider Agreement a provider must administer the COVID-19 Vaccine regardless of the vaccine recipient's ability to pay an administration fee.

4. *Can I bill health insurance for administering a COVID-19 vaccine?*

Yes. Under §3203 of the CARES Act health insurance providers are required to cover, without cost-sharing, any qualifying coronavirus preventive service. Under the CARES Act a qualifying coronavirus preventive service includes an immunization that is intended to prevent or mitigate COVID-19 and that has in effect a recommendation from the Advisory Committee on Immunization practices of the Centers for Disease Control and Prevention with respect to the individual involved, e.g. an FDA approved COVID-19 vaccine administered to an individual within the age group approved by ACIP is chargeable to insurance.

5. *What happens if a COVID-19 vaccine recipient does not pay and does not have insurance?*

The COVID-19 Uninsured Program was established and funded under the FFRCA, PPPHCEA, and CARES Act to provide reimbursements to providers for claims that are attributed to treatment of COVID-19 for uninsured individuals. Treatment for purposes of the COVID-19 Uninsured Program includes immunization for COVID-19. The COVID-19 Uninsured Program is administered by UnitedHealth Group.

6. *Where can I get more information about the COVID-19 Uninsured Program?*

The Health Resources and Service Administration (HRSA) within the Department of Health and Human Services (HHS) is the federal agency operating the Program. More information can be found on their website at

<https://www.hrsa.gov/CovidUninsuredClaim>.

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Vaccine Administration Legal Requirements

1. *Who can Administer Vaccines in the State of Missouri*

Under Missouri law and regulations, Physicians have the inherent authority to prescribe and administer vaccines. The prescription and administration of vaccines by someone other than a physician, e.g. pharmacist, registered nurse, nurse practitioner, physician assistant, and paramedic, occurs through authority delegated to that individual by a physician.¹ Students in the medical field, such as nursing and medical school students, are also permitted to administer vaccines under the direct supervision of a properly licensed medical provider.

2. *Under what process can a pharmacist prescribe and administer a vaccine under Missouri Law.*

The ability of a pharmacist to prescribe and administer vaccines without a doctor's prior prescription is governed by: § 338.010, RSMo – "Practice of Pharmacy defined"; 20 CSR 2150-5.025 – "Administration of Vaccines Per Protocol"; and 20 CSR 2220-6.050 – "Administration of Vaccines Per Protocol."² Under the protocol process a pharmacist must be qualified by completing the appropriate training and filing a Notification of Intent (NOI) to administer vaccines with the Missouri Board of Pharmacy.³ In addition to the filing of the NOI, a pharmacist must enter into a written protocol with a Missouri licensed physician for a period not to exceed 1 year.⁴ The protocol must contain certain provisions which include the identification of the vaccines authorized to be administered, the patient or group of patients authorized for vaccination, and if applicable, authorization to create a prescription for each administration under the physician's name.⁵ Of most importance by entering into the protocol, the physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.⁶

3. *How does the Governor of the State of Missouri address responding to public health emergencies?*

Under § 44.100, RSMo the Governor is authorized to declare a state of emergency. Upon the declaration of a state of emergency the Governor may waive or suspend the operation of any statutory requirement or administrative rule regarding the licensing, certification or issuance of permits evidencing professional, mechanical, or other skills.⁷ The Governor is also vested with the authority to waive or suspend the operation of any statutory requirement or administrative rule prescribing procedures for conducting state business, where strict compliance would prevent, hinder, or delay necessary action by the department of health and senior services to respond to the declared emergency or increased health threat to the population.⁸

4. *Has the Governor of the State of Missouri declared a state of emergency in relation to COVID-19?*

On 13 March 2020, the Governor issued Executive Order 20-02 invoking the provisions of § 44.100 and § 44.110 and declaring a state of emergency within the State of Missouri due to the spread of COVID-19. Shortly thereafter on 18 March 2020, the Governor issued Executive Order 20-04 whereby he delegated authority to the Directors of the Department of Health and Senior Services, Department of Public Safety, Department of Social Services, Department of Commerce and Insurance, Division of Professional Registration and its Boards, and the Office of Administration to temporarily waive or suspend the operation of statutory or administrative rule or regulation under their purview that would best serve public health and safety during the period of emergency and the subsequent recovery period.⁹

5. *Does the Governor have the authority to expand the types of individuals who could be authorized to administer a vaccine in the state of Missouri?*

Based on the statutory authority granted to the Governor, and through the specific authority granted to Department Directors under the Governor's current Executive Orders it is permissible to enlarge the group of individuals who are authorized to not only prescribe but administer any COVID-19 vaccination.¹⁰ This would be accomplished through the Director of the Department of Health and Senior Services entering an order approved by the Governor. However, such an order would need consultation from other agencies and boards, e.g. Department of Public Safety, Board of Nursing, Board of Registration for the Healing Arts, Board of Pharmacy, and DHSS Bureau of EMS. To the extent that individuals identified in the enlarged group of administrators could fall within the purview of one of the aforementioned departments or boards, corresponding orders would also be required from those entities. Regardless of the issuing authority the order would outline the individuals authorized to administer, along with the conditions on which the vaccine could be administered and the training required of the individual administering prior to the administration of the vaccine.

6. *Does the United States Government have the ability to circumvent requirements under state of Missouri law concerning vaccine administration?*

It is important to note that any requirements, conditions, or restrictions that currently exist under Missouri law concerning the prescription, dispensing and administration of vaccines or the scope of practice of medical professional could be preempted by the Federal Government through Department of Health and Human Services PREP Act Declarations or FDA Emergency Use Authorizations. In particular, the Office of the Secretary for Health within the Department of Health and Human Services issued guidance on 3 September 2020 specifically preempting any State or local law that prohibits or effectively prohibits a pharmacist or pharmacist intern qualified under the guidance from ordering or administering COVID-19 vaccines.¹¹

Vaccine Site Security

1. *Can the National Guard be utilized to provide security at vaccination sites?*

Under Missouri law, the National Guard provides for the protection of life and property as well as preserving peace, order, and public safety. This is historically accomplished by placing the National Guard in State Active Duty (“SAD”) status. When placed in this status the National Guard reports to the Governor and is funded with state funds. Generally, federal concerns regarding SAD operations are limited to issues of regulatory compliance and issues of reimbursement for federal property and expenditures.

The Adjutant General may employ the National Guard in SAD status for purposes of law enforcement. However, the Adjutant General should strongly consider using SAD in a back-up role for law enforcement, rather than in a “front line” role in which there might be increased chance of adverse interaction with civilians. It may also be more beneficial for using SAD to provide force protection to critical infrastructure and state facilities, thereby freeing up civilian law enforcement to perform security functions.

When placed in SAD status for purposes of law enforcement or force protection considerations must be made regarding armed status, arming orders, and rules on the use of force. SAD use of federal equipment provided by the Department of Defense is subject to reimbursement through the United States Federal Property Office.

Vaccine Injury Compensation Program vs. Countermeasures Injury Compensation Program Comparison Chart

	Vaccine Injury Compensation Program	Countermeasures Injury Compensation Program
Standard of Injury	Injury occurring after the receipt of a covered vaccine ¹ that was not the result of any other possible causes	Seriously Physical Injury ² , including death
Filing Deadline	3 years after first symptom or within 2 years of death and 4 years after the first symptom resulting in death	1 year from the date the covered countermeasure was received or used
Can a Representative File on behalf of victim?	Yes	Yes. If a recipient is a minor a legal or personal representative must be used.
Can I file with other Third-Party Payers for Compensation?	Yes. VICP does not pay when payment has been made or can reasonably be expected to be paid by a third-party.	Yes, but CICP is payer of last resort. Can only reimburse or pay for those things not covered by other third-party payers, such as Worker's Compensation.
Compensatory Damages	<ul style="list-style-type: none"> • Past and Future non-reimbursable medical, custodial care, and rehabilitation costs • Up to \$250,000 for actual and projected pain and suffering • Lost Earnings • For a death, up to \$250,000 as a death benefit 	<ul style="list-style-type: none"> • Unreimbursed Medical Expenses • Lost Employment Income • Survivor Death Benefit
Attorneys' Fees	Are available	Not Available
Is COVID-19 Vaccine Covered?	No	Yes

Marketing/Communications Activity Plan

Interim
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OVERVIEW AND ESTIMATE

Thank you for the opportunity to propose an activity plan for the 2020-2021 COVID vaccination campaign for the Missouri Department of Health and Senior Services (DHSS). As we understand it, the overarching goal of this campaign is to encourage Missourians to get the COVID-19 vaccination with 3 primary objects that align with the national CDC strategies.

- Protect Communities
- Empower Families
- Stop Myths
 - Highlight vaccine safety and privacy
 - Address the differences in FDA emergency use and approval

We will help achieve this goal by increasing awareness and educating key audiences on not only the benefits of the forthcoming vaccine, but the phased rollout MO is employing. In addition to the identified targeted populations, urban/minorities and rural/underserved populations will also be primary recipients for messaging

This campaign will have three phases, each with slightly different goals and targets.

BEFORE

- Timing
 - As soon as possible up to the beginning of Phase I
- Target:
 - Missourians across the state including:
 - Healthcare personnel (i.e., organizations and clinicians who will receive information about receiving and administering vaccine)
 - Health insurance issuers and plans (coverage for vaccine, in-network providers)
 - Employers
 - Government and community partners and stakeholders
 - Public/consumers
- Goal:
 - Building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation, are critical to ensure vaccine uptake.
- Messaging:
 - Communicate the safety of vaccines in general and have easily accessible, government information to address myths, questions, and concerns.
 - Keep the public, public health partners, and healthcare providers well-informed about COVID-19 vaccine(s) development, recommendations, and public health's efforts.
- Budget allocation:
 - 20% of total

PHASE 1



- Timing:
 - Vaccine availability + 90 days (estimated Oct / Nov 20 through Dec 20)
- Target:
 - Group A - Skilled Nursing Facility Staff: Concentrating on the skilled nursing facility (SNF) staff
 - Group B - Inpatient Healthcare Personnel 18-65 years of age with underlying health conditions.
- Goal:
 - Vaccinate 50,600 SNF workers and 60,000 healthcare personnel
 - Executive Intent/Sub-focus:
 - Reduce mortality and morbidity of COVID-19 within the State of Missouri, and to provide relief to critically stressed healthcare and community resources.
- Messaging:
 - To include information regarding the standard health and safety practices as it relates to COVID (i.e. mask wearing, 6 ft of distance, hand washing, etc.).
- Budget allocation:
 - 30% of total

PHASE 2

- Timing:
 - Approximately 90-180 days (after vaccine availability)
- Target:
 - Group C - Essential workers 18-55 years of age with underlying health conditions
 - Additional groups to focus on are African American/Minority Adults with lower social economic factors as these individuals are associated with higher mortality.
- Goal:
 - Vaccinate 24,400 people
 - Executive Intent/Sub-focus:
 - Protect those citizens engaged in supporting critical infrastructure or economic re-opening within the State of Missouri.
- Key Messages:
 - Promote the safety of the vaccine and the importance of being vaccinated so that Missouri can continue to reopen safely. In addition, messaging to include information regarding the standard health and safety practices as it relates to COVID (i.e. mask wearing, 6 ft of distance, hand washing, etc.).
- Budget allocation:
 - 30% of total

PHASE 3

- Timing:
 - 181 days and beyond
- Target:



- General populace
- Goal:
 - Gain herd immunity
 - Executive Intent/Sub-focus:
 - Provide widespread vaccine availability to Missouri citizens, with particular emphasis on those at high-risk from COVID-19 infections.
- Messaging:
 - Exact messaging is TBD, but will include educational information as well as accepted health guidelines.
- Budget allocation:
 - 20% of total

In order to accomplish these goals, we recommend the following scope:

MESSAGING AND CREATIVE CAMPAIGN CONCEPTING

- Develop 3 creative concepts to drive awareness throughout the campaign. Concepts will be flexible enough to speak to audiences as the campaign proceeds into the subsequent phases.

MEDIA PLAN AND RESEARCH

- Using third party research and marketplace intelligence, we will develop a paid media plan to reach the intended audience in an impactful manner. In order to use the budget most efficiently, we will pull research for a more general audience of Missourians along with key influencers and will make recommendations that are able to reach and best connect with urban, rural and culturally different audiences as much as possible.

MEDIA BUYING AND REPORTING

- Purchase of media, tracking and verification, media optimizations as needed, and monthly reporting

CREATIVE EXECUTION

- Development of various creative assets and copy to be used in traditional/non-traditional ad placements. Creative assets will be determined by the proposed media plan.
- Resize ads used in the campaign for use in a toolkit that can be used by partner organizations for use on social media, posters/flyers and insert-style handouts.
- Educational materials
 - this material will be used by DHSS to form training videos to ensure consistent messaging and training across the state



- An additional fact sheet/brochure will be produced that will target underserved/minority populations and be easily understood by those individuals with a low literacy level.

WEBSITE DESIGN

- Elasticity to design two homepage options and one option for an estimated five subpages. Each provided design will have one round of edits. All development to be handled by ITSD.

MIX OF ACTIVITIES

Elasticity will utilize the following activities in support of the campaign:

Media Strategy/Planning/Buying — The media planning team will determine the appropriate budget level, media usage and technology habits to provide a strategic media plan recommendation. The media buying team will negotiate and place the chosen media on behalf of DHSS.

Media Tracking and Verification — The media team will track, verify and regularly optimize all media placed on behalf of DHSS.

Media Reporting — The media team will compile campaign performance data to be shared with DHSS.

Account Management — A main point of contact will be provided to manage the delivery and scheduling of action items in addition to the feedback from the initial kickoff meeting up to the final post-project meeting.

Creative Direction — The creative director will work with DHSS to gain a firm understanding of the project's parameters and overall goals, which will then be communicated to the rest of the Elasticity team.

Art Direction — The art director will work with the creative director to ensure the visual style of all creative matches the campaign style.

Design — The graphic design team will create any on-screen graphics, title cards or text treatments needed for video production and provide them to the post-production team. They will also develop any creative assets necessary to fulfill the media plan.

Copywriting — The copywriter will work with the creative director to write copy that follows the messaging, tone and overarching brand style of DHSS and the campaign.

Proofreading — The copy editor will review copy for tone of voice, style, length and clarity



Production Management/Traffic — The production manager will work with the creative director to arrange talent, manage schedules, oversee budget and general coordination, as needed, to complete the video project.

Art Direction and Production — The art director will work with the director of photography to ensure the visual style of all photography matches the campaign style.

Photo Direction/Production — The director of photography and the crew will capture still photography to support the video campaign.

Audio/Video Direction/Production — Our director of photography will work with the graphics production and post-production team to edit and animate videos to match the agreed upon concept for the overall campaign. A sound designer will edit the audio and video as well as music overlay to bring the story to life.

Graphics Production — The graphics producer will create illustrations and animate graphics for video production.

Multimedia Design — The multimedia designer will work with the client to design all elements required for the website.

APPROACH

Generally, the following steps will be followed through the project cycle, with the deliverables for each step. (Durations are best-guess estimates based on experience with projects of similar scope.)

MEDIA PLAN DEVELOPMENT AND RESEARCH

Description: The media team will pull third party research and media inventory availability to determine the appropriate budget level, media usage and technology habits to provide a strategic media plan recommendation. Both traditional and non-traditional media will be considered including, but not limited to airport signage, billboards, buses, social, search, etc.

Deliverables:

- Elasticity will deliver a strategic media plan that outlines the recommended media placements, budget level and flighting of all media activity based on the media usage and technology habits of the target audience. Creative specifications and anticipated deadlines will also be provided at this time.

CREATIVE CAMPAIGN CONCEPTING

Description: Creative concepts will be presented as mood boards that are inclusive of theme, “write-up” to convey the idea, visual direction, color palette, etc.



Deliverables:

- Elasticity to develop key message points for DHSS, for each phase, that will serve as a guide to ensure that the voice, tone and key messages remain consistent across all communications materials/channels.
 - Elasticity will make sure to have tailored messaging specifically for the vaccine hesitant group and will have questions included in the concept testing survey for research to ensure that our messages and creative is addressing their concerns surrounding a 'rushed' vaccine.
- Elasticity to develop and present visual creative concepts to drive the audience to follow health and safety guidelines (i.e. wearing a mask, washing hands frequently, staying 6ft apart from others, staying home if feeling sick, etc.) and educate them regarding MO's roll out plan to targeted groups and the two step vaccine process, ensuring that the vaccine is safe and encourage them in getting the vaccine.

CREATIVE FULFILLMENT

Description: Elasticity will develop various creative assets and copy, to be used in digital/traditional ad placements, print collateral, etc. Creative assets will further be determined by the proposed media plan.

Deliverables:

- Various creative assets and copy to be used in digital/traditional ad placements. Creative assets will be determined by the proposed media plan.
- An educational video (length TBD) that will explain how vaccines are tested and how they help to fight off viruses in your system.
- Resize ads used in the campaign for use in a toolkit that can be used for distribution internally and partner organizations for use on social media, posters/flyers, e-newsletters, and insert-style handouts.
- Educational materials (this material will be used by DHSS to form training videos to ensure consistent messaging and training across the state)
 - Elasticity to provide assistance to DHSS to ensure consistent messaging across all materials related to the campaign such as drafting and/or reviewing scripts and official materials to match messaging.
 - A general toolkit with materials in a variety of sizes that partner organizations can use (most likely additional social media graphics/copy, posters (8.5x11, 8.5x14, 11x17 mainly), insert size (half page), etc.)
 - A fact sheet/brochure specifically for underserved/minority populations with a low literacy level.



WEBSITE DESIGN

Description: Elasticity to design two homepage options and one option for an estimated five subpages. Each provided design will have one round of edits. All development to be handled by ITSD.

Deliverables:

- Elasticity to provide two versions of the homepage for consideration. Following a call with the client, each design to receive one round of edits per provided direction. Client to select between one of the two edited options. High-res artwork will be provided of the approved design for development by ITSD.
- Following homepage approval, Elasticity to provide one version of up to five TBD subpages for consideration. Following a call with the client, each design to receive one round of edits. Client to approve following the edits. High-res artwork will be provided of the approved design for development by ITSD.

MEDIA BUYING AND REPORTING

Description: Upon client approval of the recommended media plan, the Elasticity media team will purchase all media as recommended in the media plan.

The media buy should accomplish the following key goals in order to be deemed a success:

- Reach the intended target audience in an impactful manner.
- Purchase of advertising placements per the approved recommendations of the media plan.
- Delivery of creative to media vendors per required specifications.

Deliverables:

- Elasticity will deliver a monthly paid media report that will measure the success of the media campaign.
- Elasticity will provide monthly proof of placement for each element of the media buy.

TIMELINE

MEDIA PLAN DEVELOPMENT

- Elasticity to deliver the paid media plan within 2-3 weeks of the approval of the project and budget.
- DHSS to provide feedback and final approval within 1 week of media plan submission.

MESSAGING AND CAMPAIGN CONCEPT DEVELOPMENT

- Elasticity to deliver key message points and creative concepts within 2-3 weeks of the approval of the project and budget.
- DHSS to provide feedback and approval within 1 week of messaging and concept presentation.



WEBSITE DESIGN

**Exact timeline for deliverables to be determined based on when Elasticity receives the site map and how many pages it entails. Below ranges subject to change based on the required number of subpages.*

- Elasticity will deliver a wireframe of the proposed homepage within 2 business days of receiving the final, approved site map from DHSS.
- Elasticity will deliver a design of the proposed homepage within one week of receiving homepage wireframe approval.
- Elasticity will deliver a wireframe of all subpages needed within 2 business days of receiving final approval for the homepage design.
- Elasticity will deliver subpage designs within one week of receiving subpage wireframe approval. Every attempt will be made to deliver as quickly as possible.

CREATIVE FULFILLMENT

- Elasticity will deliver a recommendation for creative fulfillment within 2 weeks of receiving final approval from DHSS on all of the following: campaign concepts, key messages, and media plan.
- Exact timeline for deliverables to be determined by the media plan and upon approval by DHSS of recommended creative fulfillment.

MEDIA BUYING AND REPORTING

- The media team will purchase all media according to the approved media plan specifications within 2 weeks of media plan approval.
- Elasticity to deliver the paid media report monthly within 2 weeks of the end of each month the campaign runs.

MEASUREMENT OF RESULTS

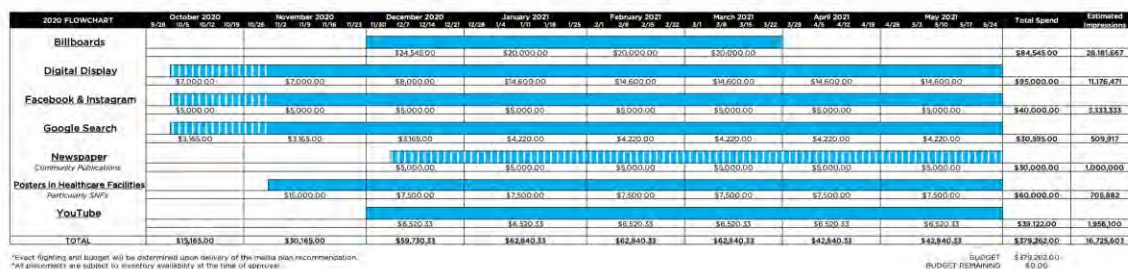
Exact measurement expectations and goals will be determined as part of the media plan.

Evaluation Measures: Could include indicators such as impressions, clicks or website page views attributed to paid media activity.

Measurement of Success 16.7 Million Impressions

MEDIA FLOWCHART

The following flowchart represents the budget and flighting recommended by placement as well as estimated total impressions by placement. Please note that these are subject to change when finalizing the media plan for client approval.



Our recommendation is to focus on placements that will help us drive significant reach and trust among our intended target audiences and the general public of Missouri to build faith in the vaccine.

For Digital Display and Facebook/Instagram placements, we will build target audience parameters designed to directly engage with the intended targets of each intended group, leveraging location-based and behavioral targeting. We will also work with DHSS to determine priorities based on identified outbreaks so that we can easily shift our marketing dollars towards those locations/regions throughout the lifetime of the campaign.

Billboards will be used to drive significant reach and can be placed in regions that are more likely to have Skilled Nursing Facilities or lower income communities while also having the potential to reach a wider audience passing through the area.

Google Search will be used primarily to drive people to the website to learn more as they are searching for more information about the vaccine and its availability.

We are recommending the purchase of community newspapers in St. Louis and Kansas City to directly reach out and build trust in the vaccine with the African American communities of each region.

The Posters in Healthcare Facilities will be primarily distributed and posted in more crowded staff areas, mostly within Skilled Nursing Facilities. Assets created could also be used for internal distribution.

YouTube placements will be non-skippable videos targeted to individuals looking for COVID-19 related news and information, and broader news viewing category.



PROPOSED BUDGET

The following budget is the projected cost to fulfill the above recommendations through June 30, 2021.

Task	Billable Rate	Total Hours	Total Budget
4.1 MEDIA PLANNING AND PLACEMENT/PUCHASE			
Media Budget	Net Media + 5.5% Commission		\$379,262
Media Strategy/Planning/Buying	\$125.00	50	\$6,250
Media Tracking and Verification	\$90.00	238	\$21,420
Media Reporting	\$90.00	56	\$5,040
4.2 Creative Services			
Account Management	\$135.00	100	\$13,500
Account Coordination	\$80.00	80	\$6,400
Creative Direction	\$150.00	70	\$10,500
Art Direction	\$135.00	25	\$3,375
Design	\$120.00	225	\$27,000
Copywriting	\$90.00	165	\$14,850
Proofreading	\$70.00	50	\$3,500
4.3 Media Production			
Production Management/Traffic	\$90.00	25	\$2,250
Art Direction and Production	\$135.00	38	\$5,130
Photo Direction/Production	\$150.00	28	\$4,200
Audio/Video Direction & Production	\$150.00	260	\$39,000
Graphics Production	\$80.00	36	\$2,880
Photo/B-roll Research	\$70.00	10	\$700
OOP Costs (Hard Drive to deliver all creative assets to DHSS)	\$250.00	1	\$250
OOP Costs: Translation Services (Spanish)	\$500.00	6	\$3,000
OOP Costs (Voiceover talent - Web license)	\$600.00	6	\$3,600
OOP Costs (Music beds - Web license)	\$50.00	6	\$300
4.4 Non-Traditional Media & High-Tech Marketing			
Multimedia Design	\$120.00	85	\$10,200
Search Marketing Direction	\$140.00	30	\$4,200
Search Marketing Analysis/Coordination	\$110.00	180	\$19,800
Social Media Direction/Strategy	\$150.00	10	\$1,500



ACTIVITY PLAN

Missouri Department of Health and Senior Services
COVID Vaccination Campaign

Social Media/Brand Conversation Monitoring, Customer Care, Outreach	\$80.00	96	\$7,680
OOP Costs: Netbase Licensing Fee (Social Listening Tool)	NA		\$4,200
TOTAL BUDGET			\$599,987

APPROVALS

DHSS

By: _____

Name: _____

Title: _____

Date: _____

ELASTICITY

By: _____

Name: _____

Title: _____

Date: _____

PPE Requirements for Vaccinators

Interim
Draft

Implement Universal Source Control Measures

Source control refers to use of [cloth face coverings](#) or facemasks to cover a person's mouth and nose to prevent spread of respiratory secretions when they are talking, sneezing, or coughing. Because of the potential for asymptomatic and pre-symptomatic transmission, source control measures are recommended for everyone in a healthcare facility, even if they do not have symptoms of COVID-19.

- Patients and visitors should, ideally, wear their own cloth face covering (if tolerated) upon arrival to and throughout their stay in the facility. If they do not have a face covering, they should be offered a facemask or cloth face covering, as supplies allow.
 - Patients may remove their cloth face covering when in their rooms but should put it back on when around others (e.g., when visitors enter their room) or leaving their room.
 - Facemasks and cloth face coverings should not be placed on young children under age 2, anyone who has trouble breathing, or anyone who is unconscious, incapacitated or otherwise unable to remove the mask without assistance.
- HCP should wear a facemask at all times while they are in the healthcare facility, **including in breakrooms or other spaces where they might encounter co-workers**.
 - When available, facemasks are preferred over cloth face coverings for HCP as facemasks offer both source control and protection for the wearer against exposure to splashes and sprays of infectious material from others.
 - Cloth face coverings should NOT be worn instead of a respirator or facemask if more than source control is needed.
 - To reduce the number of times HCP must touch their face and potential risk for self-contamination, HCP should consider continuing to wear the same respirator or facemask ([extended use](#)) throughout their entire work shift, instead of intermittently switching back to their cloth face covering.
 - Respirators with an exhalation valve are not recommended for source control, as they allow unfiltered exhaled breath to escape.
 - HCP should remove their respirator or facemask, perform hand hygiene, and put on their cloth face covering when leaving the facility at the end of their shift.
- Educate patients, visitors, and HCP about the importance of performing hand hygiene immediately before and after any contact with their facemask or cloth face covering.

Encourage Physical Distancing

Healthcare delivery requires close physical contact between patients and HCP. However, when possible, physical distancing (maintaining 6 feet between people) is an important strategy to prevent SARS-CoV-2 transmission.

Examples of how physical distancing can be implemented for patients include:

- Limiting visitors to the facility to those essential for the patient's physical or emotional well-being and care (e.g., care partner, parent).
 - Encourage use of alternative mechanisms for patient and visitor interactions such as video-call applications on cell phones or tablets.
- Scheduling appointments to limit the number of patients in waiting rooms.

- Arranging seating in waiting rooms so patients can sit at least 6 feet apart.
- Modifying in-person group healthcare activities (e.g., group therapy, recreational activities) by implementing virtual methods (e.g., video format for group therapy) or scheduling smaller in-person group sessions while having patients sit at least 6 feet apart.
 - In some circumstances, such as higher levels of community transmission or numbers of patients with COVID-19 being cared for at the facility, and when healthcare-associated transmission is occurring, facilities might cancel in-person group activities in favor of an exclusively virtual format.

For HCP, the potential for exposure to SARS-CoV-2 is not limited to direct patient care interactions. Transmission can also occur through unprotected exposures to asymptomatic or pre-symptomatic co-workers in breakrooms or co-workers or visitors in other common areas. Examples of how physical distancing can be implemented for HCP include:

- Reminding HCP that the potential for exposure to SARS-CoV-2 is not limited to direct patient care interactions.
- Emphasizing the importance of source control and physical distancing in non-patient care areas.
- Providing family meeting areas where all individuals (e.g., visitors, HCP) can remain at least 6 feet apart from each other.
- Designating areas for HCP to take breaks, eat, and drink that allow them to remain at least 6 feet apart from each other, especially when they must be unmasked.
- **HCP working in facilities located in areas with moderate to substantial community transmission** are more likely to encounter asymptomatic or pre-symptomatic patients with SARS-CoV-2 infection. If SARS-CoV-2 infection is not suspected in a patient presenting for care (based on symptom and exposure history), HCP should follow [Standard Precautions](#) (and [Transmission-Based Precautions](#) if required based on the suspected diagnosis). They should also:
 - Wear eye protection in addition to their facemask to ensure the eyes, nose, and mouth are all protected from exposure to respiratory secretions during patient care encounters.
 - Wear an N95 or equivalent or higher-level respirator, instead of a facemask, for:
 - Aerosol generating procedures (refer to [Which procedures are considered aerosol generating procedures in healthcare settings FAQ](#)) and
 - Surgical procedures that might pose higher risk for transmission if the patient has COVID-19 (e.g., that generate potentially infectious aerosols or involving anatomic regions where viral loads might be higher, such as the nose and throat, oropharynx, respiratory tract) (refer to [Surgical FAQ](#)).
 - Respirators with exhalation valves are not recommended for source control and should not be used during surgical procedures as unfiltered exhaled breath would compromise the sterile field.
- **For HCP working in areas with minimal to no community transmission**, HCP should continue to adhere to [Standard](#) and [Transmission-Based Precautions](#), including use of eye protection and/or an N95 or equivalent or higher-level respirator based on anticipated exposures and suspected or confirmed diagnoses. Universal use of a facemask for source control is recommended for HCP.

Vaccine Administration Skills Checklist

Interim
Draft

Skills Checklist for Vaccine Administration

During the COVID-19 pandemic, the CDC recommends additional infection control measures for vaccination (see www.cdc.gov/vaccines/pandemic-guidance/index.html).

The Skills Checklist is a self-assessment tool for healthcare staff who administer immunizations. To complete it, review the competency areas below and the clinical skills, techniques and procedures outlined for each area. Score yourself in the Self-Assessment column. If you check **Needs to Improve**, you indicate further study, practice, or change is needed. When you check **Meets or Exceeds**, you indicate you believe you are performing at the expected level of competence, or higher.

Supervisors: Use the Skills Checklist to clarify responsibilities and expectations for staff who administer vaccines. When you use it to assist with performance reviews, give staff the opportunity to score themselves in advance. Next, observe their performance as they

administer vaccines to several patients, and score in the Supervisor Review columns. If improvement is needed, meet with them to develop a Plan of Action (see bottom of page 3) to help them achieve the level of competence you expect; circle desired actions or write in others.

The DVD “Immunization Techniques: Best Practices with Infants, Children, and Adults” helps ensure that staff administer vaccines correctly. It may be ordered online at www.immunize.org/dvd. Another helpful resource is CDC’s Vaccine Administration eLearn course, available at www.cdc.gov/vaccines/hcp/admin/resource-library.html.

competency	clinical skills, techniques, and procedures	Self-Assessment		Supervisor Review		
		needs to improve	meets or exceeds	needs to improve	meets or exceeds	plan of action
Patient/Parent Education	1. Welcomes patient/family and establishes rapport.					
	2. Explains what vaccines will be given and which type(s) of injection(s) will be done.					
	3. Answers questions and accommodates language or literacy barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure.					
	4. Verifies patient/parents received Vaccine Information Statements (VISs) for indicated vaccines and has had time to read them and ask questions.					
	5. Screens for contraindications (if within employee’s scope of work).					
	6. Reviews comfort measures and aftercare instructions with patient/parents, and invites questions.					
Medical and Office Protocols	1. Identifies the location of the medical protocols (e.g., immunization protocol, emergency protocol, reference material).					
	2. Identifies the location of epinephrine, its administration technique, and clinical situations where its use would be indicated.					
	3. Maintains up-to-date CPR certification.					
	4. Understands the need to report any needlestick injury and to maintain a sharps injury log.					
	5. Demonstrates knowledge of proper vaccine handling, e.g., maintains vaccine at recommended temperature and protects MMR from light.					

continued on the next page ♦

Adapted from California Department of Public Health, Immunization Branch

competency	clinical skills, techniques, and procedures	Self-Assessment		Supervisor Review		
		needs to improve	meets or exceeds	needs to improve	meets or exceeds	plan of action
Vaccine Preparation	1. Performs proper hand hygiene prior to preparing vaccine.					
	2. When removing vaccine from the refrigerator or freezer, looks at the storage unit's temperature to make sure it is in proper range.					
	3. Checks vial expiration date. Double-checks vial label and contents prior to drawing up.					
	4. Prepares and draws up vaccines in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed.					
	5. Selects the correct needle size for IM and Subcut based on patient age and/or weight, site, and recommended injection technique.					
	6. Maintains aseptic technique throughout, including cleaning the rubber septum (stopper) of the vial with alcohol prior to piercing it.					
	7. Shakes vaccine vial and/or reconstitutes and mixes using the diluent supplied. Inverts vial and draws up correct dose of vaccine. Rechecks vial label.					
	8. Prepares a new sterile syringe and sterile needle for each injection. Checks the expiration date on the equipment (syringes and needles) if present.					
	9. Labels each filled syringe or uses labeled tray to keep them identified.					
Administering Immunizations	1. Rechecks the provider's order or instructions against the vial and the prepared syringes.					
	2. Utilizes proper hand hygiene with every patient and, if it is office policy, puts on disposable gloves. (If using gloves, changes gloves for every patient.)					
	3. Demonstrates knowledge of the appropriate route for each vaccine.					
	4. Positions patient and/or restrains the child with parent's help.					
	5. Correctly identifies the injection site (e.g., deltoid, vastus lateralis, fatty tissue over triceps).					
	6. Locates anatomic landmarks specific for IM or Subcut injections.					
	7. Prepares the site with an alcohol wipe, using a circular motion from the center to a 2" to 3" circle. Allows alcohol to dry.					

continued on the next page ♦

competency	clinical skills, techniques, and procedures	Self-Assessment		Supervisor Review		
		needs to improve	meets or exceeds	needs to improve	meets or exceeds	plan of action
Administering Immunizations (continued)	8. Controls the limb with the non-dominant hand; holds the needle an inch from the skin and inserts it quickly at the appropriate angle (90° for IM or 45° for Subcut).					
	9. Injects vaccine using steady pressure; withdraws needle at angle of insertion.					
	10. Applies gentle pressure to injection site for several seconds (using, e.g., gauze pad, bandaid).					
	11. Uses strategies to reduce anxiety and pain associated with injections.					
	12. Properly disposes of needle and syringe in “sharps” container.					
	13. Properly disposes of vaccine vials.					
Records Procedures	1. Fully documents each vaccination in patient chart: date, lot number, manufacturer, site, VIS date, name/initials.					
	2. If applicable, demonstrates ability to use state/local immunization registry or computer to call up patient record, assess what is due today, and update computerized immunization history.					
	3. Asks for and updates patient’s vaccination record and reminds them to bring it to each visit.					

Plan of Action

Circle desired next steps and write in the agreed deadline for completion, as well as date for the follow-up performance review.

- | | |
|--|--|
| <ul style="list-style-type: none"> a. Watch video on immunization techniques and review CDC’s Vaccine Administration eLearn, available at www.cdc.gov/vaccines/hcp/admin/resource-library.html. b. Review office protocols. c. Review manuals, textbooks, wall charts, or other guides. d. Review package inserts. e. Review vaccine storage and handling guide-lines or video. f. Observe other staff with patients. g. Practice injections. | <ul style="list-style-type: none"> h. Read Vaccine Information Statements. i. Be mentored by someone who has demonstrated appropriate immunization skills. j. Role play (with other staff) interactions with parents and patients, including age appropriate comfort measures. k. Attend a skills training or other appropriate courses/training. l. Attend healthcare customer satisfaction or cultural competency training. m. Renew CPR certification. Other _____ |
|--|--|

File the Skills Checklist in the employee’s personnel folder.

plan of action deadline _____

date of next performance review _____

employee signature date

supervisor signature date

Best Practices for Satellite, Temporary, and Off-Site Clinics

Interim
Draft




CHECKLIST of

Best Practices FOR Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

OVERVIEW OF THIS DOCUMENT

This checklist is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. It should be used in any non-traditional vaccination clinic setting, including but not limited to: workplaces, community centers, schools, makeshift clinics in remote areas, and even medical facilities when vaccination occurs in the public areas or classrooms. Temporary clinics also include mass vaccination events, and vaccination clinics held during pandemic preparedness exercises. This checklist outlines CDC guidelines and best practices that are essential for patient safety and vaccine effectiveness. **A clinic coordinator/supervisor at the site should complete, sign, and date this checklist EACH TIME a vaccination clinic is held.** To meet accountability and quality assurance standards, all signed checklists should be kept on file by the company that provided clinic staffing.

INSTRUCTIONS

1. A staff member who will be at the vaccination clinic should be designated as the clinic coordinator/supervisor. (This individual will be responsible for completing the steps below and will be referred to as "you" in these instructions.)
2. Review this checklist during the planning stage of the vaccination clinic—well in advance of the date(s) when the clinic will be held. This checklist includes sections to be completed before, during, and after the clinic.
3. **Critical guidelines for patient safety and vaccine effectiveness are identified by the stop sign icon: . If you check "NO" in ONE OR MORE answer boxes that contain a , DO NOT move forward with the clinic. Follow your organization's protocols and/or contact your state or local health department for guidance BEFORE proceeding with the clinic. Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.**
4. Contact your organization and/or health department if you have any concerns about whether vaccine was transported, stored, handled, or administered correctly, concerns about whether patients' personal information was protected appropriately, or concerns about other responses that you have marked as "NO" on rows that do not have the .
5. This checklist should be used in conjunction with CDC's Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. For information about specific vaccines, consult the vaccine manufacturer's package insert.
6. **This checklist applies ONLY to vaccines stored at REFRIGERATED temperatures** (i.e., between 2–8° Celsius or 36–46° Fahrenheit).
7. Sign and date the checklist upon completion of the clinic or completion of your shift (whichever comes first). *(If more than one clinic coordinator/supervisor is responsible for different aspects of the clinic, you should complete only the section(s) for which you were responsible.)*
8. Attach the staff sign-in sheet (with shift times and date) to the checklist (or checklists if more than one clinic supervisor is overseeing different shifts), and submit the checklist(s) to your organization to be kept on file for accountability.

Name and credentials of clinic coordinator/supervisor:

Name of facility where clinic was held:

Address where clinic was held (street, city, state):

Time and date of vaccination clinic shift (the portion you oversaw):

Time (AM/PM)

Date (MM/DD/YYYY)

Time and date when form was completed:

Time (AM/PM)

Date (MM/DD/YYYY)

Signature of clinic coordinator/supervisor:



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

BEFORE THE CLINIC (Please complete each item before the clinic starts.)**VACCINE SHIPMENT**

YES NO N.A.

☐ ☐ ☐ Vaccine was shipped directly to the facility/clinic site, where adequate storage is available. (*Direct shipment is preferred for cold chain integrity.*)

VACCINE TRANSPORT (IF IT WAS NOT POSSIBLE TO SHIP VACCINES DIRECTLY TO THE FACILITY/CLINIC SITE)

YES NO N.A.

☐ ☐ ☐ Vaccines were transported using a portable vaccine refrigerator or qualified container and pack-out designed to transport vaccines within the temperature range recommended by the manufacturers (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines).
Coolers available at general merchandise stores or coolers used to transport food are NOT ACCEPTABLE. See CDC's Vaccine Storage and Handling Toolkit for information on qualified containers and pack-outs: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

☐ ☐ ☐ The person transporting the vaccines confirmed that manufacturer instructions for packing configuration and proper conditioning of coolants were followed. (*Your qualified container and pack-out should include packing instructions. If not, contact the company for instructions on proper packing procedures.*)

☐ ☐ ☐ The person transporting the vaccines confirmed that all vaccines were transported in the passenger compartment of the vehicle (NOT in the vehicle trunk).

☐ ☐ ☐ A digital data logger with a buffered probe and a current and valid Certificate of Calibration Testing was placed directly with the vaccines and used to monitor vaccine temperature during transport.

☐ ☐ ☐ The amount of vaccine transported was limited to the amount needed for the workday.

VACCINE STORAGE AND HANDLING (UPON ARRIVAL AT FACILITY/CLINIC)

YES NO N.A.

☐ ☐ ☐ If vaccines were shipped, the shipment arrived within the appropriate time frame (according to manufacturer or distributor guidelines) and in good condition.

☐ ☐ ☐ If the vaccine shipment contained a cold chain monitor (CCM), it was checked upon arrival at the facility/clinic, and there was no indication of a temperature excursion (i.e., out-of-range temperature) during transit. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer). *Note: CCMs are for one-time use and should be thrown away after being checked.*

☐ ☐ ☐ Upon arrival at the facility/clinic (either by shipment or transport), vaccines were immediately unpacked and placed in proper storage equipment (i.e., a portable vaccine refrigerator or qualified container and pack-out specifically designed and tested to maintain the manufacturer-recommended temperature range). *Follow the guidance for unpacking and storing vaccines specified in CDC's Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.*

☐ ☐ ☐ Upon arrival at the facility/clinic, vaccines were still within the manufacturer-recommended temperature range (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines).

☐ ☐ ☐ Upon arrival at the facility/clinic, vaccines remained protected from light (per manufacturer's package insert) until ready for use at the vaccination clinic.

☐ ☐ ☐ Upon arrival at the facility/clinic, expiration dates of vaccines and any medical equipment (syringes, needles, alcohol wipes) being used were checked, and they had not expired.

CLINIC PREPARATION AND SUPPLIES

YES NO N.A.

☐ ☐ ☐ A contingency plan is in place in case vaccines need to be replaced. The plan addresses scenarios for vaccine compromised before arrival at the clinic and for vaccine compromised during clinic hours.

☐ ☐ ☐ An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of the clinic.


☐ ☐ ☐ All vaccination providers at the site are certified in cardiopulmonary resuscitation (CPR), are familiar with the signs and symptoms of anaphylaxis, know their role in the event of an emergency, and know the location of epinephrine and are trained in its indications and use.

☐ ☐ ☐ There is a designated area at the site for management of patients with urgent medical problems (e.g., fainting).

☐ ☐ ☐ Adequate infection control supplies are provided, including biohazard containers and supplies for hand hygiene. If administering injectable vaccines, adhesive bandages, individually packaged sterile alcohol wipes, and a sufficient number of sterile needles, syringes, and a sharps container are provided.

☐ ☐ ☐ Needles in a variety of lengths are available to optimize injection based on the prescribed route/technique and patient size.

☐ ☐ ☐ Reasonable accommodations (e.g., privacy screens) are available for patient privacy during vaccination.

» If you check "NO" in ONE OR MORE answer boxes that contain a  **DO NOT move forward with the clinic.**

- Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.
- Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	N	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff members administering vaccines have reviewed vaccine manufacturer instructions for administration before the vaccination clinic.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If using a standing order protocol, the protocol is current and available at the clinic/facility site.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A sufficient number of screening forms are available at the clinic/facility site.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A sufficient number of vaccine information statements (VISs) for each vaccine being offered are available at the clinic/facility site.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A designated clean area for vaccine preparation has been identified and set up prior to the clinic.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A qualified individual has been designated to oversee infection control at the clinic.

DURING THE CLINIC (Please complete each item while the clinic is occurring and review at the end of your shift.)

VACCINE STORAGE AND HANDLING (AT FACILITY/CLINIC)


YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being kept in proper storage equipment that maintains the manufacturer-recommended temperature range (i.e., a portable vaccine refrigerator or qualified container and pack-out specifically designed and tested to maintain correct temperatures when opened and closed during the clinic).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccine temperature is being monitored during the clinic using a digital temperature data logger with a buffered probe (placed directly with vaccines) and a current and valid Certificate of Calibration Testing. <i>Follow the temperature monitoring guidance specified in CDC's Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If vaccines are being stored in a storage unit at the site, vaccine temperature data are being reviewed and documented a minimum of 2 times during each clinic workday (preferably at the beginning and middle of an 8-hour shift) to ensure they remain at correct temperatures (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines). <i>If you are a VFC provider, check with your state immunization program for specific requirements for vaccine temperature monitoring during mass vaccination clinics.</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If vaccines cannot be stored in a storage unit at the site, they are being kept in the portable vaccine refrigerator or qualified pack-out with a temperature monitoring device (with a probe in a thermal buffer) placed as closely as possible to the vaccines, and temperatures are being read and recorded at least once an hour. The container is being kept closed as much as possible.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being protected from light during the vaccination clinic per the manufacturer's package insert.

VACCINE PREPARATION

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Expiration dates of vaccines (and diluents, if applicable) are being checked again during preparation, and only vaccines that have not expired are being administered. <i>(Of note: If you are using multidose vials, be sure to review beyond use dates, along with expiration dates.)</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being prepared in a clean, designated medication area, away from any potentially contaminated items.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If using reconstituted vaccines, they are being prepared according to the manufacturer's guidelines.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being prepared at the time of administration.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If vaccines are predrawn from a multidose vial, only the contents of 1 multidose vial are being drawn up at one time by each staff member administering vaccines (the maximum number of doses per vial is described in the package insert).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If using single-dose or multidose vials, syringes are being labeled with the name of the vaccine.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Once drawn up, vaccines are being kept in the recommended temperature range. <i>(Questions about specific time limits for being out of the recommended temperature range should be referred to the manufacturer.)</i>

VACCINE ADMINISTRATION

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccine information statements (VISs) are being provided to every patient, parent, or guardian before vaccination (as required by federal law).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All patients are being screened for contraindications and precautions for the specific vaccine(s) in use before receiving that vaccine(s).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is using proper hygiene techniques to clean hands before vaccine administration, between patients, and anytime hands become soiled. www.cdc.gov/handhygiene/providers/index.html


» If you check "NO" in ONE OR MORE answer boxes that contain a , **DO NOT move forward with the clinic.**

- Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.
- Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	N	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If gloves are being worn by staff administering vaccines, they are being changed and hands are being cleaned using proper hygiene techniques between each patient.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is triple-checking labels, contents, and expiration dates or beyond use dates (as noted in the manufacturer's package insert, if applicable) before administering vaccine.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are normal in appearance (i.e., not discolored, without precipitate, and easily resuspended when shaken).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Each staff member is administering only the vaccines they have prepared.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If more than one vaccine type is being administered, separate preparation stations are set up for each vaccine type to prevent medication errors.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being administered using aseptic technique.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is administering vaccine to the correct patient (e.g., if a parent/guardian and child or two siblings are at the vaccination station at the same time, patient's name and date of birth are verified prior to vaccination).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is administering vaccines using the correct route per manufacturer instructions.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is administering the correct dosage (volume) of vaccine.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff has checked age indications for the vaccines and is administering vaccines to the correct age groups.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	For vaccines requiring more than 1 dose, staff is administering the current dose at the correct interval, if applicable. <i>Follow the recommended guidelines in Table 3-1 of the "General Best Practice Guidelines on Immunization": www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html#t-01.</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If vaccine administration errors are observed, corrective action is being taken immediately.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any persons with a needlestick injury, a vaccine administration error, or an urgent medical problem are being evaluated immediately and referred for additional medical care if needed.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Patients are being encouraged to stay at the clinic for 15 minutes after vaccination to be monitored for adverse events.

ADMINISTRATION OF INJECTABLE VACCINES (In this section, N.A. is ONLY an option if the clinic is EXCLUSIVELY using non-injectable vaccines, such as live, attenuated influenza vaccine.)

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A new needle and new syringe are being used for each injection. (Needles and syringes should never be used to administer vaccine to more than one person.)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Single-dose vials or manufacturer-filled syringes are being used for only one patient.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being administered following safe injection practices.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Seats are provided so staff and patients are at the same level for optimal positioning of anatomic site and injection angle to ensure correct vaccine administration.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is identifying injection site correctly. (For intramuscular route: deltoid muscle of arm [preferred] or vastus lateralis muscle of anterolateral thigh for adults, adolescents, and children aged ≥3 years; vastus lateralis muscle of anterolateral thigh [preferred] or deltoid muscle of arm for children aged 1–2 years; vastus lateralis muscle of anterolateral thigh for infants aged ≤12 months. For subcutaneous route: thigh for infants aged <12 months; upper outer triceps of arm for children aged ≥1 year and adults [can be used for infants if necessary].)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is inserting needles quickly at the appropriate angle: 90° for intramuscular injections (e.g., injectable influenza vaccines) or 45° for subcutaneous injections (e.g., measles, mumps, rubella vaccine).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Multidose vials are being used only for the number of doses approved by the manufacturer.

» If you check "NO" in ONE OR MORE answer boxes that contain a , **DO NOT move forward with the clinic.**

- Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.
- Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Vaccines are never being transferred from one syringe to another.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Used needles and syringes are being immediately placed in a sharps container following administration. (Needles are NOT being recapped.)

VACCINE DOCUMENTATION

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Each vaccination is being fully documented with name of person vaccinated; vaccination date; vaccine type, lot number, manufacturer; patient receipt of vaccine information statement (VIS), including edition date and date VIS was provided; injection site; vaccination route; dosage; and name, title, and office/company address of person who administered the vaccine.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Your state's immunization information system (IIS) was used to document vaccinations administered. (CDC recommends using your state's IIS to document vaccinations.)
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Patients are receiving documentation for their personal records and to share with their medical providers.

AFTER THE CLINIC (Please complete each item after the clinic is over.)

POST-CLINIC ACTIONS


YES	NO	N.A.	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Temperature of remaining vaccine was checked and recorded at the end of clinic. If not still at manufacturer-recommended temperature (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines), follow your organization's protocols and/or contact your state or local health department for guidance.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any remaining vaccine in provider predrawn syringes, opened multidose vials, or activated manufacturer-filled syringes (MFSs) was properly discarded. <i>An MFS is activated when the sterile seal is broken (i.e., cap removed from needle or needle added to the syringe). If absolutely necessary, a partially used multidose vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained, the vaccine is normal in appearance, and the maximum number of doses per vial indicated by the manufacturer has not already been withdrawn, or the beyond use date indicated by the manufacturer has not been met. However, a partially used vial cannot be transferred from one provider to another or across state lines, or returned to the supplier for credit.</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Viable, unused vaccine was placed back in proper storage equipment that maintains the manufacturer-recommended temperature range at the end of the clinic day, and was not stored in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances. (This includes vaccine transported for a multi-day clinic to a remote location where adequate storage at the site is not available.)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any needlestick injuries were recorded in a sharps injury log and reported to all appropriate entities (e.g., local health department and your organization).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any vaccine administration errors were reported to all appropriate entities.
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	All biohazardous material was disposed of properly.

POST-CLINIC DOCUMENTATION

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccinations were recorded in the jurisdiction's immunization information system (IIS) or vaccine registry, where available.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If not submitted to an IIS or vaccine registry, vaccination information was sent to primary health care providers as directed by an established procedure based on state or jurisdiction regulations.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any adverse events were reported to the Vaccine Adverse Event Reporting System (VAERS): vaers.hhs.gov/index .
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	All patient medical information was placed in secured storage locations for privacy protection.
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	The staff sign-in sheet was attached to this document (with shift times, clinic location, and date).

N.A. means Not Applicable.

This checklist was adapted from materials created by the California Department of Public Health, the Centers for Disease Control and Prevention, and the Immunization Action Coalition.

» If you check "NO" in ONE OR MORE answer boxes that contain a , **DO NOT move forward with the clinic.**

- Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.
- Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

ADDITIONAL INFORMATION AND RESOURCES

If you are concerned that CDC guidelines were not followed during your vaccination clinic held at a satellite, temporary, or off-site location, contact your organization and/or state or local health department for further guidance.

- » CDC's guidelines and resources for vaccine storage, handling, administration, and safety:
 - Vaccine storage and handling: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
 - Vaccine administration:
 - www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
 - www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
 - www.cdc.gov/vaccines/hcp/admin/resource-library.html
 - Injection safety: www.cdc.gov/injectionsafety/providers.html
 - Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/
 - Videos on preparation and administering LAIV: www.cdc.gov/vaccines/hcp/admin/resource-library.html (includes videos on intramuscular injections and administration of live, attenuated influenza vaccine)
- » The Immunization Action Coalition has a skills checklist for staff administering vaccines: www.immunize.org/catg.d/p7010.pdf.
- » The Immunization Action Coalition and the Alliance for Immunization in Michigan have patient education materials available:
 - Screening tools: <http://www.immunize.org/handouts/screening-vaccines.asp>
 - Vaccination after-care:
 - Children: www.immunize.org/catg.d/p4015.pdf
 - Adults: www.aimtoolkit.org/docs/vax.pdf
- » The Immunization Action Coalition has information on the medical management of vaccine reactions:
 - Children and adolescents: www.immunize.org/catg.d/p3082a.pdf
 - Adults: www.immunize.org/catg.d/p3082.pdf
- » Manufacturers' product information and package inserts with specific, detailed storage and handling protocols for individual vaccines: www.immunize.org/packageinserts/pi_influenza.asp.

This checklist is a valuable resource for use in temporary mass vaccination clinics and other vaccination exercises, such as those conducted at vaccine points of dispensing (PODs) or vaccination and dispensing clinics (VDCs) as part of public health emergency preparedness (PHEP) program activities.

Medical waste disposal is regulated by state environmental agencies. Contact your state immunization program or state environmental agency to ensure that your disposal procedures comply with state and federal regulations.

States have laws on vaccine documentation, immunization information systems (IIS) usage, and the types of health care providers who can administer vaccines.

Considerations for Curbside / Drive Thru Immunization Clinics

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Considerations for Planning Curbside/Drive-Through Vaccination Clinics

Because of COVID-19, there has been a decrease in non-urgent, face-to-face, routine medical visits, including those for routine vaccinations. But unfortunately, postponing or canceling routine vaccinations for children and adults leaves individuals vulnerable to becoming infected with vaccine-preventable diseases and increases the risk of vaccine-preventable disease outbreaks. One way to ensure that people continue to receive needed vaccines is to set up a curbside or drive-through vaccination clinic. If you are planning a curbside or drive-through vaccination clinic, some issues for consideration include:

- When to screen for contraindications and precautions
- How to store, handle, and prepare vaccines properly
- How to follow infection control practices
- How to ensure patient and health care provider safety while administering vaccines
- What measures to take if the driver is being vaccinated

This guidance should be used in conjunction with [Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#) and the [Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist](#).

Planning for the clinic

- Start by finalizing clinic specifics, such as what vaccine(s) will be offered to which age group(s) and/or what patient health insurance requirements need to be met.
- Identify the clinic site, considering how much space will be needed based on clinic activities, physical distancing practices, enhanced infection control procedures (including handwashing stations), proper vaccine storage, handling, preparation, and administration practices, traffic and weather considerations, and safety issues for patients and health care personnel. The Advisory Committee on Immunization Practices and CDC ask providers to strongly consider observing patients for 15 minutes after vaccination because syncope (fainting) is possible after vaccination. This is critical at a drive-through vaccination clinic because of the potential for injury when the vaccinated person is the driver. Enough parking should be available for drivers to wait the recommended 15 minutes after vaccination. If possible, this should be done in the same space the vaccination occurs, or in a staff-monitored parking area nearby.
- Internet access may be needed so you can retrieve information from or enter information into an immunization information system (IIS) or electronic medical record.
- Establish logistics and clinic flow. How will you practice social distancing when possible? What safety guidelines are needed (for example, having passengers remain in their vehicles, restraining children properly, not allowing pets that could possibly bite health care personnel, etc.)? Ideally, vehicles should be able to enter and exit in separate areas.

Before the vaccination encounter

- Determine staff training needs. Staff may need to practice:
 - Proper storage and handling
 - How to access patients in a potentially limited space (including multiple patients in a vehicle, different vehicle heights)
 - Proper injection site identification and injection technique
- Consider offering clinic services by appointment only. This will allow staff to:

- Review the patient's vaccination record in the IIS or electronic medical record, screen for contraindications and precautions, and provide after-care instructions by phone or email.
- Obtain health insurance information if needed.
- Inform patients of any clinic requirements (such as wearing masks, post-vaccination waiting periods, and clinic restrictions [such as patient age, vehicle type, or number of patients per vehicle, etc.]). Include information on requirements and restrictions in all electronic communications and promotional materials and on websites.

During the vaccination encounter

- Staff should wear appropriate personal protective equipment and patients should wear face coverings.
- Provide the patient or parent with the appropriate vaccine information statements and a screening checklist for contraindications and precautions.
- Review and assess the completed contraindications and precautions checklist and any vaccination records provided by the patient, along with those in the IIS and electronic health record (if available).
- Obtain insurance information if needed.
- Inform the driver they will need to wait 15 minutes before leaving the clinic area.
- Ensure staff follows proper vaccine administration practices, including:
 - Aseptic practices for administration supplies (e.g., bandages, alcohol swabs, and syringes and needles)
 - Proper patient positioning
 - Identification of the recommended injection site (does a car door need to be opened to administer vaccine correctly?)
 - Making sure patients are seated to prevent injury from a fall if the patient faints

After the vaccination encounter

- Give patients a record of the vaccines they received.
- Document all vaccinations in the immunization information system and electronic medical record (if possible).

Resources

[Advisory Committee on Immunization Practices General Best Practice Guidelines for Immunization](#)

[Tools to Assist Satellite, Temporary, and Off-Site Vaccination Clinics](#)

[CDC Vaccine Storage and Handling Toolkit](#)

[Vaccine Administration Practices](#)

[You Call the Shots web-based training courses](#)

[Information for Healthcare Professionals about Coronavirus \(COVID-19\)](#)

[Administering Flu Vaccine During the COVID-19 Pandemic](#)

[Immunization Information Systems](#)



Refrigerated Vaccine Storage/Monitoring

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Storage Best Practices for Refrigerated Vaccines—Celsius (C)

1 Unpack vaccines immediately



1. Place the vaccines in trays or containers for proper air flow.
2. Put vaccines that are first to expire in front.
3. Keep vaccines in original boxes with lids closed to prevent exposure to light.
4. Separate and label vaccines by type and public (VFC) or private.

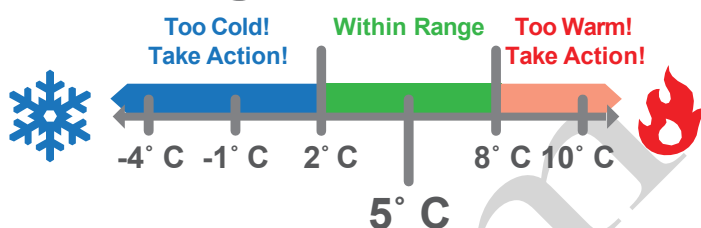
2 Store vaccines at ideal temperature: 5° C



Never freeze refrigerated vaccines!

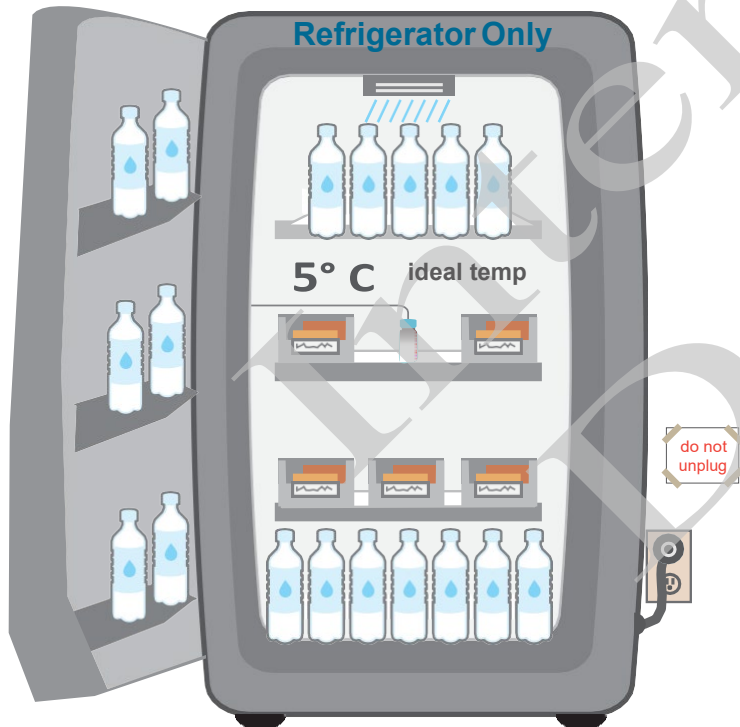
Exception: MMR can be stored in refrigerator or freezer

Refrigerated Vaccines



Report out-of-range temperatures immediately!

3 Use vaccine storage best practices



DO

- ✓ Do make sure the refrigerator door is closed!
- ✓ Do replace crisper bins with water bottles to help maintain consistent temperature.
- ✓ Do label water bottles "Do Not Drink."
- ✓ Do leave 2 to 3 inches between vaccine containers and refrigerator walls.
- ✓ Do post "Do Not Unplug" signs on refrigerator and near electrical outlet.



- Don't use dormitory-style refrigerator.
- Don't use top shelf for vaccine storage.
- Don't put food or beverages in refrigerator.
- Don't put vaccines on door shelves or on floor of



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Visit www.cdc.gov/vaccines/SandH
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refrigerator.



Don't drink from or remove water bottles.



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Visit www.cdc.gov/vaccines/SandH
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more information.

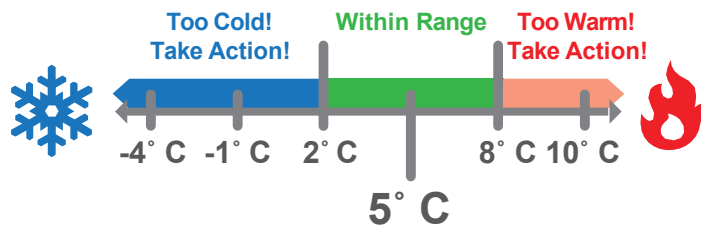
1 Store vaccines at ideal temperature: 5° C



Never freeze refrigerated vaccines!

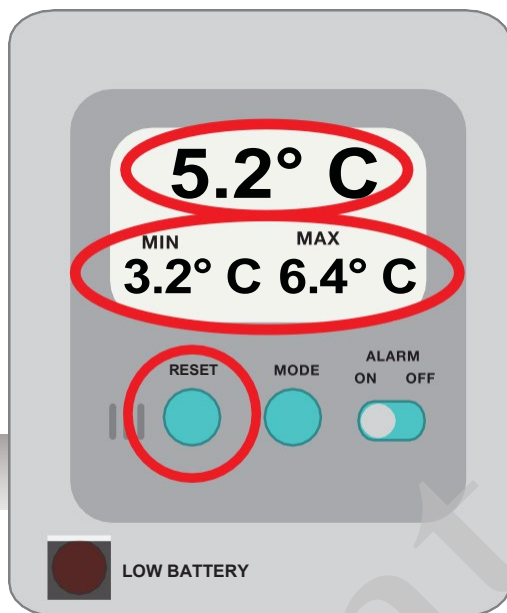
Exception: MMR can be stored in refrigerator or freezer

Refrigerated Vaccines



Report out-of-range temperatures immediately!

2 Record daily temperatures



3 steps, daily: Check and record min/max temperatures at the start of the workday.

1

Min/Max: The coldest and warmest temperatures in the refrigerator since you last reset the thermometer

Note: If your device does not display min/max temperatures, then check and record current temperature a minimum of 2 times (at start and end of workday)

2

Reset: The button you push after you have recorded the min/max temperatures

3

Current temperature: Check current temperature each time you access vaccines in the refrigerator



Best Practices

3 Take action if out of range!

- Contact your state or local health department immediately. Or for private vaccines, call the manufacturer directly.
- Tell them the total amount of time the refrigerator temperature was out of range.
- **Take your time.** Check and record temperatures accurately.
- **Make your mark!** Initial the log when recording temperatures.
- **Leave it blank.** If min/max temperatures were not recorded, leave the space blank!

Frozen Vaccine Storage/Monitoring

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Storage Best Practices for **Frozen Vaccines—Celsius (C)**

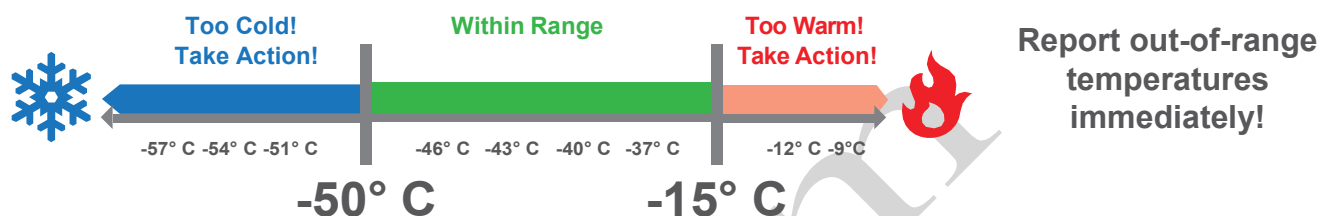
1 **Unpack vaccines immediately**



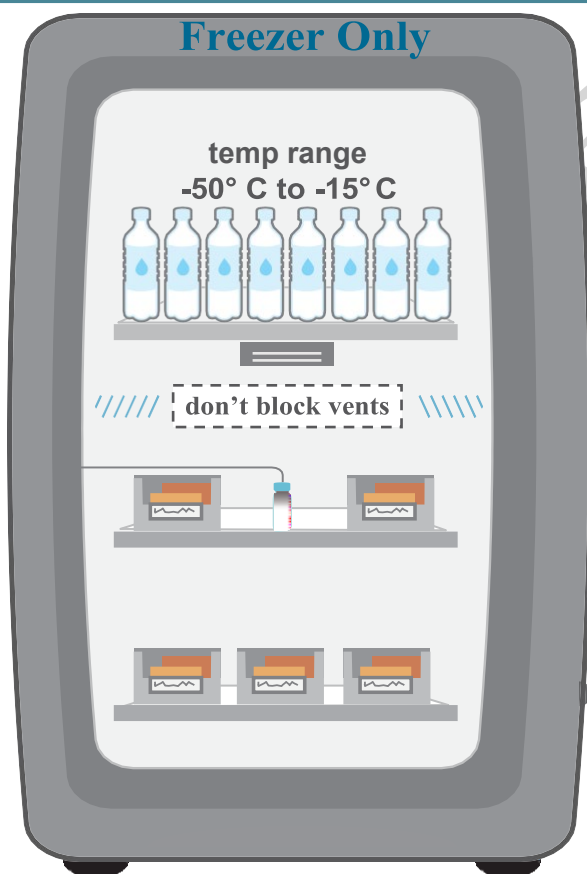
1. Place the vaccines in trays or uncovered containers for proper air flow.
2. Put vaccines that are first to expire in front.
3. Keep vaccines in original boxes with lids closed to prevent exposure to light.
4. Separate and label vaccines by type and public (VFC) or private.

2 **Thermostat should be at the factory-set or midpoint temperature setting**

Frozen Vaccines



3 **Use vaccine storage best practices**



DO

- ✓ Do make sure the freezer door is closed!
- ✓ Do use water bottles to help maintain consistent temperature.
- ✓ Do leave 2 to 3 inches between vaccine containers and freezer walls.
- ✓ Do post "Do Not Unplug" signs on freezer and by electrical outlet.

DON'T

- ⊘ Don't use dormitory-style refrigerator/freezer.
- ⊘ Don't use combo refrigerator/freezer unit.
- ⊘ Don't put food in freezer.
- ⊘ Don't store vaccines on shelves in freezer door.

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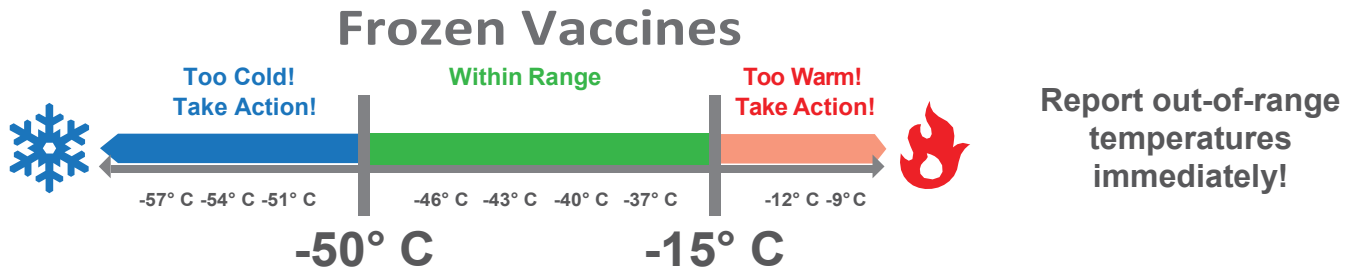
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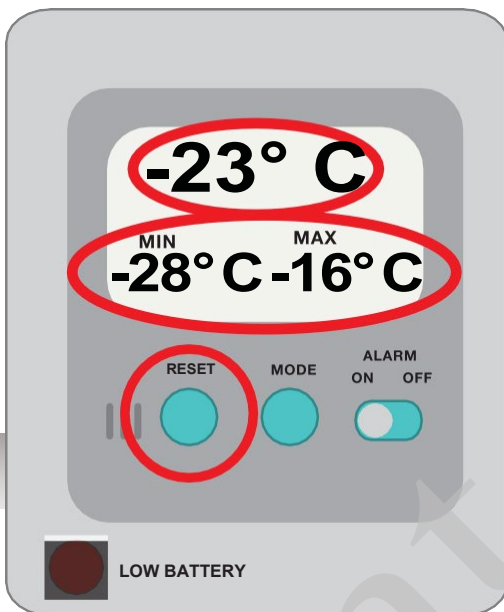
Visit www.cdc.gov/vaccines/SandH
or contact your state health department for
more information.

Temperature Monitoring Best Practices for Frozen Vaccines—Celsius (C)

1 Thermostat should be at the factory-set or midpoint temperature setting



2 Record daily temperatures



3 steps, daily: Check and record min/max temperatures at the start of the workday.

- 1 Min/Max:** The coldest and warmest temperatures in the refrigerator since you last reset the thermometer

Note: If your device does not display min/max temperatures, then check and record current temperature a minimum of 2 times (at start and end of workday)

- 2 Reset:** The button you push after you have recorded the min/max temperatures

- 3 Current temperature:** Check current temperature each time you access vaccines in the refrigerator

Best Practices

3 Take action if out of range!

- Contact your state or local health department immediately. Or for private vaccines, call the manufacturer directly.
- Tell them the total amount of time the freezer temperature was out of range.
- **Take your time.** Check and record temperatures accurately.
- **Make your mark!** Initial the log when recording temperatures.
- **Leave it blank.** If min/max temperatures were not recorded, leave the space blank!



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