COVID-19 Vaccination Program Nevada's Playbook for Statewide Operations V3

NEVADA STATE IMMUNIZATION PROGRAM; DIVISION OF PUBLIC & BEHAVIORAL HEALTH; DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Executive Summary

Immunization with a safe and effective COVID-19 vaccine is a critical component of the United States strategy to reduce COVID-19-related illnesses, hospitalizations, and deaths and to help restore societal functioning. The goal of the U.S. government, and of the State of Nevada, is to have enough COVID-19 vaccine for all people who wish to be vaccinated. Early in the COVID-19 Vaccination Program, there may be a limited supply of COVID-19 vaccine, and vaccination efforts may focus on those who are critical to the COVID-19 pandemic response, providing direct care, and maintaining societal function, as well as those at highest risk for developing severe illness from COVID-19. The key to Nevada COVID-19 vaccination preparedness planning is continuous quality improvement. Gaps in program planning are often identified when plans are tested whether through a real event or a full-scale vaccination exercise. The Nevada Division of Public and Behavioral Health (DPBH), Nevada State Immunization Program (NSIP) has assigned roles and responsibilities with target completion dates for specific tasks to ensure effective implementation of the COVID-19 Vaccination Program in Nevada.

The success of the COVID-19 Vaccination Program requires a wide range of public- and private-sector partners, including immunization and public health emergency preparedness programs, emergency management agencies, healthcare organizations, industry groups that include critical infrastructure sectors , policy makers, immunization coalitions (Immunize Nevada) and community vaccination providers (e.g., pharmacies, occupational health settings, doctors' offices). Many of these partners are engaged regularly in Nevada's seasonal influenza and other outbreak vaccination campaigns, and many served as vaccination providers during the 2009 H1N1 pandemic. However, significant additional planning is needed to operationalize a vaccination response to COVID-19, which is much larger in scope and complexity than seasonal influenza or other previous outbreak-related vaccination responses.

Federal guidance suggests states should anticipate limited vaccine supply at the beginning of the U.S. COVID-19 Vaccination Program. A prioritized process for vaccine administration focusing on critical populations has been developed using evidence-based prioritization from the Centers for Disease Control and Prevention (CDC) and the National Academies of Sciences, Engineering, and Medicine (NASEM). States now await formal critical population and related vaccine administration recommendations from the CDC's Advisory Committee on Immunization Practices (ACIP); these recommendations will come within 48 hours of the first vaccine receiving licensure or emergency use authorization from the U.S. Food and Drug Administration (FDA). Critical populations of focus for initial COVID-19 vaccination may include healthcare workers likely to be exposed to or treat people with COVID-19; people at increased risk for severe illness from COVID-19, including those with underlying medical conditions and people ages 65 years and older; and other occupation groups deemed essential to basic societal functioning during the COVID-19 pandemic.

To be successful, NSIP needs to understand the state's overall potential COVID-19 vaccine administration capacity to ensure there is statewide capacity for equitable access to the COVID-19 vaccine to all Nevadans regardless of public demand. Occupational health settings, temporary vaccination clinics, and closed/private Point of Dispensing (POD) sites will be necessary during the initial phases of the COVID-19 Vaccination Program, when vaccine supply may be limited. Once vaccine supply increases, Nevada will need to leverage a wide variety of community providers and settings to provide equitable access to COVID-19 vaccination for all people in all communities.

An adequate network of trained, technically competent COVID-19 vaccination providers in accessible settings across the state is critical to Nevada's success. NSIP is initially focusing on engaging vaccination providers which can rapidly vaccinate the prioritized critical infrastructure workforce as soon as a COVID-19 vaccine is available. NSIP is using federal guidance to help prepare public health vaccinators and residential facilities to host or conduct closed/private PODs to reach initially targeted critical population groups, including residential facilities staff and residents. This guidance is appropriate for hospitals, nursing homes, residential living facilities, large occupational locations, etc.

Throughout the response, NSIP will recruit and enroll enough providers to vaccinate all Nevadans who want to receive a COVID-19 vaccine. Anticipated COVID-19 vaccine administration sites for the general public will include, but may not be limited to:

- Healthcare provider offices and other outpatient clinic settings
- Public health clinics, such as those operated by Nevada's Local Health Authorities, Community Health Nursing offices in rural counties, Federally Qualified Health Centers, and Rural Health Centers
- Chain and independent pharmacies
- Worksites and other occupational health clinics
- Hospitals
- Temporary or off-site/mobile vaccination clinics which can be held by public or private vaccinators

This document serves as the Playbook for Nevada, statewide local public health programs, and related public health and emergency management partners on how the state has planned and will operationalize a vaccination response to COVID-19, including how Nevada will order, store, distribute, track, promote, and administer the COVID-19 Vaccination Program. The sections contained within cover specific areas of COVID-19 vaccination program planning and implementation and provide key guidance documents and links to resources to assist those efforts. Many, but not all, of the COVID-19 Vaccination Program activities described may overlap with routine Immunization Program activities; routine immunization and pandemic influenza program activities serve as the foundation for Nevada's COVID-19 vaccination program planning.

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Development of the Nevada COVID-19 Vaccination Program Playbook included review and alignment with the CDC's *COVID-19 Vaccination Program Interim Playbook for Jurisdictional Operations* as well as review of the 2009 H1N1 pandemic vaccination response plans and lessons learned in the after-action reports and improvement plans from that time. The Nevada COVID-19 Vaccination Program will also implement elements of the Federal Emergency Management Agency (FEMA) Homeland Security Exercise and Evaluation Program.

The Playbook is a dynamic document. Periodic review and revision of the Playbook are integral to the improvement process. Nevada will support continuous quality improvement while moving through the different phases of the nationally coordinated COVID-19 vaccine response. Information in this Playbook will be updated as new information (e.g., recommendations for pregnant women or pediatric populations) becomes available or situational analysis requires.

Version 2.0 edits and updates are highlighted in yellow throughout the document.

Version 3.0 edits and updated are highlighted in blue throughout the document.

Acronyms

ACIP	Advisory Committee on Immunization Practices
ACOG	American College of Obstetrics and Gynecology
ADSD	Aging and Disability Services Division
AIM	Association of Immunization Managers (AIM)
BIPOC	Black, Indigenous and Persons of Color
BoP	Bureau of Prisons (federal agency)
BRFSS	Behavioral Risk Factors Surveillance System
CCHHS	Carson City Health and Human Services
CDC	Centers for Disease Control and Prevention
CHN	Community Health Nurse(ing)
CMS	Centers for Medicare and Medicaid Services
DCFS	Division of Child and Family Services
DDLs	Digital Data Loggers
DEM	Division of Emergency Management
DETR	Department of Employment, Training and Rehabilitation
DoD	Department of Defense (federal agency)
DoS	Department of State (federal agency)
DPBH	Division of Public and Behavioral Health
DPS	Nevada Department of Public Safety
DUA	Data Use Agreement
DWSS	Division of Welfare and Supportive Services
EHR	Electronic Health Record
EMS	Emergency Medical Services
EMTs	Emergency Medical Technicians
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FQHC	Federally Qualified Health Center
FSE	Full Scale Exercise
HCQC	Health Care Quality and Compliance
HL7	Health Level 7
HRSA	Health Resources and Services Administration

IHS	Indian Health Services
IIS	Immunization Information System
JIC	Joint Information Center
LHA	Local Health Authority
LTCF	Long Term Care Facility
MMWR	Morbidity and Mortality Weekly Report
MOU	Memorandum of Understanding
NAC	Nevada Administrative Code
NDA	Nevada Department of Agriculture
NDC	National Drug Code
NDE	Nevada Department of Education
NDOC	Nevada Department of Corrections
NHA	Nevada Hospital Association
NOMHE	Nevada Office of Minority Health and Equity
NRHP	Nevada Rural Hospital Partnership
NRS	Nevada Revised Statute
OWS	Operation Warp Speed
PHP	Public Health Preparedness
POCs	Points of Contact
POD	Point of Dispensing event
PPE	Personal Protective Equipment
RHC	Rural Health Centers
SAMS	CDC's Secure Access Management System
SNHD	Southern Nevada Health District
UIHC	Urban Indian Health Center
ULT	Ultra Low Temperature
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children
VHA/VA	Veteran's Health Administration
VIS	Vaccine Information Statement
VTrckS	CDC's Vaccine Tracking System
WCHD	Washoe County Health District

Section 1: Public Health Preparedness Planning

Pandemic vaccination response planning requires collaboration among a wide range of public- and private-sector partners, including immunization and public health emergency preparedness programs, emergency management agencies, healthcare organizations, industry groups that include critical infrastructure sectors, policy makers, immunization coalition (Immunize Nevada) and community vaccination providers (e.g., pharmacies, occupational health settings, doctors' offices). Many of these partners are engaged regularly in Nevada's seasonal influenza and other outbreak vaccination campaigns, and many served as vaccination providers[1] during the 2009 H1N1 pandemic. However, significant additional planning is needed to operationalize a vaccination response to COVID-19, which is much larger in scope and complexity than seasonal influenza or other previous outbreak-related vaccination responses. Following the planning and improvement guidance in this document can assist in developing a baseline readiness to launch the COVID-19 Vaccination Program in Nevada. Nevada's COVID-19 testing and mortality data should be continually assessed during the COVID-19 vaccine response. Rapid and timely modification of messages and priority groups may be necessary to reach populations most affected by COVID-19.

Improvement Planning

Improvement planning is the identification of strengths, areas for improvement, and corrective actions that results from workshops, exercises, or real-world events. Nevada is following a consistent approach for improvement-related activities across all COVID-19 vaccination preparedness planning components. Gaps in program planning are often identified when plans are tested whether through a real event or a full-scale vaccination exercise. DPBH/NSIP has assigned roles and responsibilities with target completion dates for specific tasks to ensure effective implementation of the COVID-19 Vaccination Program in Nevada. Periodic review and revision of this Playbook are integral to the improvement process. Nevada will support continuous quality improvement while moving through the different phases of workshops, exercises, and actual COVID-19 vaccination program implementation, making and operationalizing improvements in an ongoing manner.

COVID-19 Vaccination Program Planning

Nevada reviewed and is following the COVID-19 Vaccination Planning Assumptions for Jurisdictions issued by the CDC which assisted staff with early planning efforts (*Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions (**revised 10/29/2020**)*).

In addition to current situational awareness, there is much to learn from Nevada's past experiences. To prepare for the COVID-19 vaccine response, NSIP and Public Health

[1] For the purposes of this document, "vaccination provider" refers to any facility, organization, or healthcare provider licensed to possess/administer vaccine or provide vaccination services. A "COVID-19 vaccination provider" is any vaccination provider who has been enrolled in the COVID-19 Vaccination Program.

Preparedness (PHP) staff reviewed the 2009 H1N1 pandemic vaccination response plans and lessons learned in the after-action reports and improvement plans from that time; Nevada can build on prior strengths and identify known gaps that may still need to be addressed.

As of November 25th, NSIP and PHP staff have held two internal Tabletop Exercises to test the state's vaccine plan. The first was held on September 29, 2020. The focus of the first tabletop was to read through the scenarios presented in the CDC Playbook appendices regarding "Vaccine A" and "Vaccine B." As there were many unknowns at that time, the exercise was a broad review of expectations based on what was known about the ongoing clinical trials and ultracold vaccine storage and redistribution. The second tabletop exercise was held on November 21, 2020; the focus of this exercise was to do a full "dry-run" of the first seven days after the CDC allocates a vaccine allotment to Nevada. NSIP assigned specific roles and responsibilities to staff, including a lead for each of Nevada's 17 counties. Other tasks included reviewing the vaccine ordering and distribution plan for both ultracold (Pfizer) and frozen (Moderna) vaccines to reach Nevada's identified Tier 1 workforce groups. Based on information from Operation Warp Speed (OWS), Nevada expects to receive enough vaccine in its federal allocation to get through Tier 1 by the end of January 2021 and move quickly into the remaining prioritized groups during January and February 2021.

On December 9th, 2020, Nevada executed a Full-Scale Exercise (FSE), planned for 8 to 10 hours to travel the different ultracold vaccine delivery routes throughout Nevada. The exercise was limited to delivery and transfer of COVID vaccine to different locations across the state. The objectives of the FSE were:

1. Deliver the vaccine from ultracold storage to county drop sites.
2. Test the time to package vaccine into transport bundles at ultracold storage sites and transfer to starting point of delivery route.
3. Department of Public Safety (DPS) escort of vaccine to county drop sites to identify any security and safety issues.
4. Notification to county drop site points of contact prior to arrival and verify preparedness to receive vaccine.
5. Procedure for verification of vaccine and vial count procedure with county drop points.
6. Communications between the delivery units, county drop points, and State Emergency Operations Center.
7. Intelligence briefing prior to transport of vaccine.

The FSE demonstrated the knowledge and expertise of NSIP staff in their performing their responsibilities efficiently, including packaging the Pfizer COVID-19 vaccine out of its ultracold status for vaccine redistribution. Some areas of improvement identified were to make better use of checklists, double or triple-check labeling, and identifying less trafficked entrances to facilities to ensure quick and efficient delivery and ensure social distancing and safety for all parties.

Nevada's 2020-2021 influenza season is also serving as practice for eventual COVID-19 vaccine distribution. In mid-summer 2020, Nevada received supplemental influenza funding which has been awarded to the statewide immunization coalition, Immunize Nevada, and the three local health authorities (LHAs: Carson City Health and Human Services, Washoe County Health District and Southern Nevada Health District). Local partners engaged their communities to learn new strategies for satellite, temporary, or offsite vaccination events and partner outreach during the COVID-19 pandemic. Partners were explicitly told they should plan and consider the current flu season as practice for COVID-19 vaccine distribution and administration.

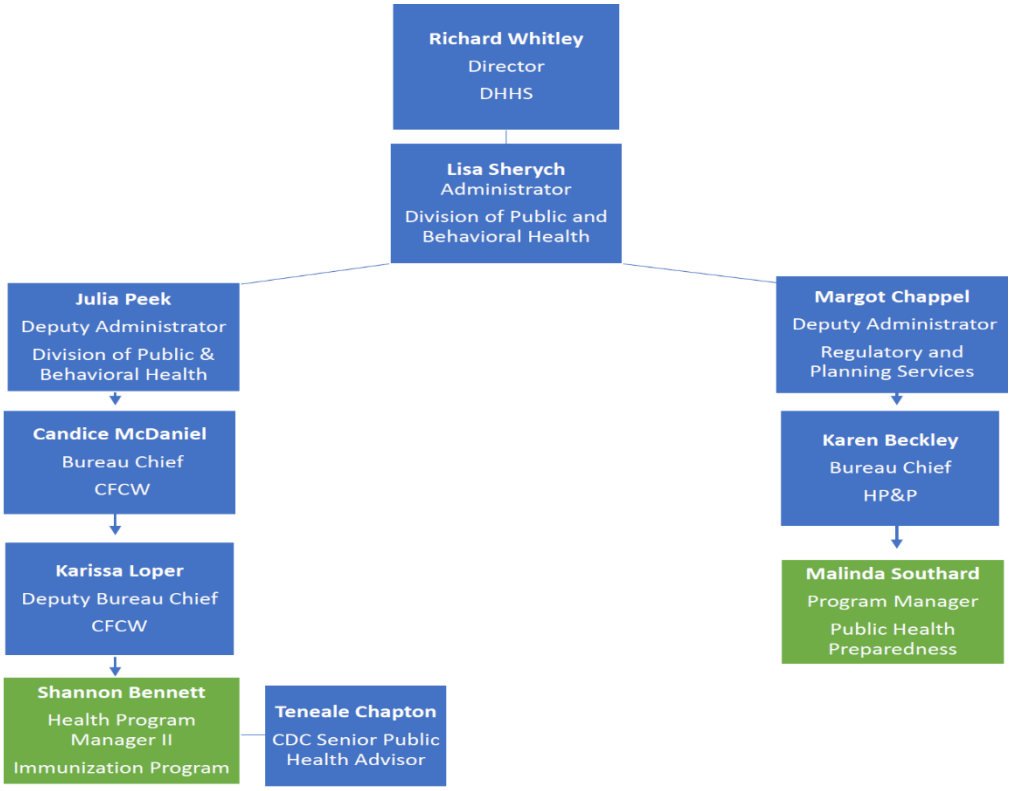
NSIP and partners have implemented new and innovative vaccination strategies to reach vulnerable Nevadans, as well as safely host satellite, temporary, or off-site vaccination events, and solidified new partnerships. The work being accomplished for the 2020-2021 flu season is serving as a real-time, full-scale exercise for the COVID-19 Vaccination Program. This has been particularly valuable for activities planned with external partners. Specific procedures assessed include cold chain management, vaccine administration and documentation, traffic flow, social distancing, communication with non-traditional partners, and ensuring proper sanitation measures. FEMA has posted information on its Homeland Security Exercise and Evaluation program that has helped Nevada plan exercises.

Section 2: COVID-19 Organizational Structure and Partner Involvement

Pandemic vaccination planning is a combined state and local responsibility requiring close collaboration between public health, external agencies, and community partners. It is imperative the State of Nevada, local jurisdictions, and tribal organizations and their planning partners clearly understand each other's roles and responsibilities in the COVID-19 Vaccination Program.

Nevada Planning and Coordination Team (Internal)

An internal COVID-19 Vaccination Program planning and coordination team is critical to ensure the vaccination response to COVID-19 is thoughtfully and successfully executed. A wide array of expertise is represented among Nevada team members. NSIP and PHP team members aligned themselves in planning efforts and are leveraging strengths within each team. Team members have been assigned responsibilities based on their individual expertise to best enhance plan development and activities coordination before and during the response. To mitigate any unexpected situations affecting a team member, each team member has or will be cross-trained so backup representatives are available to ensure coverage of each specialty area remains intact throughout the COVID-19 Vaccination Program. Current efforts are underway to onboard temporary contractors to assist the program with the high volume of vaccine planning and response activities necessary to be successful.



Roles and Responsibilities

Nevada's Chief Medical Officer or designee provides direction for the state's immunization program.

NSIP will order, store, distribute, track, administer operations, and provide guidance for the COVID-19 Vaccination Program in Nevada. NSIP will communicate through established chain-of-command with the internal planning and coordination team.

Nevada PHP manages all Point of Dispensing (POD) activities in Nevada's rural/frontier counties.

Nevada Joint Information Center (JIC), Nevada DHHS Public Information Office, and the Governor's Office provide emergency/risk/crisis communications expertise for the COVID-19 Vaccination Program in Nevada.

Carson City Health and Human Services (CCHHS) manages the Quad Counties POD activities (covering Carson City, Storey, Lyon, and Douglas Counties).

Washoe County Health District (WCHD) manages POD activities for Washoe County.

Southern Nevada Health District (SNHD) manages POD activities for Clark County.

State-Local Coordination

It is imperative state and local authorities combine and coordinate efforts for the COVID-19 vaccine response. State personnel will closely monitor activities at the local level to ensure the COVID-19 Vaccination Program is implemented statewide in adherence with federal guidance and requirements, and that there is equitable access to COVID-19 vaccination across all areas. Local personnel have a better understanding of perceptions, unique challenges, and successful mitigation strategies within their communities. Aligning areas of responsibility as well as specific tasks can help complement rather than duplicate efforts at either level, maximizing the efficient use of resources and overall quality of the COVID-19 Vaccination Program.

Detailed planning meetings have occurred individually with each of Nevada's LHA's immunization and public health preparedness programs. Rural emergency managers have been contacted to confirm POD plans in rural and frontier areas. Ultra-cold chain vaccine options and barriers have been discussed at length. A surge capacity NSIP lead staff/LHA coordinator has been assigned to each county across Nevada to ensure all local jurisdictions receive the support necessary for them to execute a proper COVID-19 vaccine response. NSIP and PHP began meeting with local emergency managers, preparedness staff, and immunization staff in August 2020. Weekly calls with these partners are held regularly and will continue throughout the COVID-19 vaccine response; calls may be scheduled more frequently if necessary.

Tribal Communities

Although CDC is working directly with the Indian Health Service (IHS) at the federal level, it is important to the State of Nevada to include tribal leaders, tribal health organizations, and IHS in COVID-19 vaccine planning efforts.

For the COVID-19 Vaccination Program, tribal nations have two options for receiving vaccine:

1. Through the jurisdiction's allocation and distribution mechanism
2. Through the IHS allocation and distribution mechanism

While IHS may provide vaccination services to the populations they serve, plans are currently in development at the federal level regarding vaccine distribution to tribal health facilities, including urban facilities, that are not officially connected to IHS. These facilities may need to work through NSIP to receive vaccine. If a tribal nation or any of the health facilities serving that tribal nation receive vaccine from the jurisdiction's allocation, they are responsible for adhering to vaccine storage, handling, distribution, and reporting requirements outlined in the *CDC COVID-19 Vaccination Program Provider Agreement.*

It is also critical for NSIP and the LHAs to reach out to any non-federally recognized tribes, such as Urban Indian Health Centers (UIHCs), in Nevada to ensure they have access to vaccination services. IHS may be able to support distribution to UIHCs and will be formally engaging with UIHCs to solicit their feedback. NSIP is making every effort to engage individually with all tribal communities across Nevada, including UIHCs, and has many existing contacts with tribes participating in the Vaccines for Children (VFC) Program.

NSIP recognizes and appreciates that each tribal nation has the sovereign authority to provide for the welfare of its people and, therefore, has the authority to:

- Choose among the jurisdiction or IHS options for accessing COVID-19 vaccine
- Determine the population(s) it chooses to serve [and in what order]
- Choose how vaccines are distributed to its community
- Establish priority groups when there is limited supply of COVID-19 vaccine or other accompanying resources

As of November 25, 2020, it is NSIP's understanding that **all Nevada tribal communities have chosen a federal allocation (i.e., working through IHS to receive COVID-19 vaccines for their communities). NSIP is using the CDC Tribal Engagement Tool to document engagement and tribal choice.** No tribe has requested allocation from NSIP. NSIP recommends tribal partners using this Playbook as a guide consider reviewing the CDC's Tribal Engagement Tool which includes all

If any tribe decides differently during the response, NSIP will use this plan to ensure continued access to the COVID-19 vaccine. If a tribe requests state allocation, then an individualized allocation plan will be developed in collaboration with the tribe pending receipt of current,

locally verified population numbers. NSIP and PHP are engaged with numerous groups representing tribes across Nevada as well as tribal liaisons across numerous state agencies. Although NSIP has attempted to engage all tribes, not all tribes are actively involved in contingency planning. Efforts continue to be made to contact and plan with tribes across the state. In addition, emergency managers in counties serving areas where tribes are located are also being encouraged to reach out to the tribe in their local community.

Tribal Health Clinics in Nevada				
Tribal Health Clinic	**County**	**Public Health Jurisdiction**	**Allocation Choice**	
			IHS	**State**
Pyramid Lake Tribal Health Clinic	Washoe	WCHD	X	
Reno-Sparks Tribal Health Center	Washoe	WCHD	X	
Nevada Urban Indians, Inc.	Washoe	WCHD	X	
Washoe Tribal Health Clinic	Douglas	CCHHS	X	
Yerington Tribal Health Clinic	Lyon	CCHHS	X	
Las Vegas Clinic	Clark	SNHD	X	
Irene Benn Medical Center (Moapa)	Clark	SNHD	X	
Southern Bands Health Center	Elko	NV DPBH	X	
Owyhee Community Health Facility	Elko	NV DPBH	X	
Battle Mountain Band Clinic	Lander	NV DPBH	X	
Duckwater Health Clinic	Nye	NV DPBH	X	
Ely Shoshone Tribal Clinic	White Pine	NV DPBH	X	
Fallon Tribal Health Clinic	Churchill	NV DPBH	X	
Ft. McDermitt Health Clinic	Humboldt	NV DPBH	X	
Walker River Tribal Health Clinic	Mineral	NV DPBH	X	

COVID-19 Vaccination Program Implementation Committee (Internal and External)

Reaching intended vaccine recipients is essential to achieving desired levels of COVID-19 vaccination coverage. To ensure equitable access to vaccinations, information about populations within a local jurisdiction and the logistical requirements for providing them access to COVID-19 vaccination services requires collaboration with external entities and community partners who are familiar with how the target group obtains healthcare and other essential services.

COVID-19 Vaccination Program planning has multiple layers in Nevada. The Bureau of Child, Family and Community Wellness leadership team and NSIP staff meet multiple times a week for internal logistics planning. In addition, the DPBH Administrator meets with Bureau and NSIP leadership weekly and has reviewed and confirmed the priority groups as well as the final Nevada COVID-19 Vaccination Program Playbook.

Additionally, the following groups are being engaged by the DPBH/NSIP planning team:

- Other NV DHHS/DPBH public health programs are being engaged for information on priority populations, such as Community Health Services, Chronic Disease Prevention

and Health Promotion, Maternal, Child and Adolescent Health, the Office of Public Health Investigations and Epidemiology, the Nevada Office of Minority Health and Equity (NOMHE), etc.

- NSIP has solicited information and feedback from other state agencies, including the Division of Health Care Financing and Policy (Nevada Medicaid), the Nevada State Board of Nursing, Nevada State Board of Medical Examiners, the Nevada State Board of Pharmacy, the Nevada State Board of Dental Examiners, the Aging and Disabilities Services Division (ADSD), the Division of Welfare and Supportive Services (DWSS), the Division of Child and Family Services (DCFS), DPS, the Division of Emergency Management (DEM), the Nevada Department of Education (NDE), the Department of Employment, Training and Rehabilitation (DETR), the Nevada Department of Corrections (NDOC), and other agencies as the need arises.
- External Community Partners, such as Immunize Nevada, the statewide non-profit immunization coalition, have assisted NSIP in engaging traditional and non-traditional community partners who represent and/or serve high-risk population groups such as the retail association, pharmacies, insurers, literacy council, community resource centers, community coalitions, Alzheimer's Association, physician groups, etc.
- LHA Health Officers, County Health Officers, and staff and county-based Emergency Managers have been involved in logistics planning and will closely inform eventual local vaccine distribution.
- University of Nevada, Reno and University of Nevada, Las Vegas
- The Nevada Hospital Association (NHA), Nevada Rural Hospital Partners (NRHP), and every Nevada acute care hospital, psychiatric hospital, and limited large-scale inpatient/outpatient medical practice.

Other partners NSIP has engaged or is trying to engage with more closely:

- Federally Qualified Health Centers (FQHC)
    - Nevada Health Centers
    - Community Health Alliance
    - Northern Nevada HOPES
- The Nevada Primary Care Association which represents Nevada's FQHCs
- Long-term care facilities (LTCFs; includes nursing home, assisted living, independent living (e.g., intermediate care facilities for individuals with intellectual and developmental disabilities), skilled nursing facilities) via ADSD and the Bureau of Health Care Quality and Compliance (HCQC)
- Nevada Sheriffs and Chiefs Association
- Local Emergency Managers as a group and individually

Partners Nevada is starting to engage in outreach to Frontline/Other Essential Workers:

- Businesses and occupational health organizations, including Chambers of Commerce

- Nevada Retail Association
- Nevada Broadcasters Association
- Faith-based organizations or local religious leaders and trusted institutions
- Trusted local media outlets
- Additional organizations serving racial and ethnic minority groups
- Additional organizations serving people with disabilities
- Additional organizations serving people with limited English proficiency
- Additional trusted community representatives

Collaboration among a variety of stakeholders is necessary in advocating for and developing strategies to ensure equitable access to COVID-19 vaccination services. If necessary, DPBH/NSIP will execute Memoranda of Understanding (MOUs) between the state and various partners to help cement roles, responsibilities, and the level of support that is expected to be provided by each party.

Weekly calls are being held each Friday at 12pm for enrolled providers to obtain and share timely information regarding COVID-19 vaccine and the response in Nevada. The calls are initially being held with enrolled hospitals, LHAs, and the rural community health nursing (CHN) offices, as these facilities have been prioritized to receive the initial doses of COVID-19 vaccine allocated to Nevada. These groups have been chosen to serve Tier 1 as they have proximity to Tier 1 occupation groups (i.e., those occupations considered to be the highest-level critical infrastructure workforce who keep the rest of Nevadans safe and healthy). Additionally, Immunize Nevada is hosting physician calls (focused on M.D.s and D.O.s right now) every Tuesday evening in which NSIP lead staff answer questions about enrollment, distribution, vaccine storage and handling, recommended priority groups, known clinical data, etc. The first of these calls was held November 24, 2020 with over 200 physician attendees.

Related Guidance and Reference Materials

CDC's public health preparedness resources can assist states, local jurisdictions, and tribal organizations with strategic planning to strengthen their public health capabilities.

Pandemic-influenza-specific resources on vaccine and other medical countermeasures may be helpful in strategizing for other COVID-19-related situations.

Section 3: Phased Approach to COVID-19 Vaccination

Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning needs to be flexible but as specific as possible to accommodate a variety of scenarios. A key point to consider is vaccine supply will be limited at the beginning of the response, so the allocation of doses must focus on vaccination providers and settings for vaccination of limited critical populations as well as outreach to these populations. The vaccine supply is projected to increase quickly over the proceeding months, allowing vaccination efforts to be expanded to additional critical populations and the general public. It is important to note recommendations on the various population groups to receive initial doses of vaccine could change after vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors.

Final decisions are being made at the federal level about the use of initially available supplies of COVID-19 vaccines. These decisions will be informed by the proven efficacy of the vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination may include:

- Healthcare personnel (paid and unpaid persons serving in healthcare settings) likely to be exposed to or treat people with COVID-19 or be exposed to infectious materials
- Staff and Residents of Long-Term Care Facilities
- Non-healthcare essential workers
    - Frontline workers
    - Other essential workers
- People 70 years of age and older
- People 64-69 years of age
- People 16-64 years of age with high-risk medical conditions who possess risk factors for severe COVID-19 illness

Nevada's COVID-19 Vaccination Playbook is prioritized by high-risk status and county. Dependent upon federal guidance, NSIP intends to distribute the state's initial vaccine allocation to counties to cover the critical infrastructure workforce (see *Section 4: Critical Populations).* If Nevada receives a large enough vaccine allocation from the CDC, then the vaccine allocation to each county is intended to be enough to immunize the Tier 1 group in the region to at least 80% coverage.[2] Based on anticipated uptake, Nevada's vaccination goal is to reach 80% of the Tier 1 critical infrastructure workforce by priority groups in each community with two doses of COVID-19 vaccine within 60 days. Special considerations and adaptability are

[2] 80% coverage is the planning assumption for pandemic influenza; a herd immunity coverage level for a COVID-19 vaccine is not known at this time. NSIP will continue to use the 80% coverage standard until further guidance is issued.

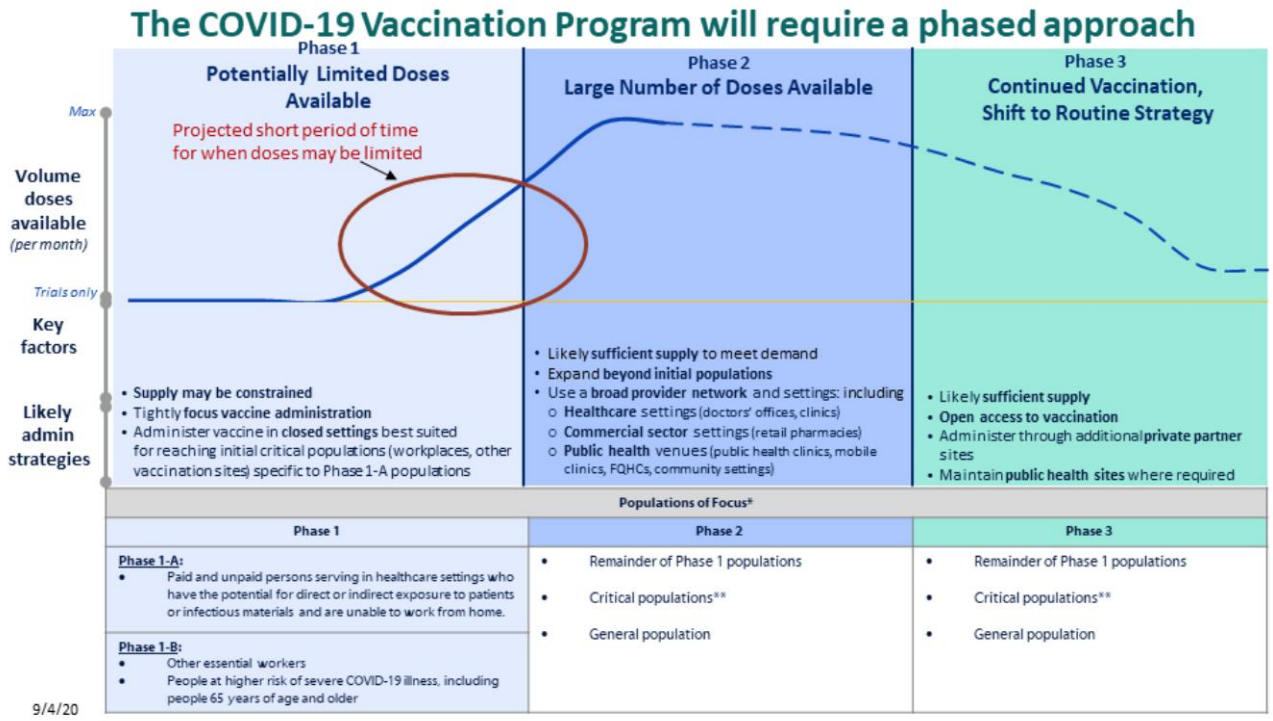
necessary when allocating COVID-19 vaccine to cover this workforce (see *Appendix B*: *Considerations for Frontline Health Care Workers*).

Nevada is planning the COVID-19 vaccine response in terms of three phases:

1. **Phase 1: Potentially limited supply of COVID-19 vaccine doses available**
    - **a.** Focus initial efforts on reaching healthcare personnel, people at increased risk for severe illness from COVID-19, people aged 65 years and older, and other essential workers who keep Nevada's infrastructure operating.
    - **b.** Ensure vaccination locations selected can reach populations, manage cold chain requirements, and meet reporting requirements for vaccine supply and uptake.
2. **Phase 2: Large number of vaccine doses available**
    - **a.** Focus on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the general population.
    - **b.** Expand the provider network.
3. **Phase 3: Sufficient supply of vaccine doses for entire population (surplus of doses)**
    - **a.** Focus on ensuring equitable vaccination access across Nevada's population.
    - **b.** Monitor vaccine uptake and coverage.
    - **c.** Reassess strategies to increase uptake in populations or communities with low coverage.

Nevada is also considering low-demand scenarios, especially in the beginning phases of the U.S. COVID-19 Vaccination Program. Nevada is collaborating with the University of Nevada, Reno School of Medicine on a healthcare provider survey to obtain feedback on vaccine acceptance and uptake and how these elements will impact the COVID-19 vaccine allocation process in Nevada.

The following graph illustrates the three phases of the COVID-19 Vaccine Program and populations of focus in each phase.



Planning should consider that there may be initial age restrictions for vaccine products.

Phase 1: Potentially Limited COVID-19 Vaccine Doses Available

CDC's Roadmap to Implementing Pandemic Influenza Vaccination of Critical Workforce provides additional information and tools NSIP has used to help operationalize specific plans for targeting critical workforce groups during an influenza pandemic response. It also includes tools and resources for tracking progress on critical workforce vaccination planning and activities within a state or jurisdiction. NSIP continues to review this tool to adopt specific tracking methods as appropriate for the COVID-19 vaccination response. Though currently specific to an influenza pandemic, this tool is helping to inform the approach for COVID-19 vaccination planning for Nevada's critical workforce.

In the initial phase, or Phase 1, of the COVID-19 Vaccination Program, initial doses of vaccine will be distributed in a limited manner, with the goal of maximizing vaccine acceptance and public health protection while minimizing waste and inefficiency. The key considerations in planning for Phase 1 are:

- COVID-19 vaccine supply may be limited.
- COVID-19 vaccine administration efforts must concentrate on the initial populations of focus to achieve vaccination coverage in those groups.
- Inventory, distribution, and any repositioning of vaccine will be closely monitored through reporting to ensure end-to-end visibility of vaccine doses.

Nevada will employ the following strategies to address these constraints:

- Concentrate early COVID-19 vaccine administration efforts on the initial critical populations identified above and in *Section 4: Critical Populations*.
- Provide COVID-19 vaccination services in closed POD settings that allow for the maximum number of people to be vaccinated while maintaining social distancing and other infection control procedures (e.g., large hospitals and satellite, temporary, or off-site settings).[3]

NSIP staff will prioritize enrollment activities for vaccination providers and settings who will administer the COVID-19 vaccine to the populations of focus for Phase 1 (e.g., all Nevada's acute care hospitals), giving consideration to those who live in rural and frontier regions of Nevada and may have difficulty accessing vaccination services. Additional information on COVID-19 vaccination provider outreach and clinic settings is in *Section 5: COVID-19 Provider Recruitment and Enrollment.*

As NSIP is performing Phase 1 activities, staff will simultaneously be planning ahead for Phase 2, considering needs for additional vaccinators to staff PODS, contract needs for vaccination services, and reviewing state law to allow for expanded professional practice if necessary, such as the recent emergency regulation signed by Governor Sisolak to allow pharmacy technicians to administer vaccinations under the direction of a supervising Pharmacist. Research is being conducted to understand potential emergency directives and other creative solutions to identify and allow for new vaccinators across the state, such as allowing all levels of emergency medical technicians (EMTs) to vaccinate.

Point-of-Dispensing (POD) Sites

POD planning is the framework used for COVID-19 vaccine distribution in Phases 1 and 2. Social distancing will be required at Nevada POD sites. POD staffing will occur via a combination of public/private public health agencies and employees, state and local health agency employees, and clinical and non-clinical volunteers. POD staffing is the responsibility and at the discretion of local county and tribal organizers, supplemented by Nevada public health and government employees at the state level. Each local jurisdiction has a POD plan in place which will be leveraged accordingly as vaccine becomes available.

Emergency POD Sites

As part of an overall vaccine distribution and dispensing plan for Nevada, local communities, working with the LHA or county's CHN and Emergency Manager have plans in place to implement emergency PODS for residents in their community.

Each LHA has similar plans in place for their jurisdiction and are considered experts in hosting satellite/temporary/off-site vaccination events for their populations. Nevada's three LHAs, and

[3] https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html

each county's Emergency Manager, have satellite/temporary/off-site vaccination POD plans in place which will be used during the COVID-19 vaccine response. Communication has been initiated with all partners and will continue as the details of the vaccine response are further developed. Nevada is using CDC's *Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations* to assist with jurisdictional planning and implementation of these types of clinics by public and private vaccination services organizations. These same guiding principles will be used when planning the response for Phase 1.

The guidance is divided into four categories:

1. Planning activities
2. Pre-clinic activities
3. During clinic activities
4. Post-clinic activities

The guidance also provides information on additional considerations required for the COVID-19 vaccine response, including physical distancing, using personal protective equipment (PPE), and enhanced sanitation efforts.

Healthcare Strike Teams

Healthcare "strike teams", or "field teams," are an innovative model for combating COVID-19. These teams of multidisciplinary healthcare and social service employees apply an emergency response model traditionally used in natural disasters like hurricanes, floods, and wildfires to combat COVID-19 outbreaks. These teams have been increasingly used across the United States to combat outbreaks in long-term care facilities. SNHD and other jurisdictions across the country used strike teams to help reach and vaccinate people in the homeless community during the Hepatitis A outbreaks of 2018-19.[4]

COVID-19 Vaccine Strike Teams are another viable option that will be used to reach isolated community members who are home-bound but not living in a LTCF or skilled nursing facility, who are homeless, or who reside within the jail/prison systems. The use of such strike teams is being practiced by Nevada LHAs to vaccinate their communities against influenza this season. NSIP staff are also investigating how to organize and deploy nurse strike teams, once the COVID-19 vaccines are available, as needed using Nevada DPBH authorities and Registered Nurses on NSIP staff with help from appropriately licensed/certified and supervised medical volunteers.

Reaching Homebound Nevadans

Contracted nursing services and other mobile vaccinating Emergency Medical Services (EMS) units (e.g., REMSA in Northern Nevada) can be enrolled in Nevada's COVID-19 Vaccination Program to reach assisted living and homebound populations. NSIP is considering all innovative

[4] https://www.health.state.mn.us/diseases/hepatitis/a/vaxguideapxb.pdf

approaches to expand access to are reach homebound and similar populations. DPBH partnerships with other state agencies, such as ADSD, are vital to implementing a confident messaging campaign to reach these population groups.

Efforts are being made to reach Nevadans who have *intentionally* chosen to stay home through the pandemic with the message it is safe to go into their community to get an influenza vaccine now and the COVID-19 vaccine when it is available. This population is large in number and characteristically different than the traditional elderly or disabled homebound populations.

Nursing Homes, Behavioral Health Centers, and Assisted Living Facilities

Nevada has opted into the Pharmacy Partnership Program through the federal government. This program pairs a LTCF with a local CVS or Walgreens pharmacy. Staff from those pharmacies will deploy to LTCFs to vaccinate residents and staff. Nearly every LTCF in the state has been matched with a CVS or Walgreens pharmacy. There are only a few exceptions in which NSIP and/or the LHA is working directly with facilities to ensure they have alternate vaccinating plans. The ACIP has recommended LTCF staff and residents be vaccinated at the same time, therefore, the Pharmacy Partnership Program will deploy to vaccinate both staff and residents concurrently within each facility. (see *Appendix C: Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination)*

Nevada Department of Corrections (NDOC)

NDOC staff will be invited to closed vaccination events within their community, hosted either by NDOC clinicians or through the local health district or rural CHN. NDOC inmates will be vaccinated in their facility of residence by NDOC clinicians (or appropriate contracted healthcare staff).

Phase 2: Large Number of Doses Available; Supply Likely to Meet Demand

As the national supply of available vaccine increases, distribution will expand, increasing access to vaccination services for a larger population. When larger quantities of vaccine become available, there will be two simultaneous national objectives:

1. To provide equitable access to COVID-19 vaccination for all critical populations to achieve high COVID-19 vaccination coverage in these populations across Nevada.
2. To ensure high uptake in specific populations, particularly in groups that are higher risk for severe outcomes from COVID-19.

The key considerations in planning for Phase 2 are:

- COVID-19 vaccine supply will likely be sufficient to meet demand for critical populations as well as the general public.
- Additional COVID-19 vaccine doses available will permit an increase in vaccination providers and locations.

- A surge in COVID-19 vaccine demand is possible, so a broad vaccine administration network for surge capacity will be necessary.
- Low COVID-19 vaccine demand is also a possibility, so jurisdictions should monitor supply and adjust strategies to minimize vaccine wastage.

Nevada will adapt to the increase in COVID-19 vaccine supply levels by:

- Reviewing availability and uptake data to make considerations for any group in Phase 1 which was not able to receive vaccination due to supply shortages.
- Expanding vaccination efforts beyond initial population groups identified in Phase 1 with emphasis on equitable access for all populations.
- Distributing vaccine widely for administration through:
    - Commercial and private sector partners (e.g., doctors' offices, satellite, temporary, or off-site vaccination events, etc.)
    - Pharmacies not already enrolled by the federal government
    - Public health sites (mobile or drive-through vaccination events, FQHCs, Rural Health Centers (RHCs), LHA vaccine clinics, temporary/off-site clinics, etc.)

Phase 3: Likely Sufficient Supply

Ultimately, COVID-19 vaccine will be widely available and integrated into routine vaccination programs, run by both public and private partners.

The key considerations in planning for Phase 3 are:

- Likely sufficient COVID-19 vaccine supply where supply might exceed demand
- Broad vaccine administration network for increased access to all Nevadans

Through Phase 3, Nevada will:

- Continue to focus on equitable access to vaccination services
- Monitor COVID-19 vaccine uptake and coverage in critical populations using the state's immunization information system (IIS), NV WebIZ
- Enhance strategies to reach populations with low vaccination coverage or uptake
- Partner with commercial and private entities in addition to public health partners to ensure COVID-19 vaccine and vaccination services are widely available
- Monitor vaccine inventories across the state and physically transfer or facilitate transfer of vaccine products to minimize wastage if necessary

Section 4: Critical Populations

CDC's ACIP, the National Institutes of Health, and NASEM have issued guidance to help jurisdiction's determine populations of focus for COVID-19 vaccination and ensure equity in access to COVID-19 vaccination availability across the United States. CDC has established an ACIP work group to review evidence on COVID-19 epidemiology and burden as well as COVID-19 vaccine safety, vaccine efficacy, evidence quality, and implementation issues to inform recommendations for COVID-19 vaccination policy. A key policy goal for these groups is to determine critical populations for COVID-19 vaccination, including those groups identified to receive the first available doses of COVID-19 vaccine when supply is expected to be limited.

After a short period of potentially limited vaccine supply, supply is expected to increase quickly, allowing vaccination efforts to be expanded to include additional critical populations as well as the general public. Nevada has developed the following plans to ensure equitable access to vaccination for the critical populations currently identified by the CDC.

Identifying and Estimating Critical Populations in Nevada

Since COVID-19 vaccine will be limited at the beginning of the vaccination program, Nevada has developed a priority decision support tool to guide the state's COVID-19 vaccination strategy. Per the CDC Interim Playbook, *"The critical infrastructure workforce varies by jurisdiction. Each jurisdiction must decide which groups to focus on when vaccine supply is limited by determining key sectors that may be within their populations (e.g., port-related workers in coastal jurisdictions)."*

Nevada's plan is a living document and will be supported with additional content as needed as Nevada moves through the response to meet the needs of Nevada residents. The following updates are based on guidance from the ACIP and the Cybersecurity and Infrastructure Security Agency (CISA). Four ethical principles guided the creation of these recommendations for the allocation of COVID-19 vaccine while the supply is limited, in addition to scientific data and considering Nevada's unique implementation challenges:

1) maximize benefits and minimize harms;

2) promote justice;

3) mitigate health inequities; and

4) promote transparency.

With these considerations at the forefront, Nevada's vaccination plan is designed to mitigate as much disease spread and death as possible, beginning with the occupational groups in Tier 1 whose ability to remain healthy helps protect the health of others and minimizes disruption to society and the economy. It is also vitally important to reduce the spread of the disease among the staff of, and anyone living in, a residential/congregate setting and encourage businesses to

continue to allow those who can, to work from home. The mitigation measures we have all been following for most of this year will still be necessary until vaccine supply increases enough in 2021 to be widely available; until then, Nevada will follow these ethical principles to allocate the state's limited supply of vaccine doses.

Tribal communities are not specifically called out in Nevada's prioritized structure, because all tribes have chosen to receive COVID-19 vaccine from the IHS. If a tribal member is also a healthcare worker or employed in another Tier 1 workforce category, then they have been included in the counts below and may be reached either via their employer or by the health care facility chosen to vaccinate the tribal community where they live.

Prioritization and Eligibility for COVID-19 Vaccination

Nevada's COVID-19 Vaccination Playbook V3 has been updated to incorporate recent recommendations provided by the CDC and other adjustments meant to tailor the plan to Nevada's unique needs. This Playbook remains a living, working document and may be revised throughout the course of the vaccination process based on data, science, and availability of the vaccine.

As outlined in V3, once Nevada's "Tier 1/Phase 1a—Health Care Workforce & Support" is completed, **vaccinations may begin to occur concurrently in two lanes: 1) Essential Workforce; and 2) General Population.** The population groups in each lane should be vaccinated in priority order.

IMPORTANT: Each county throughout Nevada may be at a different vaccination pace based on availability of vaccine, uptake in the population, and the size of the population groups in the two lanes.

Frontline/Essential Workforce Lane

Due to the limited number of initial COVID-19 vaccine doses allocated to Nevada, and considering the need to protect the functioning of Nevada's critical infrastructure and the safety of workers in the state, it will be necessary to prioritize vaccine eligibility among and within the identified frontline/essential workforce categories.

Following ACIP recommendations, which specify prioritization within population groups should be based on the risk of acquiring infection and the risk of transmitting infection to others, the key determining factor to determine initial vaccination eligibility is if performing the employee's position requires unavoidable, close and prolonged contact with others.

Therefore, within each eligible population listed, an individual whose position can work remotely or socially distancing is possible while performing work duties is not recommended to receive the COVID-19 vaccination in the initial prioritized rollouts.

Mere employment within a prioritized population category does NOT automatically make an individual eligible for initial vaccination. It is the responsibility of each organization/employer to evaluate each employee's position or each job title, using the exclusion criteria, to determine priority vaccination eligibility. The goal of these evaluations is to prioritize true **frontline** employees within an organization whose job cannot be made remote or accommodate social distancing and to conserve limited vaccine allocations for individuals facing higher risk.

Additional information regarding the ACIP recommendations can be found here.

A standardized criteria list and current CDC guidance was used to determine the groups populating the following priority lists:

1. Level of exposure to COVID-19
    a. Population has unavoidable, close contact with those who may have COVID-19
2. Length of exposure
    a. Population has unavoidable, sustained contact with those who may have COVID-19
3. Importance of job/special technical skill
    a. Population has a special technical skill that is not easily replaced (i.e., doctor, meat packing plant employee, utility worker, teacher)
    b. Population has a job that others in the community depend on for overall community safety and well-being
4. Likelihood of increasing community spread
    a. Populations that would increase spread within the community or within a closed, residential facility
5. Mortality rate
    a. Population has an increased likelihood of death from COVID-19
6. Morbidity rate
    a. Population has an increased likelihood of COVID-19 infection
7. Immune response
    a. Vaccine shown to provide a proper immune response in the population vaccinated (e.g., older people often do not show a strong immune response to vaccination)

CURRENTLY VACCINATING:

TIER 1/PHASE 1A HEALTH CARE WORKFORCE AND SUPPORT

Upon completion of Tier 1, vaccinations may begin to occur concurrently in the following two lanes:

Essential Workforce & General Population

The population groups in each lane will be vaccinated in priority order

Last updated 1/12/2021 8:21 AM

Prioritization Lanes

Frontline/Essential Workforce

PUBLIC SAFETY & SECURITY

- NV Dept. of Corrections Staff
- Law Enforcement, Public Safety, and National Security
- State and Local Emergency Operations Managers/Staff

FRONTLINE COMMUNITY SUPPORT

- Education (Pre-K & K-12) and Childcare – public/private/charter school settings
- Nevada System of Higher Education (NSHE) Frontline Educators, Staff & Students
- Community Support Frontline Staff (i.e. frontline workers who support food, shelter, court/legal and social services, and other necessities of life for needy groups and individuals)
- Continuity of Governance (State and Local)
- Essential Public Transportation
- Remaining Essential Public Health Workforce
- Mortuary Services

FRONTLINE SUPPLY CHAIN & LOGISTICS

- Agriculture and Food Processing
- End-to-End Essential Goods Supply Chain (includes manufacturing, transport, distribution and sale of essential items)
- Utilities and Communications Infrastructure
- Nevada Department of Transportation and Local Emergency Road Personnel
- Frontline Airport Operations
- Other Essential Transportation

FRONTLINE COMMERCE & SERVICE INDUSTRIES

- Food Service and Hospitality
- Hygiene Products and Services
- Depository Credit Institution Workforce

FRONTLINE INFRASTRUCTURE

- Infrastructure, Shelter and Housing (Construction)
- Essential Mining Operations

OTHER

- Community Support Administrative Staff
- NSHE Students living in campus-sponsored residential settings (e.g., dorms, campus-sponsored apartments, etc.)
- NSHE Remaining Workforce

General Population

NEVADANS 70 YEARS & OLDER

NEVADANS 65-69 YEARS

NEVADANS 16-64 YEARS WITH UNDERLYING CONDITIONS;

INDIVIDUALS WITH DISABILITIES;

NEVADANS EXPERIENCING HOMELESSNESS

HEALTHY ADULTS, 16-64 YEARS

NDOC INMATES & TRANSITIONAL OFFENDER GROUP HOUSING

NDOC inmates will be vaccinated following the same tiered prioritization as the general

NEVADA HEALTH RESPONSE

Vaccination Priority Group Descriptions

Tier 1/Phase 1a Health Care Workforce and Support
1.1 General Medical and Surgical Hospitals (Acute and Non-Acute Care)
Hospitalists, pharmacists, clinical and non-clinical support staff, all other hospital employees, including clinical student residents, those in rotations, or in any other volunteer or learning relationship with the facility.
1.2 Long Term Care Facility Staff and Residents
All staff and residents of nursing care facilities, assisted living facilities, continuing care retirement communities, specialty hospitals, residential intellectual and developmental disability facilities, residential mental health and substance abuse facilities. These settings include Intensive Supported Living Arrangements (ISLA) and Supported Living Arrangements (SLA) for staff and residents.
1.3 Psychiatric and Substance Abuse Hospitals
1.4 Emergency Medical Services (EMS)
Emergency Medical Technicians and Firefighters with EMS/EMT credentials (most firefighters)
1.5 Frontline Public Health Workforce and Volunteers
Includes all public health vaccinators (CHNs, EMTs, etc.) and volunteers as well as frontline vaccine event coordinators who are helping/interacting with participants and the clinical staff.
1.6 Laboratory Workers (clinical/public health settings)
1.7 Pharmacists and Pharmacy Technicians
1.8 Outpatient and Home Health Providers
Physician's offices (including mental health providers), both clinical and non-clinical staff; HMO/MCO medical centers; Federally Qualified Health Centers; physical, occupational, and speech therapists, and audiologists (including in school settings); school nurses and clinical aides; family planning centers; outpatient mental health and substance abuse treatment centers; kidney dialysis centers; freestanding ambulatory surgical and emergency centers; all other outpatient care types; diagnostic imaging centers; home health care services agencies and providers; care services for the elderly and persons with disabilities; all other ambulatory health care services; blood and organ banks; dentists; optometrists; chiropractors; mental health providers (non-physician); podiatrists.

WORKFORCE DEFINITIONS
PUBLIC SAFETY & SECURITY
Nevada Department of Corrections (NDOC) Staff
Law Enforcement, Public Safety, and National Security
Nevada Department of Public Safety (DPS) and associated Divisions (e.g., juvenile detention and probation, parole and probation, Nevada Highway Patrol, Division of Emergency Management, etc.); local Sheriffs' Offices and Police Departments; School and University Police; Airport Police; other peace officers not specifically named; Nevada Threat Analysis Center; mission critical national security workforce not covered by one of the five federal agencies receiving direct vaccine allocation.
State and Local Emergency Operations Managers/Staff

FRONTLINE COMMUNITY SUPPORT
K-12 Education and Childcare (public/private/charter school settings)
Educators in pre-school and K-12 settings, including teachers, aides, special education and special needs teachers, ESOL teachers, and para-educators; workers who provide services necessary to support educators/students, including but not limited to administrators, administrative staff, IT staff, media specialists, librarians, guidance counselors, essential workers in the Nevada Dept. of Education, etc.; workers who support the transportation and operational needs of school settings, including bus drivers, crossing guards, cafeteria staff, cleaning and maintenance staff, and bus depot and maintenance staff.
Nevada System of Higher Education (NSHE) Frontline Educators and Staff
Instructional and administrative faculty and all non-instructional staff types across the NSHE system who must work on campus, in close contact with others, and who cannot and have not been able to conduct their job duties from home. Most of this group includes medical and health faculty, staff, and students.
Community Support Frontline Staff
Frontline workers who support food, shelter, court/legal services, and social services, and other necessities of life for needy groups and individuals, including in-need populations and COVID-19 responders, including food bank distributors and food preparers (if applicable), front-facing state service staff (e.g., DETR, WIC, DWSS, DMV, ADSD, etc.), community coalition advocates/volunteers in the field (e.g., CHWs, Home Visitors, and others with public interaction). Veterinary nurses, technicians, veterinarians, and other services supporting individuals and organizations with service animals, search and rescue dogs, and support animals.

FRONTLINE COMMUNITY SUPPORT, CONT.
Continuity of Governance and Services (State and Local)
Other workers supporting the operations of the courts system, including judges and others providing critical in-person legal assistance; state, local, and other elected officials and support staff (e.g., Legislative Counsel Bureau, etc.).
Essential Public Transportation
Public transportation system employees at the state and local levels (urban, interurban, and rural transit authorities), taxi and ride share services (e.g., Uber, Lyft, etc.), and other ground transport services not specifically named.
Remaining Essential Public Health Workforce
Public health and environmental health workers specializing in sanitary and infection control, healthcare facility safety and emergency preparedness planning, public health/community health workers (including call center workers) who conduct community-based public health functions, conducting epidemiologic surveillance and compiling, analyzing, and communicating public health information, who cannot and have not been working from home.
Mortuary Services
Workers who prepare the deceased for burial or interment, conduct funerals, and/or operate sites or structures reserved for interment or cremation.

FRONTLINE SUPPLY CHAIN & LOGISTICS
Agriculture and Food Processing
Food manufacturer workers and their supplier workers including those employed at food ingredient production and processing facilities; aquaculture and seafood harvesting facilities; slaughter and processing facilities for livestock, poultry, and seafood; animal food manufacturing and processing facilities; human food facilities producing by-products for animal food; industrial facilities producing co-products for animal food; beverage production facilities; the production of food packaging; and workers supporting agriculture irrigation infrastructure. • *Farmers, farm and ranch workers, and agribusiness support services, including workers involved in auction and sales; in food operations, including animal food, grain and oilseed storage, handling, and processing; in ingredient production; in manufacturing of veterinary drugs and biologics (e.g., vaccines).* *Animal agriculture workers to include those employed in veterinary health (including those involved in supporting emergency veterinary or livestock services); raising, caring for and management of animals for food, as well as pets; animal production operations; livestock*

markets, slaughter and packing plants, manufacturers, renderers, and associated regulatory and government workforce.
End-to-End Essential Goods Supply Chain
Warehouses, processing, packaging, storage, and distribution workforce (e.g., USPS, FedEx, UPS, messengers, truck drivers (local and long-haul), wholesale traders, etc.); workers enabling the sale of human food (e.g., grocery stores), animal food (including pet food, animal feed, and raw materials/ingredients), and beverage products at groceries, pharmacies, and convenience stores, including staff in retail customer support and IT support necessary for online orders, pickup, and/or delivery; warehouse operators, including vendors and support personnel critical for business continuity (including heating, ventilation, and air conditioning (HVAC) and electrical engineers, security personnel, and janitorial staff), e-commerce or online commerce, and customer service for essential functions. ***Essential Manufacturing*** *Workers necessary for the manufacturing of materials and products needed for medical supply chains, and for supply chains associated with transportation, energy, communications, food and agriculture, chemical manufacturing, nuclear facilities, the operation of dams, water and wastewater treatment, emergency services, and the defense industrial base.*
Utilities and Communications Infrastructure
Water and wastewater workers, dam workers, natural gas, energy/electric sectors, internet and mobile services, telephone service providers, news broadcasters (Radio and Television), newspaper publishers, including back-office staff as well as frontline journalists, and workers responsible for ensuring persons with disabilities have access to and the benefits of communications platforms.
Nevada Department of Transportation (NDOT) & Local Emergency Road Personnel
CDL operators, street cleanup crews, snowplow drivers, district training officers, safety/loss control section, and traffic incident management, emergency road crews.
Frontline Airport Operations
Workers who support air transportation for cargo and passengers, including operation, distribution, maintenance, and sanitation. This includes air traffic controllers, flight dispatchers, maintenance personnel, ramp workers, fueling agents, flight crews, airport safety inspectors and engineers, airport operations personnel, aviation and aerospace safety workers, security, commercial space personnel, airport operations personnel, accident investigators, and flight instructors.
Other Essential Transportation
Vehicle repair, maintenance, and transportation equipment manufacturing and distribution facilities; workers who support the construction and maintenance of electric vehicle charging stations; workers critical to the manufacturing, distribution, sales, rental, leasing, repair and maintenance of vehicles and other equipment and the supply chains that enable these operations to facilitate continuity of travel-related operations for essential workers.

FRONTLINE COMMERCE & SERVICE INDUSTRIES
Food Service and Hospitality
*Restaurant and quick serve food operations, including dark kitchen and food prep centers, carry-out, and delivery food workers. Workers in cafeterias used to feed workers or other congregate settings not already captured in an occupation group above. *Specific to Nevada: frontline casino and resort employees not in food service who have prolonged/sustained customer interaction.*
Hygiene Products and Services
Workers who produce hygiene products; workers in laundromats, laundry services, and dry cleaners, workers providing personal and household goods, repair, and maintenance; workers providing disinfection services for essential facilities and modes of transportation and who support the sanitation of all food manufacturing processes and operations from wholesale to retail; workers necessary for the installation, maintenance, distribution, and manufacturing of water and space heating equipment and components; support required for continuity of services, including commercial disinfectant services, janitorial and cleaning personnel, and support personnel functions that need freedom of movement to access facilities; workers supporting the production of home cleaning, pest control, and other essential products necessary to clean, disinfect, sanitize, and ensure the cleanliness of residential homes, shelters, and commercial facilities.
Depository Credit Institution Workforce
Workers who are needed to provide, process, and maintain systems for processing, verifying, and recording financial transactions and services, including payment, clearing, and settlement; wholesale funding; insurance services; consumer and commercial lending; and public lending. Workers who are needed to provide business, commercial, and consumer access to bank and non-bank financial and/or lending services, including ATMs, lending and money transmission, lockbox banking, and armored car services.

FRONTLINE INFRASTRUCTURE
Infrastructure, Shelter and Housing (construction)
Workers performing housing and commercial construction related activities, including those supporting the sale, transportation, and installation of manufactured homes. Workers supporting government functions related to the building and development process, such as inspections, permitting, and plan review services that can be modified to protect the public health, but fundamentally should continue and enable the continuity of the construction industry. Workers such as plumbers, electricians, exterminators, builders (including building and insulation), contractors, HVAC Technicians, technicians for elevators, escalators and moving walkways, landscapers, and other service providers who provide services, including

temporary construction, that are necessary to maintaining safety, sanitation, and essential operation of residences, businesses and buildings, such as hospitals and senior living facilities.
Essential Mining
This category includes frontline mining and processing operations and supplier/vendor industries essential to such operations.

OTHER
Community Support Administrative Staff
Food Bank, state service office (e.g., DETR, WIC, DWSS, DMV, ADSD, etc.), and Community Coalition administrative and other support staff who can and have been working from home.
NSHE Students living in campus-sponsored residential settings (e.g., dorms, campus-sponsored apartments, etc.)
NSHE Remaining Workforce

Describing and Locating Critical Populations in Nevada

To improve vaccination among critical population groups, Nevada must ensure these groups have access to vaccination services. While many adult and pediatric healthcare providers and hospitals currently work with NSIP to ensure access to vaccination services for eligible groups statewide, the growth in the number of providers needed to reach all 3,080,156[5] Nevadans means NSIP needs to expand communication and coordination logistics. NSIP is working with the Nevada DHHS Office of Analytics to map the locations of critical population groups and will consider this mapping when conducting provider outreach and enrollment to ensure equitable access to COVID-19 vaccination services.

For planning and vaccine allocation purposes, NSIP will focus on a person's place of employment, rather than their place of residence. Larger health systems should estimate their workforce in both inpatient and outpatient facilities as well as satellite clinics. Statewide law enforcement and public safety employees should work with their local health district and/or local emergency manager(s) to estimate their workforce in both urban centers and satellite offices across rural Nevada. Accounting for workers by place of employment will help minimize underestimation of these critical workforce populations. The convenience of receiving vaccination at the place of employment (if feasible) may also result in increased vaccination coverage. NSIP has established procedures, including weekly calls and specialized staff teams, to communicate key messages and coordinate vaccination logistics for these groups.

[5] https://www.census.gov/quickfacts/NV

NSIP has many points of contact (POCs) in various healthcare and ancillary organizations and is leveraging established relationships to enroll providers serving the critical population groups. These partners include all FQHCs, RHCs, all acute care and critical access hospitals, and many adult and pediatric healthcare providers. NSIP is working with Nevada DETR leadership to obtain POCs at the organizations and businesses that employ the non-healthcare critical workforce contained within the priority groups. NSIP is using CDC's *Vaccination Implementation Strategies for Critical Populations (Appendix D)* to help inform program efforts in this area.

Further, NSIP maintains a strong presence in Immunize Nevada, the statewide non-profit immunization coalition and a trusted community organization. Many healthcare and social/community service organizations, including community representatives from the larger chain pharmacies, are active coalition members as well, creating a strong network for promoting and communicating about the COVID-19 vaccine response.

Immunize Nevada is testing and adapting its current flu media campaign to message vaccine confidence to Nevadans. The goal will be to empower families, combat myths and misinformation, and protect Nevada's communities as we wait for a COVID-19 vaccine, while continuing to encourage Nevadans to roll up their sleeves for flu shots.

The campaign will use the following channels that will reach Las Vegas, Reno, and rural Nevada residents through Dec 1 – 31, 2020:

· Digital outdoor boards

· Cable TV - Cox (includes a sports schedule as well)

· All digital capabilities from Spectrum Statewide (display, video, etc.)

· Streaming TV

· Social media - Facebook, Instagram

People with Underlying Health Conditions

NSIP worked with PHP and the Chronic Disease Prevention and Health Promotion Section to identify people with underlying health conditions; NSIP will continue to engage these partners to message about vaccine confidence and availability to those with underlying health conditions. Additionally, NSIP reached out to a wide variety of partners across the state seeking help in reaching this population once a vaccine is available, including health insurers who can easily and quickly reach covered members. NSIP maintains this list and is engaging partners in the planning process as appropriate.

Scientists are learning more about COVID-19 every day. **The below list of underlying medical conditions is not exhaustive and only includes conditions with sufficient evidence to draw conclusions**; it is a living document that may be updated at any time, subject to potentially rapid change as the science evolves.

This list is meant to inform clinicians to help them provide the best care possible for patients, and to inform individuals about their level of risk so they can make individual decisions about illness prevention. Notably, the list may not include every condition that might increase one's risk for developing severe illness from COVID-19, such as those for which evidence may be limited (e.g., rare conditions).

Individuals with any underlying medical condition (including those conditions that are NOT on the current list) should consult with their healthcare providers about personal risk factors and circumstances to determine whether extra precautions are warranted.

NSIP is using CDC guidance to identify the specific underlying health conditions causing the person to be at increased risk for severe illness from COVID-19:

- Cancer – Anyone currently undergoing treatment for cancer is at increased risk for severe illness from COVID-19. People with cancer who are treated with chemotherapy are at more risk because of their weakened immune system. An estimated 16,450 Nevadans were newly diagnosed with cancer in 2020 (American Cancer Society Facts and Figures, 2020).
- Chronic Kidney Disease – Anyone with Chronic Kidney Disease at any stage is at increased risk for severe illness from COVID-19 because they have a weakened immune system.
- COPD (chronic obstructive pulmonary disease), Cystic Fibrosis, Pulmonary Fibrosis, and other chronic lung diseases – Anyone with COPD or a related chronic lung disease at any stage is at increased risk for severe illness from COVID-19 because they specifically have very weak lung health, and COVID-19 is a respiratory disease (i.e., a disease that targets the lungs).
- Down Syndrome - Revisions were made on December 23, 2020 to reflect recent data supporting increased risk of severe illness among persons with Down syndrome from the virus that causes COVID-19.
- Heart conditions, such as heart failure, coronary heart disease, or cardiomyopathies – Anyone with any heart condition, including hypertension (high blood pressure) or stroke, could have an increased risk for severe illness from COVID-19 because they have weakened immune systems. In Nevada, cardiovascular disease is the leading cause of disease and death among adults.
- Immunocompromised from solid organ transplant – Anyone who has had a solid organ transplant is at risk of having a weakened immune system, because the body is relearning with the new organ, which increases their risk for severe illness from COVID-19.
- Obesity (Body Mass Index, BMI, of 30-39) and Severe Obesity (BMI of 40 or greater) – Obesity and severe obesity are risk factors for many chronic conditions and increase a person's risk of suffering severe illness from COVID-19. According to 2019 data from the

Behavioral Risk Factors Surveillance System (BRFSS), approximately 30% of Nevada adults are considered obese based on BMI.

- Pregnancy - Based on what we know at this time, pregnant people are at increased risk for severe illness from COVID-19 compared to non-pregnant people. Additionally, there might be an increased risk of adverse pregnancy outcomes, such as preterm birth, among pregnant people with COVID-19.
- Sickle Cell Disease – Anyone who has been diagnosed with sickle cell disease is at increased risk for severe illness from COVID-19 because they have a weakened immune system.
- Type 2 Diabetes mellitus – People who have a blood sugar level (A1C) between 5.7% and 6.4% are in the prediabetes stage and anyone with an A1C level higher than 6.5% is indicated to have diabetes. Having Type 2 diabetes, specifically, weakens the immune system and puts the person at increased risk of severe illness from COVID-19. Having Type 1 or gestational diabetes might increase the risk of severe illness. In 2019, approximately 11% of adults in Nevada reported being told by a health professional they have diabetes (excluding prediabetes and gestational diabetes).
- Smoking – Smoking is a risk factor for many chronic conditions and can increase a person's risk for severe illness from COVID-19. Smoking weakens lung health and COVID-19 is a respiratory disease (i.e., a disease that targets the lungs). Both former (have smoked at least 100 cigarettes in their lifetime) and current (smoke cigarettes every day or some days) smokers face heightened risk. From the most recent data available (2016 BRFSS), approximately 17% of adults in Nevada reported smoking.

Vulnerable and Marginalized Populations

State and local POD plans include provisions for the identification, notification, and vaccination of vulnerable populations (e.g., people who are homebound and homeless, people with physical and/or cognitive disabilities, racial/ethnic minorities, etc.). NSIP is working with the LHAs and Immunize Nevada to understand population language needs and community culture which could impact COVID-19 access, coverage, and/or uptake. Special consideration needs to be made for the under- and uninsured populations and underserved racial and ethnic minorities in Nevada, to ensure they receive equitable vaccine access during the COVID-19 vaccine response. Community outreach processes are built into the pandemic influenza planning structure and are being adapted to fit Nevada's COVID-19 vaccine response accordingly.

To ensure Nevada achieves this commitment, several state agencies and commissions missioned to service and/or advocate on behalf of these populations have reviewed the Playbook, including the **Nevada Statewide Independent Living Council (NV SILC), Nevada Governor's Council on Developmental Disabilities (NGCDD), Nevada Commission for Person's who are Deaf and Hard of Hearing, Nevada Commission on Services for Persons with Disabilities (CSPD), Nevada Commission on Aging, NOMHE, the Nevada Center for Excellence**

in Disabilities (NCED), and the Nevada Disability Advocacy and Law Center (NDALC). These groups provided NSIP with several valuable recommendations which have informed the following commitments:

- NSIP will distribute and make easily accessible accurate information about the COVID-19 vaccines and the distribution plan for reaching the disability community. This messaging will also include reminder protocols for the 2nd dose.
- NSIP will ensure the information above is available in other languages including but not limited to American Sign Language and Spanish.
- NSIP will provide proper education regarding contraindications, potential risks and benefits of the COVID-19 vaccine to the disability community to enable individuals to make an informed personal choice.
- NSIP will work with public and private vaccinating partners to ensure vaccine sites are accessible to people with disabilities who do not drive or are in settings that do not provide transportation, including walk-in clinics, mobile clinics, and/or working with transportation providers to secure no- or low-cost rides to vaccination sites.
- Vaccination reminder tracking tools to ensure 2nd dose accessibility will also be accessible.
- NSIP will work with state and local partners and agencies to ensure equal access to all information at the state, county, and local levels. The Americans with Disabilities Act (ADA) of 1992 requires State and local governments communicate as effectively with people who have a disability as someone without. This includes, but is not limited to, providing information in plain language, in screen-reader accessible formats, including graphic format that is understandable by people who may not be able to read, having live ASL interpreters, closed captioning and audio/visual descriptors (CART). NSIP understands artificial intelligence technology will not suffice when attempting to share such critical information as it often does not provide accurate subtitles.
- NSIP and vaccinating partners are leveraging previously established place-based vaccine partnerships (especially those involving chronic disease awareness raising organizations and community-level trusted institutions, including faith-based organizations) in planning for temporary/offsite/mobile vaccination events.
- DHHS/NSIP will publish a publicly accessible data dashboard to provide summary data which can be easily understood by the general population.
- NSIP will encourage vaccinating partners to ensure all levels of staff receive cultural competency training to best serve in diverse locations and environments.
- NSIP will engage minority focused professional associations such as the Nevada Hispanic Nurses Association, Black Nurses Association, the various chapters of the Student National Medical Association, etc.
- Future changes to this Playbook will continue to be physically highlighted to make the changes easy to identify. Updates will be broadcasted widely and specifically to

impacted communities in partnership with trusted individuals/agencies in the targeted communities.

Frequently Asked Questions from Nevadans

When will the general public be able to get vaccinated? How will I know when it is my turn?

Nevada counties are currently vaccinating those in Tier 1, which includes health care, public health and public safety personnel, and those living in long term care and assisted living facilities. This plan is subject to change and based on vaccine availability. If you would like to be notified when you are eligible for the vaccine, please complete this survey which will be shared with the jurisdiction where you live: Nevada COVID 19 Vaccine Interest Form

Nevada will use a variety of methods to ensure all Nevadans who are interested in vaccination have access when it is their turn, including traditional media outlets, social media, health care provider offices, and community partners.

Why do we need a vaccine if physical distancing and wearing masks can help prevent coronavirus spread?

Stopping a pandemic requires using all the tools available. Vaccines work with your immune system so your body will be ready to fight the virus if you are exposed. Other steps, like covering your mouth and nose with a mask and physical distancing, help reduce your chance of being exposed to the virus or spreading it to others. Together, COVID-19 vaccination and following CDC's recommendations to protect yourself and others will offer the best protection from COVID-19.

How many shots of COVID-19 vaccine will be needed?

The approved Pfizer-BioNTech vaccine and the Moderna vaccine in the United States both require two (2) shots to be fully effective.

How will I know when to return for my second dose?

The VaxText text messaging resource is a free service. **By texting ENROLL to 1-833-829-8398, vaccine recipients can opt in to receive a weekly text reminder for their second dose of COVID-19 vaccine or a reminder for when they are overdue for their second dose, in English or Spanish.**

In addition to VaxText, the State of Nevada plans to use multiple ways to notify you of your second dose. COVID-19 vaccination record cards (reminder cards) will be provided when you receive the COVID-19 vaccine. The card provides room for a written reminder for a second-dose appointment. If you have a smartphone, consider taking a photo of your vaccination record and entering the date the next vaccine dose is due in your calendar.

To ensure the best protection from COVID-19, it is very important to not skip the second dose. The second dose must be from the same vaccine manufacturer, so it will be important to ensure that where you receive your second dose has the right vaccine.

If I have recovered from COVID-19, do I still need to get a vaccine?

Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible, people may be advised to get a COVID-19 vaccine even if they have been sick with COVID-19 before. Individuals are advised to talk to their health care provider about whether they should get vaccinated for COVID-19 if they have already had the virus. At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called natural immunity, varies from person to person. Some early evidence suggests natural immunity may not last very long. We won't know how long immunity produced by vaccination lasts until we have more data on how well the authorized vaccines work.

What are the side effects of the COVID-19 vaccine?

Among the 36,000+ people who have received a mRNA COVID-19 vaccine through Phase 3 clinical trials (Moderna and Pfizer-BioNTech trials), no serious safety concerns have been reported. Some participants reported transient side effects including sore arm, fever, muscle pain and fatigue that resolved in 24 hours. Older adults reported fewer and milder side effects. In a small percentage of cases these side effects were severe — defined as preventing daily activities.

For more information go to NVCOVIDFighter.org

Related Guidance and Reference Materials

The CDC's Advisory Committee on Immunization Practices Recommendations

- ACIP votes on Phase 1b and 1c:
  - Phase 1b: persons aged ≥ 75 years and frontline essential workers
  - Phase 1c: persons aged 65-74 years, persons aged 16-64 years with high-risk medical conditions, and other essential workers
  - ACIP Agenda 12/19 and 12/20
  - View AIM's public comment on 12/20 to discuss Phase 1b and Phase 1c priority populations

Vaccinating Pregnant and Lactating Patients Against COVID-19 - Latest American College of Obstetrics and Gynecology (ACOG) Practice Advisory from December 13, 2020.

The NGCDD can offer valuable resources and information to vaccinating providers who serve or want to serve Nevadans in the disability community.

NASEM Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

Johns Hopkins Center for Health Security Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

The HHS Office for Civil Rights (OCR) webpage on Civil Rights and COVID-19 has several resources, including:

- BULLETIN: Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19)
- BULLETIN: Ensuring the Rights of Persons with Limited English Proficiency in Health Care During COVID-19
- BULLETIN: Civil Rights Protections Prohibiting Race, Color, and National Origin Discrimination During COVID-19: Application of Title VI of the Civil Rights Act of 1964.
- Information on the resolution of complaints filed with HHS OCR such as those that allege age and disability discrimination due to a state's crisis standards of care guidelines, etc.

Mapping Medicare Disparities Tool can be used to identify areas of disparities between subgroups of Medicare beneficiaries in health outcomes, utilization, and spending. It can assist with investigating geographic and racial and ethnic differences in health outcomes and inform decisions to focus on certain populations and geographies.

The CDC Vulnerability Index uses 15 U.S. census variables to help government officials identify communities that may need support before, during, or after disasters. Social vulnerability refers to the potential negative effects on communities caused by external stresses on human health, including natural or human-caused disasters or disease outbreaks. Reducing social vulnerability can decrease both human suffering and economic loss.

Section 5: COVID-19 Vaccination Provider Recruitment and Enrollment

An adequate network of trained, technically competent COVID-19 vaccination providers in accessible settings across the state is critical to Nevada's COVID-19 Vaccination Program success. For this reason, COVID-19 vaccination provider recruitment and enrollment may be the most critical activity conducted **before** vaccine becomes available.

NSIP is currently focused on engaging vaccination providers and services which can rapidly vaccinate the Tier 1 Critical Infrastructure Workforce (see *Section 4: Critical Populations)* as soon as a COVID-19 vaccine is available in Phase 1. Throughout Phases 1 and 2, NSIP and temporary contracted staff will work to recruit and enroll enough providers to vaccinate all other critical populations and eventually all Nevadans who desire a COVID-19 vaccine.

NOTE: Per the CDC Interim Playbook Version 2.0, "CDC has agreements with CVS and Walgreens to assist with on-site vaccination in LTCFs. These partners have existing distribution (including cold chain), administration, and reporting infrastructure and relationships with some LTCFs to provide medication and, in some cases, vaccination services (e.g., seasonal influenza) for staff and residents; this may reduce the total burden on DPBH/NSIP and the LHAs. CDC will ensure states have visibility on this work with large pharmacy partners." NSIP has met with these pharmacy partners in Nevada and will be engaging with them throughout the response.

Vaccination Provider Recruitment

In July 2020, NSIP distributed a provider survey using lists from various Nevada professional boards to gauge the interest of Nevada's healthcare providers in becoming a COVID-19 Vaccination Program Provider. To date, NSIP has received more than 4,000 responses in the affirmative. NSIP staff are prioritizing enrollment for acute care hospitals and providers who have responded and provided contact information. COVID-19 Vaccination Program enrollment has begun with the state's hospitals and other self-prophylactic organizations and is progressing to include outreach to community POD organizers, FQHCs, RHCs, individual doctors' offices and so forth. NSIP partnerships with acute care and critical access hospitals are integral to vaccinating Phase 1 populations in rural/frontier counties.

Weekly calls have been set up for enrolled providers to obtain and share timely information regarding COVID-19 vaccine and the response in Nevada. The calls currently include hospitals, LHAs, and rural CHNs as these facilities have been prioritized to receive the initial doses of COVID-19 vaccine allocated to Nevada. The Bureau of Child, Family and Community Wellness and NSIP are hosting these calls with administrative and clinical staff to answer questions about the COVID-19 vaccines available, vaccine storage and handling, and other logistical concerns related to enrollment in and administration of the Nevada COVID-19 Vaccination Program.

All providers/settings, especially those enrolled for Phase 1, must be able to meet the reporting requirements discussed in *Section 9: COVID-19 Vaccine Administration Documentation and*

Reporting and *Section 11: COVID-19 Requirements for Immunization Information Systems or Other External Systems.*

NSIP is using program-developed checklists to ensure enrolled providers have received all necessary training (e.g., vaccine storage and handling, vaccine administration, vaccination reporting, etc.) and have the necessary technology/connections before the program will allow vaccine to be shipped to the provider. Assurance of necessary technology may be done via an in-person site visit following any current statewide public health restrictions and only if assurance cannot be obtained virtually. Virtual assurance may be done via real-time video conference or by having enrolled providers submit pictures or screenshots.

Throughout Phases 1 and 2, NSIP will recruit additional COVID-19 vaccination providers to expand equitable access to COVID-19 vaccination as the vaccine supply increases. NSIP is considering physical location and the number of critical population groups in an area, as well as provider vaccination throughput capacity, to inform provider enrollment activities. Enrollment activities will be tracked in NV WebIZ and the federal vaccine tracking system, VTrckS, so providers are not approached multiple times. NSIP is leveraging and building upon established relationships with community partners, private providers, and collaborating with medical societies, HCQC, Nevada Medicaid, the CHNs, and tribal health entities to identify COVID-19 vaccination providers and the population groups they serve. NSIP is making every effort to engage traditional and nontraditional vaccination providers and settings.

NSIP will consider infection control measures currently necessary when selecting COVID-19 vaccination clinic settings for both private and public POD sites, such as:

- Providing specific appointment times or other strategies to manage patient flow and avoid crowding and long lines
- Ensuring there are enough staff and resources to help move patients through the clinic flow as quickly as possible
- Limiting the total number of clinic attendees at any given time, particularly for people at higher risk for severe illness from COVID-19
- Setting up a unidirectional site flow with signs, ropes, or other measures to direct site traffic and ensure physical distancing
- When feasible, arranging a separate vaccination area or separate hours for people at increased risk for severe illness from COVID-19, such as older adults and people with underlying medical conditions
- Making available a point of contact for any reasonable accommodation needs for people with disabilities
- Ensuring vaccination locations are accessible to individuals with disabilities consistent with disability rights statutes such as the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973

- Selecting a space large enough to ensure a minimum distance of 6 feet between patients in line or in waiting areas for vaccination, between vaccination stations, and in postvaccination monitoring areas[6]

CDC has also posted Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

CDC has identified 6 case reports of anaphylaxis following Pfizer vaccine administration. See the ACIP presentation on this here and clinical considerations here.

- Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States (reviewed 12/20/2020)
- Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC (reviewed 12/16/2020)

Vaccination providers are reminded to review, implement, and consult CDC's Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine. All ACIP recommendations related to COVID-19 vaccine can be found at ACIP COVID-19 Vaccine Recommendations | CDC.

Vaccination Provider Enrollment

To receive and administer COVID-19 vaccine, constituent products, and ancillary supplies, Nevada's vaccination providers and facilities must enroll in the federal COVID-19 Vaccination Program coordinated through NSIP using a REDCap survey database. Providers must enroll separately in the COVID-19 Vaccination Program even if they already participate in the VFC, "317" Adult, and/or Nevada Cocooning Programs. Enrolled COVID-19 vaccination providers must be appropriately credentialed/licensed in Nevada, and sign and agree to the conditions in the *CDC COVID-19 Vaccination Program Provider Agreement*. **If you are a provider wishing to enroll or would like more information, email NSIP staff at DPBHCOVID19VAX@health.nv.gov.**

CDC's conditions are detailed in the agreement itself:

1. Administer COVID-19 vaccine in accordance with ACIP recommendations.[7]
2. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), record in the vaccine recipient's record and report required information to NV WebIZ. The provider must maintain the vaccine administration records for at least 3

[6] **ACIP recommends providers consider observing patients for 15 minutes after vaccination to decrease the risk for injury should they faint**. For mobile and drive-through vaccination clinics, it will be important to assess parking to accommodate vaccine recipients as they wait after vaccination. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

[7] ACIP will review data on the safety and efficacy of each available COVID-19 vaccine and vote on recommendations for use.

years following vaccination. These records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.

3. Not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies provided by the federal government.
4. Administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay.
5. Provide an Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as applicable, to each vaccine recipient/parent/legal representative prior to vaccination.
6. Comply with CDC requirements for vaccine management, including storage and handling, temperature monitoring at all times, complying with NSIP instructions for dealing with temperature excursions, and monitoring expiration dates. Providers must keep all records related to COVID-19 vaccine management for a minimum of 3 years.
7. Report COVID-19 vaccines and adjuvants that were unused, spoiled, expired, or wasted as required by NSIP.
8. Comply with federal instruction regarding disposal of unused COVID-19 vaccine and adjuvant.
9. Report adverse events to the Vaccine Adverse Event Reporting System (VAERS)
10. Provide a completed COVID-19 vaccination record card to every vaccine recipient/parent/legal representative.
11. Comply with the U.S. Food and Drug Administration's requirements, including EUA-related requirements, and all applicable state and territorial vaccine laws.

Failure of any enrolled COVID-19 vaccination provider organization or vaccination location under its authority to meet the conditions of the agreement may impact whether COVID-19 vaccine product orders are fulfilled and may result in legal action by the federal government.

Enrolled COVID-19 vaccination providers must also fully complete the *CDC COVID-19 Vaccination Provider Profile* form for each location where COVID-19 vaccine will be administered. The profile form collects the following variables for each location:

- Address and contact information
- Days and hours of operation
- Vaccination provider type (e.g., medical practice, pharmacy, LTCF)
- Settings where vaccine will be administered (e.g., hospital, university, temporary or off-site clinic)
- Number of patients/clients served
- Influenza vaccination capacity during the peak week of the prior (2019-20) influenza season
- Population groups served (e.g., pediatric, adult, military, pregnant women, etc.)
- Current IIS reporting status
- Vaccine storage unit capacity in volume and ability to maintain required temperatures

The Provider Profile includes a field where the brand/model/type of storage unit is to be listed, requiring an attestation from the medical/pharmacy director or vaccine coordinator[8] that each unit will maintain the relevant required temperatures (i.e., refrigerated [2°C to 8°C], frozen [-15° to -25°C], ultra-cold [-60° to -80°C]. NSIP may request photos of vaccine storage units for confirmation if a physical inspection and enrollment visit cannot be conducted. Both forms (agreement and profile) may be submitted to NSIP electronically (i.e., via e-mail).

NSIP Staff will:

- Ensure the provider agreement, profile form, and redistribution agreement (if applicable) are thoroughly and accurately completed by each enrolled provider, retained on file for at least 3 years, and made available to CDC upon request.
- Verify COVID-19 vaccination providers (prescribers only, e.g., MD, DO, RPh, NP, PA) have active, valid licensure/credentials to possess and administer vaccine.
- Onboard COVID-19 vaccination providers to NV WebIZ:
    - All vaccination providers currently report to NV WebIZ per Nevada Revised Statute (NRS) 439.265 and associated Nevada Administrative Code (NAC). Existing provider profiles must be reviewed and may need to be updated by NSIP staff to facilitate COVID-19 vaccine ordering and documentation; additional user training will be necessary for newly enrolled providers and may be necessary for existing users. Successful onboarding will be coordinated between NV WebIZ, the NSIP Vaccine Manager, and the provider's staff.
    - NV WebIZ staff will ensure incorporation of COVID-19 supporting code values into electronic health record (EHR) systems for providers currently submitting data electronically via an HL7 (Health Level 7) interface.
- Onboard COVID-19 vaccination providers to VTrckS, if necessary; VTrckS use requires access to the CDC's Secure Access Management System (SAMS).
- Enter ship-to site information for each enrolled COVID-19 vaccination provider location in VTrckS via direct entry.
- Report COVID-19 vaccination provider enrollment data electronically to CDC twice a week (i.e., Monday and Thursday by 9:00pm EST), using CDC-provided Comma Separated Values (CSV) and JavaScript Object Notation (JSON) templates to report via a Security Access Management Services (SAMS)-authenticated mechanism. CDC will monitor each jurisdiction's provider enrollment progress.
- Ensure all COVID-19 vaccination providers have been trained appropriately to receive, store/handle, administer, and report use or wastage of COVID-19 vaccine and have the appropriate equipment at their location to manage any serious adverse events.

[8] A vaccine coordinator is the POC for receiving vaccine shipments, monitoring storage unit temperatures, managing vaccine inventory, etc. Enrolled facilities/organizations will need to designate a vaccine coordinator role at each location as well as a back-up vaccine coordinator role.

  - NSIP is using program-developed checklists to ensure enrolled providers have received all necessary training (e.g., vaccine storage and handling, vaccine administration, vaccination reporting, etc.) and have the necessary technology/connections before the program will allow vaccine to be shipped to the provider.
  - For new vaccination providers and nontraditional provider settings, NSIP will furnish vaccination planning guidance to ensure optimum staffing, layout, supplies, and infection control procedures are in place.
- Follow-up by email and telephone with any providers who become non-compliant with the federal requirements of the COVID-19 Vaccination Program. Nevada providers who cannot maintain compliance to these requirements even after training, follow-up, and coaching will be removed from the Nevada COVID-19 Vaccination Program (*participation in the COVID-19 Vaccination Program, or removal therefrom, does not impact a provider's participation in the Nevada VFC, Adult 317, or Cocooning Programs*).

COVID-19 Vaccination Provider Training

Provider training is vital to ensure the success of Nevada's COVID-19 Vaccination Program. CDC will have many educational resources available for use, including some that can be co-branded. NSIP currently uses a variety of tools to train and educate the existing enrolled provider network. NSIP provider management staff use annual checklists to track that training occurs for individual provider offices enrolled in the Nevada VFC, Adult 317, and/or Cocooning Programs. These checklists are being leveraged by the NSIP COVID-19 Vaccine Provider Enrollment Team to track training progress for the COVID-19 Vaccination Program.

Provider training tools include program-developed checklists and other written aids and infographics to help providers organize and implement a vaccination program. Other tools recently released and still in development include guided training videos, which can be viewed on-demand, walking providers through vaccine ordering, vaccine inventory management, vaccine administration, how-to guides for using NV WebIZ, etc. These materials can be revamped and revised as needed to fit the needs of the COVID-19 Vaccination Program.

Nevada's COVID-19 vaccination providers must understand the following:

- ACIP COVID-19 vaccine recommendations, when available
- How to order and receive COVID-19 vaccine, including the ultracold product
- COVID-19 vaccine storage and handling (including transport requirements/restrictions) for ultracold, frozen, and refrigerated vaccines
- How to administer vaccine, including reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
- How to document and report vaccine administration via NV WebIZ

- How to manage vaccine inventory, including accessing and managing product expiration dates (see *Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management*)
- How to report vaccine inventory using VaccineFinder
- How to report and manage COVID-19 vaccine inventory using NV WebIZ
- How to manage and report temperature excursions in vaccine storage units
- How to document, report, and properly dispose of or return unused COVID-19 vaccine
- How to document and report vaccine wastage/spoilage
- Procedures for reporting moderate and severe adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets or VISs to vaccine recipients
- How to submit facility information for COVID-19 vaccination clinics to CDC's VaccineFinder (particularly for pharmacies or other high-volume vaccination providers/settings)

Vaccine Administration Fee Reimbursement

In October 2020, the federal government announced that as a condition of receiving free COVID-19 vaccines from the government, vaccination providers will be prohibited from charging consumers for administration of the vaccine. Also in October, the Centers for Medicare and Medicaid Services (CMS) announced it was taking steps to ensure all Americans, including the nation's seniors, have access to the coronavirus disease 2019 (COVID-19) vaccine at no cost when it becomes available. CMS released a comprehensive plan and proactive measures to remove regulatory barriers and ensure consistent coverage and payment for the administration of an eventual COVID-19 vaccine for millions of Americans.

To ensure broad access to a COVID-19 vaccine for America's seniors, CMS released an Interim Final Rule with Comment Period (IFC) on October 29, 2020 that established that any vaccine receiving FDA authorization, either through an Emergency Use Authorization (EUA) or licensed under a Biologics License Application, will be covered under Medicare as a preventive vaccine at no cost to beneficiaries. The IFC also implements provisions of the CARES Act that ensure swift coverage of a COVID-19 vaccine by most private health insurance plans without cost sharing from both in and out-of-network providers during the public health emergency. In addition, the rule addresses vaccine coverage for adults and children under Medicaid and CHIP.

This rule allows states to employ a broad range of strategies - based on local needs - to appropriately manage their Medicaid program costs. The guidance and flexibility provided to states in the IFC will help them maintain Medicaid beneficiary enrollment while receiving the temporary increase in federal funding in the Families First Coronavirus Response Act (FFCRA).

CMS also released new Medicare payment rates for COVID-19 vaccine administration. The Medicare payment rates will be $28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of two or more doses, the initial dose(s) administration payment rate

will be $16.94, and $28.39 for the administration of the final dose in the series. These rates will be geographically adjusted and recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the COVID-19 vaccine. Medicare beneficiaries, those in Original Medicare or enrolled in Medicare Advantage, will be able to get the vaccine at no cost.

Along with these regulatory changes, CMS is issuing three toolkits aimed at state Medicaid agencies, providers who will administer the vaccine, and health insurance plans. These resources are designed to increase the number of providers that can administer the COVID-19 vaccine and ensure adequate reimbursement for administering the vaccine in Medicare, while making it clear to private insurers and Medicaid programs their responsibility to cover the vaccine at no charge to enrollees and beneficiaries. Together, these toolkits will help ensure the health care system is prepared to successfully administer a safe and effective COVID-19 vaccine by addressing issues related to access, billing and payment, and coverage.

Following is a brief summary of the coverage requirements for each major insurance type:

- **Medicare:** Beneficiaries with Medicare pay nothing for COVID-19 vaccines and their copayment/coinsurance and deductible are waived.
- **Medicare Advantage (MA):** For calendar years 2020 and 2021, Medicare will pay directly for the COVID-19 vaccine and its administration for beneficiaries enrolled in MA plans. MA beneficiaries also pay nothing for COVID-19 vaccines and their copayment / coinsurance and deductible are waived.
- **Medicaid:** State Medicaid and CHIP agencies must provide vaccine administration with no cost sharing for most beneficiaries during the public health emergency. Following the public health emergency, depending on population, states may have to evaluate cost sharing policies and may have to submit state plan amendments if updates are needed.
- **Private Plans:** CMS is requiring that most private health plans and issuers cover a recommended COVID-19 vaccine and its administration, both in-network and out-of-network, with no cost sharing. The rule also provides that out-of-network rates cannot be unreasonably low, and references CMS's reimbursement rates as a potential guideline for insurance companies.
- **Uninsured:** For individuals wo are uninsured, providers will be able to be reimbursed for administering the COVID-19 vaccine to individuals without insurance through the Provider Relief Fund, administered by the Health Resources and Services Administration (HRSA).

COVID-19 Vaccine is No-Cost to Nevadans

Medicaid, the Silver State Health Exchange/Nevada Health Link, and the Nevada Division of Insurance (DOI) have provided the information below on how each type of patient will be covered when getting the vaccine. According to Nevada Regulation 054-20, all health insurers are prohibited from imposing cost-sharing or medical management techniques to restrict access to COVID-19 screening, testing, or vaccines. People who are insured and are charged for COVID-related services should report the case to the Nevada Insurance Commissioner and the case may be referred for investigation. Patients can file a complaint at https://doi.nv.gov/Consumers/File-A-Complaint/.

Private Plans: In 2020, the DOI passed both an emergency and permanent regulation to ensure there will be no out-of-pocket costs to Nevadans covered by health insurance for COVID-19 testing and vaccinations. This means consumers who have coverage with individual health plans, small group plans, large group plans, and catastrophic plans will be covered to receive the COVID-19 vaccine without any co-payment, co-insurance, or other form of cost-sharing, including the cost of administering the vaccine. Nevadans who are insured by other entities outside of the insurance markets the Division regulates may still be covered to receive the vaccine by federal law. Consumers who are unsure what type of health plan they have are encouraged to contact their employer or health insurance company first. If they have other questions regarding health insurance coverage, they can also contact the Division's Consumer Services via email at cscc@doi.nv.gov or call 888-872-3234.

Insured through Nevada Health Link: The vaccine is free for Nevadans insured through Nevada Health Link plans. Nevada Health Link is the only place Nevadans can qualify for subsidies to help offset the costs of monthly premiums, and four out of five Nevadans who purchase a plan on Nevada Health Link qualify for financial assistance (tax credits). All plans offered through the Exchange cover the 10 essential health benefits including pre-existing conditions and all COVID-19-related diagnosis and treatment. For more information go to NevadaHealthLink.com or call 800-547-2927.

Medicaid: Nevada Medicaid covers all vaccines that are recommended by the ACIP as a preventive services benefit; this includes the COVID-19 vaccine. All Nevada Medicaid recipients will have COVID-19 vaccine coverage. The vaccine will be provided at no cost to recipients who are eligible or enrolled in Fee-for-Service or Managed Care. Nevada Medicaid also covers COVID-19 testing and medically necessary treatment. To apply for Nevada Medicaid, go to https://accessnevada.dwss.nv.gov/.

Uninsured: For Nevadans who do not have health insurance, first go to Nevada Health Link to see if you qualify for coverage at https://www.nevadahealthlink.com/ and find free local assistance from a certified broker or navigator. Nevada Health Link applications include review for coverage by Medicaid and many other providers. The uninsured may also seek the assistance of a Federally Qualified Health Center:

http://dhcfp.nv.gov/Pgms/CPT/FederallyQualifiedHealthCenters/FQHC/. Finally, uninsured Nevadans will have multiple options throughout the spring to access free temporary/off-site POD events dedicated to COVID-19 vaccine administration.

Role of Commercial and Federal Partners

Some multijurisdictional vaccination providers (e.g., select large drugstore chains, some IHS locations, Veteran's Administration clinics and hospitals, and other federal providers) will enroll in the COVID-19 Vaccination Program directly with CDC to order and receive COVID-19 vaccine. CDC will notify jurisdictions, like Nevada, of any entities receiving direct allocations within their areas. These direct partners will be required to report vaccine supply and uptake information to each respective jurisdiction. States are being encouraged to partner with commercial entities that are enrolled directly with CDC to reach their priority population groups. Large drugstore chains, for example, may be particularly helpful in conducting private PODs to reach Nevada's Tier 1 groups. NSIP is working with drugstore chains across the state to enroll individual stores in the COVID-19 Vaccination Program (separately from their enrollment with the CDC), as necessary and in collaboration with the LHA/emergency manager, to assist in vaccinating the Tier 1 workforce.

NSIP will also engage health insurance issuers and plans statewide regarding reaching members with chronic conditions. This engagement will begin at the end of 2020 as NSIP begins strategic planning to reach Nevadans with underlying health issues or chronic conditions know to worsen the effects of COVID-19. Health insurance plans can be helpful partners to assist in informing enrollees about local vaccination efforts.

Federal Direct Allocation to Federal Entities

Outlined below are the federal entities (and their respective populations) that will receive a direct allocation of COVID-19 vaccine from the federal government.

Federal Entity	**Population Served**
Bureau of Prisons (BoP)	• All BoP-managed facilities: facility staff and inmates • Private contracted facilities and contracted residential reentry centers (RRCs) **not included**
Department of Defense (DoD)	• Active duty personnel and their dependents • Retirees (does not include their dependents) • U.S. Coast Guard (does not include their dependents) • DoD civilian and contractor employees (those who regularly receive care through DoD as well as those who don't) • To be determined: Reserves and National Guard (including those not activated)

Department of State (DoS)	• All personnel under Chief of Mission eligible to receive care through DoS • Stateside civil service employees
Indian Health Service (IHS)	• Tribal nations selecting IHS for vaccine allocation • Potentially includes IHS/Tribal/Urban facility staff and individuals served
Veterans' Health Administration (VA)	• VA staff (including volunteers and trainees) and veterans regularly receiving care at VA facilities (State Veterans' Homes **not included**)

Federal Pharmacy Partnership for COVID-19 Vaccination in Long-Term Care Facilities

CDC is collaborating with CVS and Walgreens to provide on-site vaccination clinics for LTCF residents [and staff when indicated]. CDC is working closely with LTCFs, jurisdictions, CMS, professional trade organizations that serve nursing homes and assisted living facilities, and pharmacy partners to inform facilities of their options to receive COVID-19 vaccine. In Nevada, both LTCF staff and residents are listed in the updated Tier 1 and, therefore, both population groups will be covered under this plan.

NSIP has initiated and maintains regular communication with the Nevada State Board of Pharmacy which intends to engage NSIP in its vaccine distribution plans, should NSIP not naturally be included in the process at the federal level. Additionally, regional pharmacy managers and individual pharmacists are being engaged by NSIP for planning and enrollment purposes. Immunize Nevada and the Nevada State Board of Pharmacy are assisting NSIP in convening these partners.

The CDC Long Term Care Facility (LTCF) Toolkit Is now live on the CDC website! This toolkit is meant to be a resource for explaining COVID-19 vaccination to both residents and staff in LTCFs. It includes resources for talking with staff, residents, and families, FAQs on the vaccines, and tips on how to prepare staff and vaccine safety monitoring and reporting.

https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/index.html

Federal Direct Allocation to Pharmacy Partners (Phase 2)

To vaccinate a broader population group in Phase 2, vaccine will be allocated and distributed directly from the federal government to select pharmacy partners. Direct allocation opportunities will be provided to retail chain pharmacies and networks of independent and community pharmacies[9] (those with a minimum of 200 stores). All partners must sign a pharmacy provider agreement with the federal government. As part of such agreement, before

[9] Pharmacy services administrative organizations, or PSAOs

receiving COVID-19 vaccine, the partner must propose, in writing, its minimum capacity for vaccine administration, including:

a) The number and location of facilities that will administer COVID-19 vaccine
b) The estimated number of COVID-19 vaccine doses each facility will be able to administer within defined periods
c) Their estimated cold chain storage capacity

On a daily basis, pharmacy partners must report to CDC via designated methods the number of doses of COVID-19 vaccine a) ordered by store location; and b) on hand in each store reported through VaccineFinder. Pharmacy providers will also be required to report CDC-defined data elements related to vaccine administration to jurisdiction IISs (e.g., NV WebIZ). CDC will provide information on these data elements and reporting methods if stores are not able to directly provide data to jurisdiction IISs.

Note: Because of the state law mandating use of NV WebIZ in Nevada, all pharmacy partners either enter data directly to NV WebIZ or have automatic HL-7 interfaces between their electronic health record systems and NV WebIZ.

Partnerships with pharmacies will need to be synchronized with Nevada's plans to improve vaccination coverage and ensure transparency across the COVID-19 Vaccination Program. Nevada has opted-in to this program. Nevada will have visibility on vaccine supply and uptake data by store (see *Appendix E: Federal Pharmacy Partnership Strategy for COVID-19 Vaccination Program)*.

Related Guidance and Reference Materials

HHS authorization for state-licensed pharmacists to administer vaccines

Appendix F: Nevada Licensed Health Facilities Descriptions

Web Announcement #2389 from Nevada Medicaid regarding providers who wish to enroll to administer the COVID-19 vaccine:
https://www.medicaid.nv.gov/Downloads/provider/web_announcement_2389_20201223.pdf

Web Announcement #2395 from Nevada Medicaid regarding COVID-19 vaccine administration billing:
https://www.medicaid.nv.gov/Downloads/provider/web_announcement_2395_20201231.pdf

Governor Sisolak signs emergency regulation to support immunization efforts

Section 6: Understanding Nevada's COVID-19 Vaccine Administration Capacity

Occupational health settings, temporary vaccination clinics, and closed/private PODs will be particularly useful for vaccination of Nevada's Tier 1 Critical Infrastructure Workforce and other identified critical populations early in Nevada's COVID-19 vaccination response when vaccine supply may be limited. However, once vaccine supply increases, leveraging a wide variety of public- and private-sector COVID-19 vaccination providers and settings is essential to providing equitable and broad access to COVID-19 vaccination for all Nevadans.

"Vaccine administration capacity" is defined as the maximum achievable vaccination throughput regardless of public demand for vaccination. The *CDC COVID-19 Vaccination Provider Profile* includes patient reach counts; this data provides NSIP with the state's vaccine administration capacity. The goal is to enroll enough providers to reach every Nevadan who wants the COVID-19 vaccine, even if that is all 3.1 million residents.

NSIP will consider vaccine throughput capacity when choosing provider sites to "turn on" first; in other words, facilities that can vaccinate more people faster will be prioritized for enrollment completion compared to facilities with lower/slower throughput capacity. However, any Nevada provider who can meet the requirements of the COVID-19 Vaccination Program will eventually be enrolled and able to receive COVID-19 vaccines to administer to their patient population.

Important elements NSIP is considering when estimating Nevada's vaccination capacity:

- Number of existing vaccination provider locations in Nevada, by type of vaccination setting, and by populations served (e.g., adult internist, pediatrician, family practice, etc.) = 970 immunizing providers representing 2,055 immunizing clinics.
- Estimated potential weekly COVID-19 vaccine administration capacity (throughput); NSIP is collecting COVID-19 Provider Profiles to determine this number
- Estimated vaccination provider participation rate in the COVID-19 Vaccination Program

NSIP uses aggregate data analyses from NV WebIZ of doses administered by provider location to continuously assess the state's vaccine administration capacity and will be conducting outreach beginning in October 2020 and throughout the vaccine response to a variety of vaccination provider types and settings which have the potential to be COVID-19 vaccine administration sites, including, but not limited to:

- Healthcare provider offices and other outpatient clinic settings; NSIP is working through the Nevada Board of Medical Examiners to outreach to vaccinating providers who do not already participate with the state's immunization programs
- Public health clinics, such as those operated by the LHAs, CHNs, FQHCs and RHCs across Nevada

- Chain and independent pharmacies, such as CVS, Walgreens, Walmart, grocery store chain pharmacies, etc. NSIP is working closely with the Nevada Board of Pharmacy on efforts to engage with pharmacists regarding the COVID-19 vaccine response
- Worksites and other occupational health clinics (e.g., Concentra, Nevada Injured Workers, etc.) will be nontraditional providers/settings for NSIP to collaborate with more closely; NSIP is working with Immunize Nevada, NOMHE, state universities, and other community partners to engage with and understand these settings as the state moves to serving other prioritized groups
- Hospitals – NSIP has relationships with the NHA, NRHP, has done direct individual outreach to the rural hospitals, and most hospitals are enrolled with NSIP for VFC, 317 Adult, and state-funded Cocooning vaccines for maternal populations
- Temporary or off-site vaccination clinics and mobile/remote vaccination clinics, which can be held by both public and private vaccinators

When assessing vaccine administration capacity, NSIP must consider:

- COVID-19 vaccine storage capacity at a given location (e.g., the quantity of COVID-19 vaccine that can be stored at the location, storage equipment and temperature monitoring devices that meet CDC requirements); locations that can safely store a larger quantity of COVID-19 vaccines are more likely to have a larger throughput capacity, as long as staffing levels are also sufficient
- Existing vaccine administration capacity during seasonal influenza or other high vaccination periods (e.g., back-to-school) and whether the site can realistically reach a higher capacity during the COVID-19 pandemic
- Current provider/setting staffing levels; providers with sufficient vaccinating staff who cannot easily be pulled away to other activities will have a higher throughput capacity, as long as vaccine storage capacity is also sufficient
- Routine immunization programs being conducted simultaneously that may affect throughput for COVID-19 vaccination in certain vaccination provider settings (i.e., traditional pediatricians may have lower throughput capacity for COVID-19 vaccines compared to an adult internist, because they have so many more vaccines to administer to their patients as a regular course of business)
- Infection control measures (i.e., scheduling capabilities and policies, physical distancing, donning and doffing personal protective equipment, cleaning/sanitation procedures) that may slow the vaccination process and impact capacity estimates
- Timing and duration of COVID-19 vaccination provider participation due to changes in staffing or other resources throughout the response
- Clinic closures due to environmental or other factors (e.g., seasonal weather patterns, wildfires, holidays, etc.)

NSIP will seek input throughout the vaccine response from a variety of vaccination provider types to inform this process. NSIP began engaging the hospitals and the Board of Pharmacy in

late September 2020 and all other healthcare provider types, using the Board of Medical Examiners listserv, in November 2020. Previous vaccination exercises, such as Nevada's H1N1 response and after-action reports, will also provide helpful information to inform this process.

Vaccinators in Nevada

State and local POD plans include workforce protection considerations calling for vaccination of all volunteers. Local POD plans also include a list of local healthcare workers, institutions, as well as non-medical volunteers who will staff their PODs. Further, plans include staffing configurations to operate PODS of differing sizes, as well as staffing for multiple shifts if needed. Plans further include a call-down system for volunteers. Volunteer staffing is the primary responsibility of the local Emergency Manager for each POD. Nevada maintains a Medical Reserve Corps list and a Regional Volunteer Organizations list. The Nevada State Board of Nursing, in partnership with NSIP and PHP, sent out a call to action in October 2020 requesting interested nurses to sign up to be a volunteer immunizer during the COVID-19 vaccine response.

Pharmacy Technicians can vaccinate based on state emergency regulation and federal emergency regulation beginning September 2020. Pharmacists have been vaccinators in Nevada for many years and remain a strong access point for all Nevadans in Phase 2 and beyond.

NSIP has partnered with Nevada's Emergency Medical Service program to work with Emergency Medical Technicians (EMTs) across the state to ensure they are ready and trained to vaccinate. Approximately 60 EMTs have taken the immunization training in the last month to prepare for the COVID-19 vaccine response.

Related Guidance and Reference Materials

CDC has developed a tool to assist with estimating vaccination capacity. A pandemic influenza version of this tool, the PanVax Tool for Pandemic Vaccination Planning, is available on the CDC website. The tool is currently being updated by CDC.

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

Initial supplies of COVID-19 vaccine became available the week of December 14, 2020. Early dose distribution continues to be limited; therefore, phased allocation of early doses remains necessary. Populations of focus for initial COVID-19 vaccine doses in Nevada are based on the Priority Groups in *Section 4: Critical Populations*. This group includes healthcare workers (including ancillary staff, vaccinators, and staff in LTCFs) and LTCF residents.[10] NSIP anticipates allocations to shift during the response based on vaccine supply, demand, vaccine characteristics, and disease epidemiology and is planning for high-demand and low-demand scenarios.

CDC is working with other federal partners of OWS to plan and implement a national COVID-19 Vaccination Program. The federal government's goal is to produce and deliver 300 million doses of safe and effective vaccines, with the initial doses available before the end of 2020. This approach for centralized vaccine ordering and distribution will be executed in phases by CDC in collaboration with jurisdictions, tribes, federal agencies receiving a direct allocation of vaccine, and commercial partners.

The information within this section will continue to evolve as new information becomes available.

Vaccine Allocation

The federal government will determine the amount of COVID-19 vaccine designated for each jurisdiction. COVID-19 vaccine will be allocated to Nevada (by the CDC) according to the following principles:

- Allocations will be calculated pro-rata based on the size of the jurisdiction's population and the quantity of ready-to-ship doses from manufacturers.
- Allocation amounts will be communicated to jurisdictions weekly each Tuesday. These allocations will be immediately available for ordering.
- If a jurisdiction does not order the full allocation, the remainder will roll over for future ordering. Unused allocations will not be allocated to other jurisdictions.

For the two initial vaccine products (Pfizer and Moderna), two doses will be required, **and the same product must be used for both doses.** Two-dose vaccine allocations will be managed in the following way:

- In coordination with vaccine manufacturers, CDC will reserve and store inventory of second-dose product to include in future allocations for ordering at the appropriate

[10] Subject to any vaccine product-specific age restrictions

time (e.g., 2 weeks after first doses are ordered for a product requiring the second dose on Day 21).

- CDC does not expect jurisdictions or federal and commercial partners to maintain physical inventory of second-dose product (i.e., jurisdictions will not be expected to store product for 21-28 days to prepare for second-dose administration).

In Nevada, NSIP will then be responsible for managing and approving vaccine orders from enrolled providers using the state's allotment. The amount allotted will change over time and may be impacted by COVID-19 vaccine production and availability of releasable doses from manufacturers (i.e., doses which have met specific FDA manufacturing standards). Federal agencies and additional commercial partners will also receive allocations directly from CDC. CDC is currently developing procedures to ensure jurisdictions and tribes have full visibility of COVID-19 vaccine supply and vaccination activities among these entities located within their boundaries.

NSIP has developed a prioritized allocation methodology for critical populations of focus in early- and limited-supply scenarios, following the CDC's phased methodology. NSIP will ensure the providers/settings enrolled in the COVID-19 Vaccination Program are based on the capacity of each population group they can serve. Allotments of doses to vaccination providers in Nevada will be based on:

- ACIP recommendations
- Estimated number of doses allocated to Nevada and timing of availability
- Populations served by enrolled providers and geographic location of provider settings to ensure equitable statewide distribution
- Vaccination provider site vaccine storage and handling capacity
- Minimizing the potential for wastage of vaccine, constituent products, and ancillary supplies
- Other local factors as appropriate

Nevada Expects Limited Doses of COVID-19 Vaccine

NSIP does not expect to receive enough doses of COVID-19 vaccine to cover all Nevadans in the first months of the response. A priority list has been developed for a stepped vaccination process, starting with acute care facilities, health care workers and staff, and long-term care facility residents. Eventually, Nevada will be allocated enough COVID-19 vaccine to start vaccinating larger groups, in the following general order (some individuals may overlap):

- Nevadans 70 years and older
- Frontline essential workers
- Nevadans ages 65-69 years
- Those ages 16-64 years with comorbid or underlying health conditions
- All other essential workers

NSIP will be using the methodology approved by the Governor's COVID-19 Mitigation and Management Task Force to monitor county-level disease transmission. A county is flagged for elevated disease transmission if it meets two of the three criteria:

1. **Average number of tests per day (per 100,000) < 100.** The average number of molecular tests conducted in the most recent complete two-week period in a county, divided by the number of people living in the county. This number is then multiplied by 100,000 to control for varying populations in counties. Due to reporting delay, this is reported over a 14-day period with a 7-day lag. Counties that average fewer than 100 tests per day will meet this criterion.
2. **Case rate (per 100,000) > 200.** The total number of cases diagnosed and reported over a 30-day period divided by the number of people living in the county. This number is then multiplied by 100,000 to control for varying populations in counties. Counties with a case rate greater than 200 per 100,000 will meet this criterion.
3. **Case rate (per 100,000) > 50 AND testing positivity > 8.0%.** The total number of positive molecular tests divided by the total number of molecular tests conducted. This number is then multiplied by 100 to get a percentage. Due to reporting delay (which may be different between positive and negative tests), this is reported over a 14-day period with a 7-day lag. Counties with a test positivity > 8.0% paired with case rate greater than 50 per 100,000 will meet this criterion.

Using these established criteria, NSIP will determine which counties are experiencing elevated disease transmission. Based upon real-time analyses, NSIP can allocate vaccine to those counties using a data-driven, targeted approach. Healthcare workers and healthcare facility staff within the counties determined to have elevated disease transmission are likely at greater risk of exposure and development of COVID-19 and becoming too ill to work.

Allocation Plan Using County-Level Criteria

The county-level criteria for elevated disease transmission is analyzed weekly on Mondays. This data will be used to drive the vaccine allocation decision making process when there is limited vaccine supply. The counties will be ordered by those with the most disease transmission to those with the lowest beginning the first week of November 2020.

- Once NSIP receives COVID-19 vaccine allocation, NSIP will ensure they are in proper descending order.
- Each county priority population will be allocated to 80% before moving to the next county.
    - This is subject to change if vaccine uptake in a county is significantly low
- Each population group (i.e., acute care facilities, outpatient providers, pharmacists, etc.) will be allocated all the way through the counties before moving to the next population group.
    - Example: acute care facilities will be covered to 80% allocation in a county before the county moves to the next priority group.

- If there is not adequate vaccine supply to encompass an entire priority group within a county, county leadership will be engaged to make local determinations on how to further prioritize distribution within that group.

Next steps moving forward:

- At least weekly, beginning November 1, 2020 ongoing, NSIP needs an updated list of county criteria analyses.
- If there is not enough vaccine to cover all acute care facilities in a county, the LHA will be engaged to help make decisions on critical populations to receive the initial doses. Considerations will be made for allocating a small amount of vaccine to each acute care facility in a county to cover emergency department, intensive care unit, and/or COVID unit staff.

See Section 4: Critical Populations for more information.

Vaccine Ordering

Initially, throughout the month of December and potentially during the beginning of January, COVID-19 vaccines will be allocated (i.e., ordered on behalf of the provider) by the NSIP Vaccine Manager to those providers serving Tier 1 and the Frontline Critical Workforce. As vaccine supply increases, COVID-19 vaccination providers enrolled by NSIP will be able to request COVID-19 vaccine doses using NV WebIZ following the same methods and procedures used by currently enrolled VFC, 317 Adult, and Nevada Cocooning Program providers. This process allows NSIP to submit provider's direct vaccine orders via an IIS/ExIS upload to CDC's VTrckS, the system that must be used to order COVID-19 vaccines.

CDC will provide Nevada with regular updates on the available vaccine supply and vaccine product-specific allocations for Nevada's enrolled COVID-19 vaccination providers in VTrckS. During Phase 1 of the vaccination program, when there is limited vaccine supply for critical populations, NSIP will approve COVID-19 vaccine orders based on the likely populations served by a vaccination provider, the provider's capability to store and handle various COVID-19 vaccine products, and their existing vaccine inventory.

CDC instructions for vaccine ordering:

1. Each jurisdiction, federal agency, and commercial partner will receive allocations (order caps) weekly in VTrckS.
2. Jurisdictions, federal agencies, and commercial partners will submit orders for vaccination provider sites. These orders will be processed against the allocation (order cap).
3. Orders will be schedule for delivery Monday through Friday.

Direct-Ship Vaccine (Pfizer Product):

A. The minimum order volume for the Pfizer COVID-19 vaccine is 975 doses.
B. NSIP must identify delivery sites that can receive shipments of the Pfizer COVID-19 vaccine in 975-dose increments, based on what is feasible to administer on a weekly basis.
C. Following ACIP recommendations, additional sites will be added to place orders against Nevada's allocation. Vaccine can be ordered five days a week and will be delivered on business days within 24-48 hours of order placement.
D. As stated in further detail below, along with vaccine, each site will receive ancillary kits and an initial dry ice resupply (unless opting out):
    a. Ancillary supply kits will include diluent and vaccine administration materials. Ancillary supply kits will be automatically added to vaccine orders and do not require additional action or separate orders.
    b. OWS will provide an initial dry ice resupply to facilitate storage in coordination with each vaccine shipment. Nevada's COVID-19 vaccination providers will have the option to opt out of the initial dry ice resupply if desired. Sites will receive this initial dry ice resupply in coordination with receipt of the product, as they will need to replenish the dry ice upon product receipt.

Cancelling Orders

Given the rapid order processing and shipping timelines for COVID-19 vaccines, the ability to cancel orders for these vaccines after approval is quite limited and possible only during a short window of time following order submission. The ability to support order cancellation is very restricted compared to the routine vaccine program.

COVID-19 vaccine order cancellations can only be requested by awardee (e.g., NSIP) and federal agency/pharmacy points of contact (<u>not by providers or administration sites</u>).

The ability of the manufacturer or distributor to cancel an order depends upon where the order is in the process of being filled and shipped, so if a cancellation is requested, that request should be submitted to the NSIP Vaccine Manager or the County's Surge Lead POC as soon as possible after order approval.

Ancillary Supplies

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. For centrally distributed vaccines, each kit will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
    - 25-gauge, 1" (if vaccination indicated for pediatric population)

  - 22-25-gauge, 1-1.5" (adult)
- Syringes, 105 per kit (ranging from 1-3mL)
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit
- Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)

If a COVID-19 vaccine that requires mixing with diluent is ordered and shipped from CDC's centralized distributor, a mixing kit that includes the necessary needles, syringes, and alcohol prep pads will also be automatically added to the order. For centrally distributed vaccines, providers will have the option to submit the order in a way that opts out of receiving the administration and mixing kits, if so desired. For vaccines that are shipped directly from the manufacturer, a combined kit will be included. This combined kit will include administration supplies (as noted above), mixing supplies, and vials of diluent to prepare the vaccine for use. Because it contains diluent, providers will not have the option to opt out of requesting this combined ancillary kit.

Ancillary supply kits *will not include* sharps containers, gloves, and bandages. Additional PPE also may be needed depending on vaccination provider site needs.

Facilities ordering outside of Nevada's allocation (e.g., commercial and federal entities with federal MOUs in place) will order vaccine directly from CDC, and CDC will be responsible for approval of those orders.

Contents and Quantities for Mega Kits to Support Pfizer Vaccine

On December 11, 2020, McKesson released clarification about the needles and syringes included in the COVID-19 ancillary supply kits for administering Pfizer's ultracold vaccine. Based on questions to their call centers, there has been some confusion about the quantities of needles and syringes included in the kits. Each kit supports the administration of 975 doses and is clearly labeled with a complete inventory list, including:

- 22G – 25G, 1 in Needles QTY 829
- 22G – 25G, 1.5 in Needles QTY 200
- 1mL Syringes QTY 1,024
- 21G – 25G, 1.5 in Needles QTY 205
- 3mL or 5mL Syringes QTY 205
- Sterile Alcohol Prep Pads QTY 2,458
- Needle Information Card QTY 10
- Vaccination Cards QTY 1,000
- Disposable Face Shields QTY 20
- Surgical Masks QTY 40

- 2mL Diluent QTY 200

Procuring the sheer number of needles and syringes needed to support an operation of this size involves complex logistics, which is why vaccine administrators may see variance in how the supplies are packaged. The listed products may be received as a combo, defined as a single packaged needle and syringe, or as individual components. The quantities listed on the label represent the minimum number of total combinations in each kit.

- For example, if the kit above was shipped with (829) 1ml-25Gx1" syringe/needle combos and (200) 22Gx1.5" needles for administration, the kit would only contain (200) 1ml syringes to accompany the needles. This would yield a total of (1,029) needles with accompanying syringes (some packaged together, some individually).
- If a kit contained only individual needles and syringes, there may be 5 more needles than syringes. This is intentional and is designed to improve your experience and maximize the inventory across all kits built.
    - In this scenario, the adjustment was to the 22-25Gx1.5" needles. The kit was originally configured to have 195. This was increased by 5 (to 200) to improve the administrators' experience by using two whole boxes.

Please note there will be multiple configurations used as the federal government continues to prepare to procure products to support the assembly of these and other ancillary supply kits. Regardless of configuration, the kit contents will meet the minimum quantities listed on the kit content labels and will support the same total number of doses.

Vaccine Distribution

COVID-19 vaccines and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will use its centralized distribution contract to fulfill orders for most vaccine products and associated ancillary supplies. In Nevada, vaccine is expected to be distributed using the NV WebIZ/VTrckS ordering process to communicate to the centralized distributor (e.g., McKesson for Nevada) in Aurora, CO and shipped from there directly to enrolled vaccination provider sites. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site or will by physically redistributed by NSIP or approved LHA staff (but is still ordered following the procedure above).

NSIP staff will ensure accurate and complete shipping information (e.g., shipment address, provider contact information, shipping hours, etc.) is available in VTrckS for all vaccine shipments to enrolled vaccination providers. To support more efficient distribution of vaccine, Nevada is asking providers to consider providing full day receiving hours to the extent possible. When that is not possible, locations identified to receive vaccine and ancillary supply shipments must be available during a 4-hour window on a weekday other than Monday to receive those shipments.

Per the CDC, COVID-19 vaccine (and diluent or adjuvant, if required) will be shipped to enrolled vaccination provider sites in Nevada within 48 hours of order approval [in VTrckS]. Because of cold-chain requirements, ancillary supply kits (and diluent, if applicable) will ship separately from vaccine but should arrive before or on the same day as vaccine.

The federally contracted vaccine distributor (e.g., McKesson for Nevada) uses validated shipping procedures to maintain the COVID-19 vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. Once a vaccine product has been shipped to an enrolled COVID-19 vaccination provider site, the federal government will neither redistribute the product nor take financial responsibility for its redistribution. (See *Section 8: COVID-19 Vaccine Storage and Handling* for more information).

Local Health Authorities and Community PODs

LHAs are traditional vaccination providers enrolled in other NSIP-administered programs for public vaccines; therefore, they will place vaccine orders in NV WebIZ and COVID-19 vaccine will be shipped directly to LHA or CHN clinic sites where PODs will be conducted following state/local POD protocols. Ensuring the physical security of the vaccine will be the responsibility of the LHA or CHN POD coordinating authority. If PODs are conducted off-site from the normal physical location, then LHA or CHN staff must transport the vaccine following validated cold-chain procedures in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. LHAs and CHNs will maintain vaccine inventory using NV WebIZ and document all vaccine received, including vaccine type, manufacturer, lot number, expiration date, and the quantity of vaccine received, as required by the Nevada State Immunization Program Policies and Procedures Manual.

Redistribution and Transportation of COVID-19 Vaccines

Whenever possible, vaccine should be shipped directly to the location where it will be administered to minimize potential breaks in the cold chain. However, there may be circumstances where COVID-19 vaccine needs to be redistributed beyond the identified primary CDC ship-to sites (i.e., for orders smaller than 100 doses for rural providers or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations).

In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be allowed, as approved by NSIP and when necessary, to redistribute frozen/refrigerated COVID-19 vaccines, if validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. *Redistribution of Pfizer's ultracold vaccine will only be conducted by NSIP staff or trained and authorized LHA staff.* Any entity redistributing frozen/refrigerated COVID-19 vaccines must sign and agree to conditions in the *CDC COVID-19 Vaccine Redistribution*

Agreement for the sending facility/organization and have a fully completed and signed *CDC COVID-19 Vaccination Provider Profile* form for each receiving location.

NSIP will be extremely judicious in allowing any redistribution of COVID-19 vaccines and will limit any redistribution to refrigerated vaccines only, following CDC standards and guidance. Unapproved providers transporting or redistributing vaccine (i.e., those who have not been issued a Redistribution Agreement) may face consequences up to dismissal from Nevada's COVID-19 Vaccination Program, especially if vaccines are wasted/destroyed during their unapproved/unplanned redistribution.

NSIP or LHA staff will occasionally assist providers with local transport of vaccines from one location to another within their jurisdiction, especially to prevent COVID-19 vaccine wastage whenever possible, if adherence to cold chain and tracking requirements can be maintained. NSIP may also call upon ESF 1: Nevada National Guard, DPBH PHP, County Health Officers and Emergency Managers, or the Nevada State Police to provide transportation of vaccines to supplement NSIP-contracted courier services, if necessary.

**CDC does not pay for or reimburse jurisdictions, COVID-19 vaccination provider organizations, facilities, or other entities for any redistribution beyond the initial designated primary CDC ship-to location, or for any vaccine-specific portable refrigerators and/or qualified containers and pack-outs.*

Pfizer Vaccine Redistribution Guidance

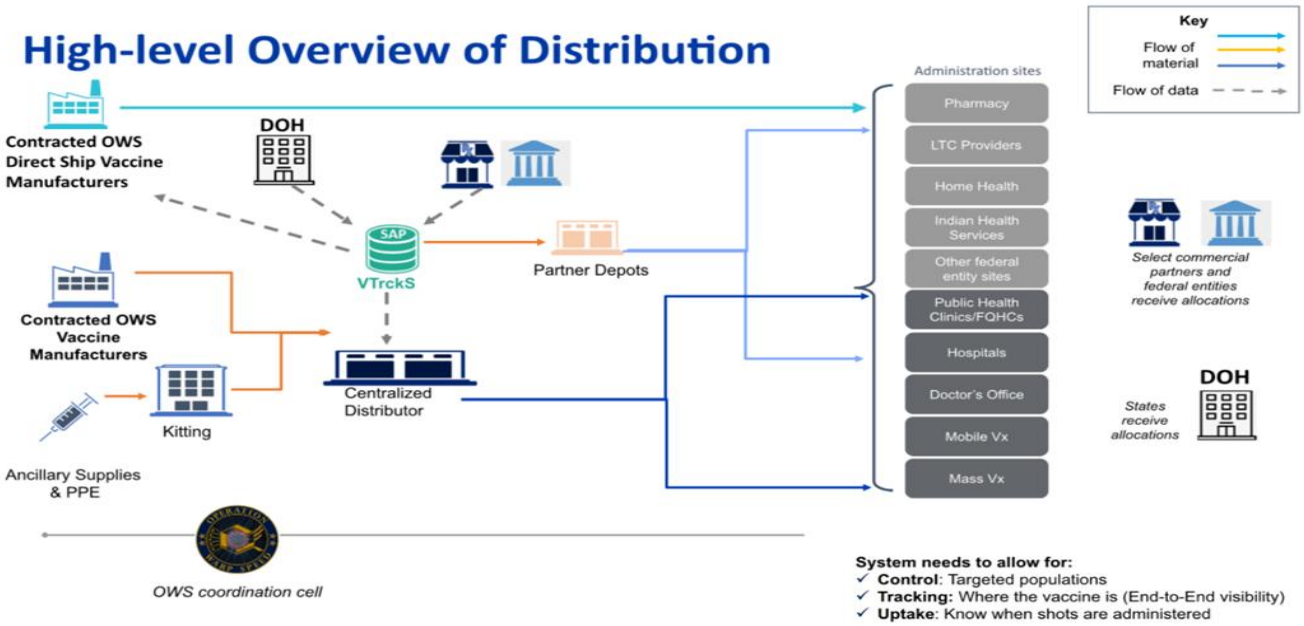
CDC recognizes that **redistribution** of vaccine may be required by state and local immunization programs or their trusted partners. Based on information to date from Pfizer-BioNTech, immunization planners should consider the following:

- *Only start the redistribution process for product that will be used as soon as it arrives at the new location; do not redistribute product to a new location for long term storage.*
- *Move only the amount of vaccine that is needed at the satellite locations/clinics.*
- *Once a vaccine vial has been removed from the tray, the thawing process has begun. The vial cannot be returned to the thermal shipping container or to an ultra-cold freezer.*
- *Vaccine, once thawed, is viable for up to 120 hours (5 days) at 2-8C. Vaccine may be transported at 2-8C if needed. After 120 hours, vaccine must be used or discarded. Any hours used for transport count against the 120-hour limit.*
- ***If needed, ultra-frozen vaccine may be transported in its original shipping container with dry ice or in a portable ultra-cold freezer that can maintain a temperature of -80º C, however, only full trays of vaccine can be redistributed using this method in order to reduce the likelihood of damaging the vaccine vials in transit.***

Moderna Vaccine Redistribution Guidance

Moderna vaccine may be shipped directly to sites in volumes of 100 doses per carton. Given the smaller shipment size compared to other vaccines, CDC recommends that each site administering vaccine receive a direct shipment. However, CDC recognizes that **redistribution** of vaccine may be required in some instances by jurisdictions, federal and pharmacy partners. Based on information to date from the manufacturer, for the Moderna COVID-19 Vaccine, immunization planners should consider the following general principles for vaccine redistribution:

- Once a vial of vaccine has been thawed, it may be stored refrigerated at 2-8°C for up to 30 days.
- Once thawed, the vaccine cannot be re-frozen.
- When thawed, the vaccine should be handled with care and protected from shocks, drops, vibration, etc.
- Vaccine being transported at temperatures others than frozen (-15 to -25°C) should begin with the vaccine in the frozen state if at all possible.
- If you must transport vaccine that has already been thawed, follow these general principles:
    - **Punctured vials should not be transported.**
    - Care must be taken to ensure vaccine does not re-freeze during transport.
    - Vaccine must be protected as much as possible from drops, shocks, and vibration whether in the carton, vial, case or cooler.
    - Vaccine should be transported in the carton whenever possible.
    - If transport must be conducted at the vial level, the vial should be placed with dunnage (padding material like bubble wrap or similar padding) to minimize movement during transport.
    - The vaccine should always be transported in insulated containers qualified to maintain 2-8°C for the duration of transport.
    - The transport containers must be secured when being transported to prevent unnecessary movement.
    - After completion of transport, vaccine should immediately be placed into a vaccine storage unit at 2-8°C.
    - Vaccine should only be transported one time and should not be transported back again to the point of origin or to a new location.
    - **Allowable timelines for transport of thawed vaccine are shown below. Total transport time should not exceed 12 hours in total.**
        - Transport while walking or using hand cart: not to exceed 1 hour
        - Vehicle transport: not to exceed 12 hours
        - Airplane transport (rotary wing aircraft not allowed): not to exceed 3 hours



Vaccine Inventory Management

COVID-19 vaccination providers will be required to report inventory of COVID-19 vaccines using VaccineFinder, and NSIP must ensure this inventory information is submitted daily. The State of Nevada through NSIP is responsible for the oversight, management, and accountability of each dose of Nevada's allotment of COVID-19 vaccine. Once providers are enrolled in VTrckS, they will be preregistered for a VaccineFinder account and provided instructions via email on how to submit daily supply information. NSIP also requires providers to submit vaccine inventories on hand when placing an order for more vaccine to help inform allocation decisions in real-time. All inventory should be managed in accordance with storage and handling requirements specific to each vaccine.

When COVID-19 vaccine arrives at an enrolled provider's location, the vaccine inventory needs to be entered in their account in NV WebIZ; provider staff enrolled with NSIP are required to maintain vaccine inventory and complete monthly inventory reconciliations using NV WebIZ. Providers will need to follow all chain-of-custody and general vaccine storage and handling practices outlined in the Nevada State Immunization Program Provider Manual.

Vaccine inventory management and accountability is paramount to ensuring patients can be called back for their second dose of the same vaccine product. Further, COVID-19 vaccine will be distributed to most providers in 100-dose increments. It is imperative for traditionally enrolled vaccination providers who are also enrolled in the COVID-19 Vaccination Program to have storage capacity in their vaccine storage units to hold COVID-19 vaccine *and their normal stock of VFC, 317, Cocooning, and Private-Purchase vaccines.*

It is anticipated COVID-19 vaccines will initially be authorized under an EUA. Vial and carton labels for vaccines *authorized* under an EUA will contain slight variations from labels typical of *approved* FDA products, including:

- **Expiration Date:** The vaccine vials and cartons may not contain a printed expiration date. Expiration dates may be updated based on vaccine stability studies occurring simultaneously with COVID-19 vaccine distribution and administration. Additional information will be provided about how to access expiry information for individual vaccines. To ensure that information systems continue to work as expected, CDC has worked with FDA and the manufacturers to include a two-dimensional (2D) barcode on the vaccine vial (if possible) and carton (required) labels that includes a National Drug Code (NDC), lot number, and placeholder expiration date of 12/31/2069 to be read by a scanner. The placeholder 12/31/2069 expiration date is not visible on the vaccine packaging nor found anywhere else; it is only to facilitate information system compatibility. CDC is developing "beyond use date" (BUD) tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration. The label templates will be available on the CDC website.
    - **The expiration date should be checked prior to preparing or administering vaccine. Expired vaccine or diluent should NEVER be used. As additional stability data become available, the expiration dates for some products may change.**
    - **For EUA COVID-19 vaccines that do not have a final expiration date, CDC has set up an expiration date of 12/31/2069 to serve as a placeholder date in VTrckS. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website.**
        - **ModernaCOVID-19 vaccine:** To determine the expiration date, providers can scan the QR code located on the vial or carton or access the manufacturer's website directly, enter the lot number and the expiration date will be displayed. CDC's COVID-19 Vaccine Expiration Date Tracking Tool can help providers keep track of the expiration date by lot number.
        - **Pfizer COVID-19 vaccine:** This vaccine product has an expiration date located on the vaccine vial. CDC will be updating VTrckS effective immediately to replace the placeholder date in VTrckS with the actual expiration date.
- **Manufactured Date:** A manufactured date will be on the packaging and should not be used as the expiration date when documenting vaccine administration. This date is provided to help with managing stock rotations; however, expiration dates should also be considered (see above) as using manufactured date alone could have some limitations.

- **2D Barcode:** The 2D barcode available on the vaccine carton (also on the vials for some vaccines) will include NDC, lot number, and a placeholder expiration date of 12/31/2069.
- **QR Code:** Each vaccine manufacturer will include a Quick Response (QR) code on the vaccine carton for accessing FDA-authorized, vaccine product-specific EUA fact sheets for COVID-19 vaccination providers and COVID-19 vaccine recipients.

A list of authorized COVID-19 vaccine products with corresponding EUA fact sheets for healthcare providers and vaccine recipients, and up-to-date expiration information by vaccine lot will be available on an HHS website.

VaccineFinder

Providers need to report on-hand COVID-19 vaccine inventory **daily, including on weekends**. **We do not have a method for retroactive reporting**, so please report inventory for the current day, even if a previous day's reporting was missed.

Please contact:

- eocevent522@cdc.gov for registration / email change help and for general COVID VaccineFinder inquiries, or
- vaccinefinder@castlighthealth.com for technical assistance with account log-in problems, password resets, file upload errors, etc.

Updated VaccineFinder trainings and factsheets can be found here: https://vaccinefinder.org/covid-provider-resources.

Incomplete Registrations (If you do not have an account yet): This listserv is sent to all email addresses that have been sent a registration email for COVID VaccineFinder.

- If you are a COVID-19 vaccine provider and are getting an email and have not created a COVID VaccineFinder account:
    - It may mean that your registration email was lost somewhere along the way. Please make sure to check your spam folder for a registration email from vaccinefinder@auth.castlighthealth.com, and please complete your registration if you are able to find your email.
    - If you are not able to find the registration email, please reach out to us at eocevent522@cdc.gov to request it be resent. We are also able to assist with connecting with your jurisdiction to update the contact email address if the registration email needs to go to a different POC for your organization or provider location.

- For newly enrolling providers, the registration email will contain instructions to complete VaccineFinder enrollment and to confirm a reporting option
    A. Centralized reporting at the provider organization level, or
    B. Reporting at the provider location level
- If the provider organization assigns inventory reporting responsibilities to their provider location(s), the provider location email address(es) submitted in the provider enrollment form in Section B will receive an email from vaccinefinder@auth.castlighthealth.com with instructions to complete VaccineFinder enrollment.
- **Changing Provider Email Addresses:** The process for changing the contact email addresses used for creating VaccineFinder accounts requires NSIP to update the Provider Enrollment Agreement and to re-submit it to the immunization data lake. We can assist with connecting with the jurisdiction to make this request for any provider that needs to update their contact emails. Please reach out to us at eocevent522@cdc.gov for assistance.

  As a note, for providers reporting inventory at the organization level, only one account will be available and will be associated with the email address listed in Section A of the Provider Agreement form. For providers reporting at the location level, two additional accounts will become available for each location under the organization and will be associated with the primary and backup vaccine coordinators listed in Section B of the Provider Agreement form.

  Please keep in mind that changing a contact email address will de-activate the VaccineFinder account for the old email address.

COVID-19 Vaccine Recovery

Details of COVID-19 vaccine recovery are still being finalized by the federal government and will be communicated to NSIP when available. NSIP will work with LHAs, Immunize Nevada, and other trusted partners to collect and redistribute unused COVID-19 vaccine and supplies to provider sites which can use the vaccine/supplies.

Related Guidance and Reference Materials

Appendix G: COVID-19 Vaccine Distribution FAQs

Section 8: COVID-19 Vaccine Storage and Handling

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit the risk of administering COVID-19 vaccine with reduced effectiveness. NSIP will work closely with staff at each COVID-19 vaccination provider site to ensure appropriate vaccine storage and handling procedures are established and followed consistently.

It is expected that cold chain storage and handling requirements for COVID-19 vaccine products will vary in temperature from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C) in the freezer or within the dry ice shipping container in which the product was received. Ongoing stability testing may impact these requirements.[11]

For a reliable cold chain, three elements must be in place:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

The cold chain begins at the COVID-19 vaccine manufacturing plant, includes delivery to and storage at the COVID-19 vaccination provider site, and ends with administration of COVID-19 vaccine to a person. NSIP and its enrolled vaccination providers are responsible for maintaining vaccine quality from the time a shipment arrives at a vaccination provider site until the doses are administered. To minimize opportunities for breaks in the cold chain, most COVID-19 vaccine will be delivered from CDC's centralized distributor directly to the location where the vaccine will be stored and administered, although some vaccine may be delivered to secondary depots for redistribution. Certain COVID-19 vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site or secondary redistribution depot. When redistributing vaccine is required, NSIP will adhere to all cold chain requirements, will not use commercial shippers to redistribute vaccine, and will limit transport of frozen or ultra-cold vaccine products to the extent possible.

Every vaccine storage unit/container must have a temperature monitoring device. NSIP requires enrolled providers to use digital data loggers (DDLs) meeting CDC specifications for continuous vaccine storage unit temperature monitoring, including within ultra-cold freezers. If providers already use data loggers, NSIP staff must verify the equipment meets specifications and need to review at least five days of temperature readouts (must show a min/max for every day). In most cases, NSIP can provide one data logger per newly enrolled provider; however, any new vaccine storage unit not yet monitored and inspected by NSIP must be able to present five days of

[11] These temperatures are based on information available as of 10/29/2020. Updated information will be provided as it becomes available.

continuous temperatures in any unit intended to hold COVID-19 vaccine. NSIP expert staff can provide more information at DPBHCOVID19VAX@health.nv.gov.

An addendum to the Vaccine Storage and Handling Toolkit that specifically addresses COVID-19 vaccines has been released by the CDC. Nevada will ensure this addendum and links to the full toolkit are easily available for providers to access.

Vaccine Storage

All COVID-19 vaccine within NSIP responsibility will be ordered, managed, and distributed via NV WebIZ/VTrckS through the centralized distributor McKesson or other centralized distribution partner selected by CDC. NSIP does not expect to need to use the Receiving, Staging, and Storage (RSS) facilities in Nevada for this response. The NSIP main office at 4150 Technology Way, Suite 210, Carson City, NV 89706 does have a small amount of vaccine storage capacity in two stand-alone refrigerators and one stand-alone freezer; current storage capacity could not accommodate large quantities of COVID-19 vaccine.

Should additional storage capacity at NSIP be necessary, emergency storage plans would be used as well as a refrigerated tractor-trailer truck(s) which can be obtained to store additional vaccine. The provision of one refrigerated truck to NSIP would provide adequate storage capacity for rural areas which may not have enough capacity for the initial vaccine inventory allocated to their county/jurisdiction. Vaccine will be repackaged and transported by NSIP and/or PHP staff in a state vehicle following the manufacturer's standards and CDC recommendations. Supplementary storage and distribution of larger quantities of vaccine may occur at the Northern Nevada RSS facility dedicated to cold storage distribution operations.

Receipt, Storage, and Handling of Ultracold Vaccine

Some of the first vaccine product expected to be allocated and distributed to states will need ultra-cold chain management, as discussed in previous sections. CDC plans to ship this vaccine in containers allowing storage of the vaccine for up to ten additional days after it arrives on site. NSIP has identified ultra-cold freezers in Reno, Elko, and Las Vegas as backup storage facilities as well as locations from which to purchase dry ice if the shipping container needs to be refilled when it arrives in Nevada and again every 5 days for a maximum of 15 days.

CDC updated its Vaccine Storage and Handling Toolkit to include a COVID-19 Vaccine Addendum, which will provide guidance on each vaccine product. CDC and Pfizer are also providing additional product-specific materials, including storage, handling and administration job aids.

Pfizer COVID-19 Vaccine Receipt, Storage, and Handling

Thermal shipping containers with Pfizer COVID-19 vaccines will arrive with a GPS-enabled temperature monitoring device that will monitor temperature excursions in transit as well as at the vaccination provider site, if used.

If a vaccine administration site plans to store Pfizer COVID-19 vaccine in an ultra-low temperature (ULT) freezer, the site must remove vaccine trays from the thermal shipping container before moving them to the freezer. The site must then monitor the temperature inside the ULT freezer using standard protocol to ensure temperature excursions are identified quickly. Once the vaccine is removed from the thermal shipping container and put in the ULT freezer, the temperature monitoring device accompanying the vaccine can no longer be used; a data logger provided by the NSIP, or other NSIP-approved monitoring method, will be needed.

A vaccine administration site may also use the thermal shipping container for temporary storage of the Pfizer COVID-19 vaccine. Instructions will be provided for monitoring vaccine temperatures in the thermal shipping container using the device that is available on the shipper. In addition, storage and handling instructions for vaccine stored in the thermal shipper will be made available by Pfizer and in CDC's storage and handling toolkit.

Pfizer COVID-19 vaccine will be managed in the following ways:

1) If a hospital/county has more than 975 people in the initial phase, the ultra-cold vaccine will be shipped directly to that facility to be used in the appropriate time frame.
2) If the hospital/county has less than 975 people in the initial phase, the ultra-cold vaccine will be shipped directly to an ultra-cold vaccine storage site centrally located in Nevada. NSIP staff will then redistribute vaccine at 2°-8°C to the hospitals/counties as necessary to vaccinate people who are in the initial phase within 120 hours (five days).

PHP developed the map below to assist in the logistical planning efforts for ultra-cold vaccine. Each circle on the map indicates a 2-hour driving radius from the nearest ultra-cold vaccine storage site.

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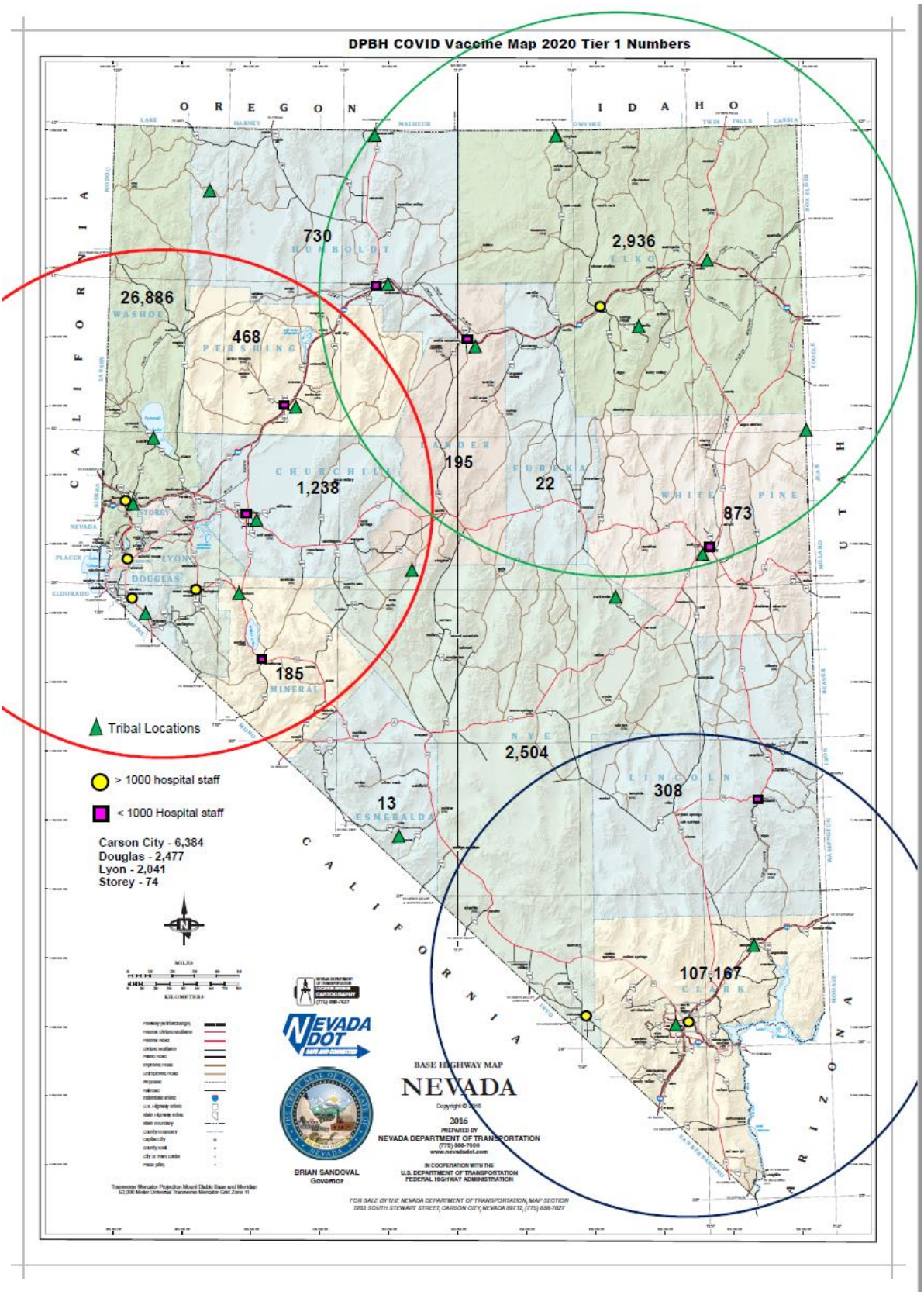

Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations

Satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators will be likely throughout Nevada's COVID-19 vaccine response to help provide equitable access to COVID-19 vaccination services. However, these situations require additional oversight and enhanced storage and handling practices, including:

- The quantity of COVID-19 vaccine transported to a satellite, temporary, or off-site COVID-19 vaccination clinic will be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport the vaccine appropriately (including with or without NSIP/LHA assistance); this is essential to minimize vaccine wastage and spoilage.
- COVID-19 vaccines may be transported – not shipped – to satellite, temporary, or off-site COVID-19 vaccination clinic settings using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. The procedures will include transporting vaccines to and from the provider site at appropriate temperatures, using appropriate equipment, as well as monitoring temperature throughout the clinic day.
- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperatures throughout the clinic day.
- Temperature data must be reviewed and documented according to guidance in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit.
- At the end of the clinic day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.
- As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions[12] at any time, the temperature excursion must be documented and reported according to NSIP procedures. The vaccines exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered or further information on disposition or recovery is received.

NSIP is using CDC's revised Guidance on Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations as well as Vaccination Guidance During a Pandemic to inform planning. These resources provide information on additional considerations necessary during the COVID-19 pandemic, including social distancing, PPE use, and enhanced sanitation efforts.

[12] A "temperature excursion" is an event in which the COVID-19 vaccine is exposed to temperatures outside the range(s) prescribed for storage and/or transport.

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

CDC requires vaccination providers enrolled in the COVID-19 Vaccination Program to report certain data elements for each dose administered within 24 hours of administration. NSIP is actively assessing the capability of Nevada's COVID-19 vaccination providers to meet federal and state reporting requirements before enrollment in the COVID-19 Vaccination Program. The required data elements are communicated to COVID-19 vaccination providers upon program enrollment. The data required include elements commonly reported for routine vaccinations. NSIP is prepared to provide additional support and technical assistance to smaller vaccination providers and rural/frontier clinic settings.

NSIP is responsible for facilitating and monitoring NV WebIZ reporting by enrolled vaccination providers. Each vaccination location should be ready (including trained staff, necessary equipment, and internet access) to report vaccine administration data to NV WebIZ at the time of vaccination. NSIP provider management staff use annual checklists to track that training occurs for individual provider offices enrolled in the Nevada VFC, Adult 317, and/or Cocooning Programs. These checklists are being leveraged by the NSIP COVID-19 Vaccine Provider Enrollment Team to track training progress for the COVID-19 Vaccination Program.

Vaccination providers must ensure the required data are reported to NV WebIZ, ideally within 24 hours, but not later than 72 hours, of administration. Providers are expected to report data consistent with Nevada's IIS reporting laws- essentially the same data that is reported for routine vaccinations, such as influenza or hepatitis B. Patient vaccination data will be transitioned daily from NV WebIZ to the CDC via upload of a file extract to the Immunization Clearinghouse. CDC has encouraged jurisdictions to leverage existing IIS reporting mechanisms where possible; federal agencies or commercial partners who receive allocations directly from CDC may report data directly to the CDC if not currently reporting to NV WebIZ. Such data is expected to be routed to NV WebIZ via the IZ Gateway "Connect" component at a future date and NV WebIZ staff may be able to initiate a direct HL7 interface with a federal/commercial partner located in Nevada, to ensure state law is met.

In addition to reporting vaccine administration, NSIP plans to leverage a text message and email service to centrally remind all COVID-19 vaccine recipients to return for a second dose. NV WebIZ facilitates documentation by vaccine product to ensure appropriate series completion. NV WebIZ's connection to the IZ Gateway will allow for the exchange of vaccination data between states/jurisdictions (that have also connected to the IZ Gateway) and receipt of vaccination data that has been reported directly to CDC.

NSIP will ensure redundant measures and procedures are in place for recording vaccine administration data in instances of connectivity problems or failures within NV WebIZ. NV WebIZ can collect the data required for reporting to CDC. NV WebIZ has completed onboarding to the IZ Gateway and will leverage the IZ Gateway Connect and Share components (if

feasible)[13] to exchange data with other jurisdictions. Planning activities include generating coverage reports for use within Nevada.

Clinical Guidance for COVID-19 Vaccine Providers

Online Resources

- COVID-19 Vaccination Planning resources for healthcare professionals
- Frequently Asked Questions about COVID-19 Vaccination
- COVID-19 Vaccines and Severe Allergic Reactions
- Vaccination Considerations for People who are Pregnant or Breastfeeding
- Subscribe here to receive the CDC's monthly Immunization Works newsletter

Pfizer Vaccine

CDC has released updated clinical guidance related to mRNA vaccines. The updated guidance can be found at Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine | CDC.

The updated guidance includes:

- Additional information on antibody therapies and COVID-19 vaccination
- Information on COVID-19 vaccination and outbreak management
- Additional information on vaccination of immunocompromised persons
- Updates to contraindications and precautions to vaccination
- Information on COVID-19 vaccination and tuberculin skin testing

Major updates include:

- Defining an immediate allergic reaction as "any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration."
- Identifying contraindications to either of the mRNA COVID-19 vaccines as:

[13] There are multiple ways to onboard to the IZ Gateway, including Connect and Share. Connect enables large national and non-traditional vaccination systems for satellite/temporary/off-site clinic settings to report and query immunization data with IISs, using the gateway's centralized data exchange, avoiding multiple individual, and point-to-point connections. Share allows exchange of immunization data between IIS jurisdictions by automating message triggers through the IIS for patients immunized outside of their jurisdiction, to route messages to the patient's state of residence through the IZ Gateway.

  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
  - Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])
  - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

- Expanding precautions to mRNA COVID-19 vaccines to include not only anaphylaxis but also any previous immediate allergic reaction to any other vaccine or injectable therapy
- Includes observation periods after vaccination as 30 minutes for any persons with a precaution to vaccination or a history of anaphylaxis due to any cause and 15 minutes for all other persons
- The FDA revised the EUA for the Pfizer COVID-19 product. It now includes wording on the sixth dose in the provider fact sheet: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine

CDC is working to update its current documents to reflect the new guidance including the screening tool and standing orders.

On December 13, 2020, CDC announced updates to several COVID-19 vaccination websites and introduced the new Pfizer-BioNTech COVID-19 Vaccine web page.

- The COVID-19 vaccination website for healthcare professionals has been updated to direct healthcare professionals to clinical information including ACIP recommendations, storage and handling information, and vaccination provider requirements and support.
- The Pre-Vaccination Screening Tool [for vaccine recipients] for the Pfizer COVID-19 vaccine is live on Pfizer-BioNTech COVID-19 Vaccine Information | CDC.
- The new Pfizer-BioNTech COVID-19 Vaccine webpage has information specific to Pfizer's vaccine, including resources to assist providers in storing, handling, and administering the vaccine. Currently the page contains storage and handling information, will be updated with administration information.
  - You also can find **updated Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions here.**
- CDC has created a new web-on-demand, self-paced training module for healthcare providers who will be administering Pfizer-BioNTech COVID-19 vaccine. This module will provide information on storage, handling, preparation, administration, and documentation

of the Pfizer-BioNTech COVID-19 vaccine. Continuing education will be available for this module. For more information, go to https://www.cdc.gov/vaccines/ed/courses.html.

  - Subscribe now if you are interested in updates to the CDC training courses.

- New updates to CDC's COVID-19 vaccine information for consumers, including:
  - What to expect at your vaccination appointment
  - What to expect after getting vaccinated
  - Post-vaccination considerations for healthcare personnel
  - Post-vaccination considerations for long-term care residents
- Providers participating in the COVID-19 Vaccination Program can find information about the requirements of the CDC COVID-19 Vaccination Provider Agreement at COVID-19 Vaccination Provider Requirements and Support | CDC and on the websites listed in the footnotes of the agreement.
- Link to translations of the Pfizer-BioNTech COVID-19 EUA Recipient/Caregiver Fact Sheet. More translations will be added to https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.

It's important to keep up to date with the latest information and NSIP recommends checking these websites frequently. Also sign up for email updates on the sites to be notified when changes and updates are made.

Moderna Vaccine

The new Morbidity and Mortality Weekly Report (MMWR) report on ACIP's COVID-19 vaccine recommendation for the Moderna vaccine is now available.

- Dedicated Website for HCPs and Vaccine Recipients: Information about Moderna COVID-19 Vaccine can be found by visiting https://www.modernatx.com/covid19vaccine-eua. Here you'll find helpful information such as:
  - Fact sheet, prescribing information, and important safety information,
  - Link to translations of the Moderna COVID-19 EUA Recipient/Caregiver Fact Sheet. More translations will be added to: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine#additional
  - A tool to determine the expiration date of each lot of vaccine,
  - Storage & handling requirements,
  - Dosing & administration information, and more.

CDC's Moderna Clinical Website, including the Pre-Vaccination Screening Tool [for vaccine recipients]: Moderna COVID-19 Vaccine Information | CDC

Following the issuance of an EUA for Moderna's COVID-19 vaccine, CDC has made available the following provider education materials:

- COVID-19 Vaccine Clinical FAQs
- Expiration date tracker
- Beyond use date tracking labels for refrigerator storage
- Vaccine storage and handling summary
- Vaccine storage and handling labels

CDC has created a new web-on-demand, self-paced training module for healthcare providers who will be administering Moderna COVID-19 vaccine. This module will provide information on storage, handling, preparation, administration, and documentation of the Moderna COVID-19 vaccine. Continuing education will be available for this module. For more information, go to https://www.cdc.gov/vaccines/ed/courses.html.

- Subscribe now if you are interested in updates to the CDC training courses.

Vaccine Data Collection and Management

NV WebIZ is Nevada's primary tool for coordinating vaccine distribution and data collection. COVID-19 vaccine orders will be placed by providers using NV WebIZ for fulfillment via the system's VTrckS upload. Provider profiles will be established to reflect POD locations statewide to facilitate documenting vaccines administered and necessary associated data, as well as vaccine ordering. NSIP is pursuing implementation of a mobile NV WebIZ application module and supporting hardware to facilitate offsite clinic/POD data collection without the need for internet connectivity (see *NV WebIZ Module/Off-site Application* on page 56).

If the vaccination providers enrolled in Phases 1 and 2 are established NV WebIZ reporters, then minimal profile preparation and user training will be required to facilitate COVID-19 vaccination data reporting. Organizations not currently vaccinating/reporting to NV WebIZ will receive user training, either as a remote web presentation or via an independent study curriculum. If appropriate and feasible, HL7 (electronic data exchange language) interfaces will be established with newly enrolled providers to ease their reporting burden.

COVID-19 vaccine providers will be directed to report vaccination data to NV WebIZ either by direct user interface or via HL7 submission (i.e., provider's EHR). A REDCap platform is being developed and will be made available to COVID-19 vaccine providers to facilitate weekly reporting of aggregate priority group counts vaccinated as well as aggregate patient race and ethnicity data which can be used for rapid monitoring and for comparison to data reported to

NV WebIZ. NSIP will communicate the parameters of each priority group to businesses/organizations employing individuals within each occupational category; these entities are expected to direct their employees to a scheduled, invitation-only satellite/temporary/off-site vaccination event/POD.

Data stored in NV WebIZ and REDCap will be used to populate a data dashboard to serve as a central indicator of COVID-19 vaccine distribution and vaccination coverage status, for both state and federal decision-making and reporting purposes.

Pfizer "Extra Doses" Guidance

As the initial doses of Pfizer vaccine have been delivered and administered across the country, immunizers have observed additional volume in the vaccine vials after proper reconstitution and administration of five (5) doses. In response, FDA has issued preliminary advice:

"At this time, given the public health emergency, FDA is advising that it is acceptable to use every full dose obtainable (the sixth, or possibly even a seventh) from each vial, pending resolution of the issue. However, since the vials are preservative free, it is critical to note that any further remaining product that does not constitute a full dose should not be pooled from multiple vials to create one dose."

If a sixth (or even seventh) dose is drawn and administered from a vial, these additional doses must be added to your NV WebIZ On-Hand Inventory. Vaccinators must take steps to document these additional doses as they are given and communicate this to their Vaccine Coordinators so that inventory counts may be increased via an inventory adjustment in NV WebIZ.

COVID-19 Vaccine Data Dashboard

In anticipation of the profound need for real-time COVID-19 vaccine distribution and administration data and the presumed impact this data will have on the economic reopening and stability of Nevada, NSIP will create and maintain a data dashboard similar to the COVID-19 testing and mortality data displayed on nvhealthresponse.gov; vaccine data is also planned to be displayed on the Nevada Health Response website. Nevada will use a variety of sources (e.g., NV WebIZ, VaccineFinder, Tiberius, etc.) to measure the accuracy of the COVID-19 vaccine dashboard.

Inventory Control and Asset Management System

The Inventory Control and Management System (ICAMS) is utilized by the DPBH RSS planning team to record, track, and manage the movement of general materials (to include Medical Countermeasures (MCM) such as vaccines) into and out of the DPBH RSS inventory. ICAMS can be used as a supplemental inventory management system in the event COVID-19 vaccines need to be stored at the Northern Nevada RSS facility. The intended functions of this inventory management system during RSS activation for vaccine storage and distribution include:

- Recording quantities and types of vaccines and supplementary vaccination materials into the RSS facility
- Recording distribution orders to regional partners or end-users (to supplement current vaccine inventory management and distribution systems used in Nevada if necessary)

Section 10: COVID-19 Vaccination Second Dose Reminders

For most COVID-19 vaccine products, two doses of vaccine, separated by 21 or 28 days, will be needed. **Because different COVID-19 vaccine products are not interchangeable, a vaccine recipient's second dose must be from the same manufacturer as their first dose.** Second-dose reminders for vaccine recipients will be critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness. **COVID-19 vaccination providers should make every attempt to schedule a patient's second-dose appointment when they get their first dose.**

COVID-19 vaccination record cards will be provided as part of the COVID-19 vaccine ancillary supplies kits. CDC and NSIP will require enrolled vaccination providers to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives a vaccine at their setting to ensure a basic COVID-19 vaccination record is provided. The card provides room for a written reminder for a second-dose appointment. NSIP will also develop messaging to help vaccination providers encourage vaccine recipients to keep the card and/or take a picture of the card on a smartphone/mobile device as documentation of previous vaccination, in the unexpected case NV WebIZ or the provider's EHR system is not available when they return for their second dose. A vaccine recipient may also use their smartphone/mobile device to record the date their next vaccine is due on their electronic calendar.

Redundant methods and systems will be used to remind vaccine recipients about their need for second doses; consistent messaging and message saturation is important considering the 21- to 28-day lag between doses. Significant events can happen in a person's life in the course of three to four weeks. NSIP urges COVID-19 vaccination providers to clearly communicate the need for a second dose during the initial vaccine dose, and to examine internal capacity and methods for reminding patients, including advance appointment scheduling, text, email or phone messages, and/or paper reminders. NSIP plans to leverage a text message and email service to centrally remind all COVID-19 vaccine recipients to return for a second dose. NV WebIZ facilitates documentation by vaccine product to ensure appropriate series completion.

Many pharmacies and healthcare systems also have their own systems for patient notifications and reminders, some using functionality within their EHR systems. Health plans can also help notify their enrollees about second doses based on claims information.

Section 11: COVID-19 Requirements for Immunization Information Systems

IISs, also known as "vaccine registries," are confidential, population-based, computerized database for recording information on vaccine doses. IISs are maintained by a jurisdiction's immunization program. In Nevada, the IIS used is called NV WebIZ, and it is administered and maintained by the Nevada State Immunization Program within DPBH. NV WebIZ has a solid infrastructure, engaged partners, efficient processes for managing vaccination, and holds comprehensive high-quality data.

Immediate Priorities for NV WebIZ Related to Data Reporting:

- Determine and implement a solution for documenting vaccine administration in temporary/off-site and/or high-volume settings
- NSIP ensures there is system capacity for data exchange, security, storage, and reporting
- Enroll vaccination provider facilities and organizations anticipated to vaccinate essential workers in NV WebIZ (if not already participating)
- Connect NV WebIZ to the CDC's IZ Gateway
- Establish required data use agreements
- Continuously assess and improve NV WebIZ data quality
    - Ensure data are available, secure, complete, timely, valid, accurate, consistent, and unique

NRS 439.265 and NAC 439.870-897 require all vaccinations administered in Nevada to be reported to NV WebIZ. Providers choosing to vaccinate are enrolled, trained, and given access to NV WebIZ to enter patient and vaccination data. User support is provided by the NV WebIZ Help Desk and training staff.

NV WebIZ has a range of capabilities, including exchanging data with EHRs via HL7 interfaces, so documentation of vaccine administration is automatically uploaded through a uni- or bidirectional data exchange between EHRs used by Nevada's vaccinating providers and NV WebIZ. HL7 connections improve the pace and accuracy of vaccine administration data capture. Some EHRs may leverage 2D barcoding technology on vaccine vials and VISs to allow for rapid, accurate, and automatic capture of vaccine administration data, such as vaccine lot number, vaccine manufacturer, and expiration date. In Nevada, many routine vaccination providers (e.g., pediatricians and family practice offices) are enrolled in NSIP-administered public vaccine programs and actively use NV WebIZ to order vaccines, report vaccine inventory, document vaccine spoilage/wastage, and remind patients when vaccine doses are due.

Using NV WebIZ to document COVID-19 vaccine dose administration is beneficial on many fronts. When using NV WebIZ, vaccination providers can easily determine if a patient is due for the first or second dose of vaccine. This ability is especially helpful in a pandemic situation

when people may receive first and second vaccine doses at different locations. NV WebIZ will also help ensure first and second doses are administered using the same vaccine product and appropriately spaced according to recommended intervals. COVID-19 vaccination providers in Nevada can use NV WebIZ to:

- Place orders for COVID-19 vaccine from NSIP
- Document vaccine administration
- Manage and report vaccine inventory
- Report vaccine spoilage/wastage
- Provide reminders to COVID-19 vaccine recipients indicating when the next dose of a multidose vaccine is due

System Infrastructure

NSIP and the NV WebIZ teams have been preparing for the COVID-19 vaccine response since March 2020; NV WebIZ is ready to support the COVID-19 Vaccination Program in Nevada, pending CDC's release of COVID-19 vaccine supporting code values. NV WebIZ can meet CDC's COVID-19 response data exchange, storage, and reporting requirements. NV WebIZ hardware and software is up to date and is on the latest version of the vendor's platform. NV WebIZ is Nevada's best tool to appropriately support COVID-19 vaccination tracking efforts. NSIP continuously assesses NV WebIZ and, other than the mobile support application described in more detail further in this section, does not anticipate needing system enhancements to appropriately support COVID-19 vaccine response efforts.

NV WebIZ supports dose-level accountability tracking – from the time the vaccine leaves the distributor until the vaccine is administered or unused vaccine is returned to the federal government – and provides data to CDC that meets their defined standards. Specifications to support data extracts have been provided by CDC to ensure data submissions align with the format required for submission to the COVID-19 clearing house (a secure data lake). NSIP has also developed protocols for paper records and fax reporting in the very low possibility the internet is unavailable.

NSIP will be implementing centralized reminder/recall functionality in NV WebIZ for sending second-dose reminders (see *Section 10: COVID-19 Vaccination Second-Dose Reminders*) to vaccine recipients. Effective reminder/recall programs are critical to ensuring recipients complete the COVID-19 vaccine series. NSIP will leverage a system that sends both email and SMS text message reminders.

NV WebIZ Mobile/Off-Site Application

NSIP has initiated the purchase of a Mobile WebIZ Module and supporting hardware. This module allows NV WebIZ administrators to define and create a cohort of up to one (1) million patients (based on age and/or geographic location) that can be securely stored on preset iPads.

This data is then accessible during an offsite or temporary POD event, even if internet connectivity is not available. POD workflows are also supported by QR code scanners and hand-held printers, and the entire module is flexible enough to support various POD stations. Hardware units (e.g., specialized iPads) are being purchased and should be ready to use in early 2021.

COVID-19 Vaccination Provider Preparation

As NSIP enrolls providers in the COVID-19 Vaccination Program (see *Section 5: COVID-19 Vaccination Provider Recruitment and Enrollment*), it is critical to also onboard newly participating vaccinators to NV WebIZ. NSIP is developing expedited processes to rapidly onboard any non-participating vaccination providers expected to support Phase 1 activities and employs efficient processes and protocols to onboard vaccination providers expected to support expanded vaccine response efforts in Phases 2 and 3.

NSIP will work with public, non-profit, and private sector partners to conduct nontraditional COVID-19 vaccination clinics, such as temporary, off-site, or mobile vaccination clinics to reach critical populations, particularly during Phases 1 and 2. NSIP will identify, enroll, and train additional partners as needed to report doses administered to NV WebIZ to support those efforts.

Data Management

NV WebIZ can collect and report data to satisfy CDC's reporting requirements (additional information on CDC data requirements is forthcoming). NSIP planning activities have included protocols to onboard newly participating providers to NV WebIZ, ensure adequate system capacity, and have established protocols and processes to ensure provider reporting ideally within 24 hours, but not later than 72 hours, of COVID-19 vaccine administration. NSIP is exploring the feasibility of leveraging the IZ Gateway Connect and Share components, if appropriate for the State of Nevada, for exchanging data with and/or querying other jurisdictions' IIS to obtain a consolidated vaccination record. NSIP is prepared to update the Clinical Decision Support (CDS) system in NV WebIZ when CDC CDSi (Clinical Decision Support for immunizations) resources are updated.

NSIP is exploring what policies or protocols need to be in place to facilitate necessary and/or required data collection and sharing with CDC and other states/jurisdictions. Per CDC, any jurisdiction onboarding to the IZ Gateway will be required to sign the Data Use Agreement (DUA) with Association of Public Health Laboratories (APHL) to participate in both IZ Gateway Connect and IZ Gateway Share and to share data with other states/jurisdictions through the IZ Gateway. Nevada has successfully executed the following DUA and Memorandum of Understanding:

- APHL – Jurisdiction DUA IZ Gateway: When executed, the APHL and jurisdiction DUA allows for the jurisdiction to participate in the Connect component and to identify which

(if any) other components to enable (*Share, Provider-initiated Multi-jurisdictional Data Exchange, Access* and/or *Access: Consumer-initiated Multi-jurisdictional Data Exchange*). This document was updated on August 3, 2020 for this expanded use and is available to CDC Immunization Awardees via their SAMS access.

- Memorandum of Understanding between Jurisdictions to Exchange Data: The Share component enables the exchange of immunization information across IIS jurisdictions. To enable the Share component, a state/jurisdiction must execute an Interjurisdictional MOU with jurisdictions with which it will exchange data. The MOU allows data exchange to occur through the IZ Gateway or an alternative mechanism with any state or jurisdiction that signed the MOU. This document is available to CDC Immunization Awardees via their SAMS access.

Finally, Nevada has executed the required DUA with CDC to facilitate the reporting of COVID-19 vaccination data. Nevada will be reporting only unidentified patient data to CDC and the federal government for national coverage data analysis.

Data Quality Monitoring

The data reported to NV WebIZ will be monitored for quality. Methods include generation of ad hoc data extracts for review, inventory management monitoring, comparison of with aggregate data collected via REDCap, and user support. As NSIP does not have dedicated data quality staff, assurance will be shared by all Program staff.

Vaccine Ordering and Inventory Management

As stated in Section 7: COVID-19 Vaccine Allocation, Ordering Distribution, and Inventory Management, NV WebIZ is the system used by all vaccinating providers who receive publicly supplied vaccines through NSIP to order, manage, and track vaccine inventories. These processes will be used for managing and tracking COVID-19 vaccine ordering and inventory. NSIP will conduct a thorough review of business processes and NV WebIZ functionality to identify and implement needed improvements. NSIP has protocols in place for ordering, monitoring, and managing COVID-19 vaccine inventory in NV WebIZ which meet CDC standards. NSIP is also exploring opportunities to adopt 2D barcoding technology to improve data quality.

Related Guidance and Reference Materials

Provider Onboarding

- CDC Provider IIS Participation Community of Practice: An overview of the CDC Provider IIS Participation Community of Practice and ideas for addressing important provider IIS participation issues, including onboarding, EHR assistance, data quality, and provider training and outreach presented as a webinar on April 10, 2019

- American Immunization Registry Association (AIRA) Data Validation Guide – for the IIS Onboarding Process (2017): A guide with recommendations on the data validation process within onboarding
- Onboarding Consensus-Based Recommendations (2018): A guide for improving and standardizing onboarding intended for technical and programmatic staff that make up IIS onboarding teams and for program administrators responsible for allocation of onboarding resources

Data Quality

- IIS Data Quality Blueprint: A guide to help CDC immunization program awardees address and advance data quality within IISs
- Data Quality Assurance in Immunization Information Systems: Incoming Data (2008): A summary of best practice guidelines and immediate actions an IIS can take to improve data quality
- IIS Data Quality Practices to Monitor and Evaluate Data at Rest (2018): Practical guidance on techniques, methodologies, and processes for IISs to use in assessing the quality of data at rest, including demographic and immunization record information that is currently in the live, production environment (e.g., database or other data store). The primary audience for the guide includes IIS managers and staff with responsibility for ensuring IIS data quality.
- Consolidating Demographic Records and Vaccination Event Records (2017): Consensus-based test practice recommendations to support the process of consolidating demographic and vaccination event records.

Immunization Gateway (IZ Gateway)

- Immunization Gateway Information Sheet (*Located in SharePoint available to immunization program staff)*
- Immunization Gateway Overview (*Located in SharePoint available to immunization program staff)*
- Immunization Gateway Q&As for IIS Awardees (*Located in SharePoint available to immunization program staff)*

Vaccine Ordering and Inventory Management

- IIS Inventory Management Operations (2012): Consensus-based test practice recommendations for IISs to support immunization program requirements for provider organizations' vaccine inventory management and associated IIS reports that support the vaccine inventory management needs of provider organizations and grantee immunization programs.

- Decrementing Inventory via Electronic Data Exchange (2016): Consensus-based best practice recommendations to support the process of decrementing inventory via electronic data exchange.
- Guidance on Unit of Sale/Unit of Use Lot Numbers (2018): Clarifications to the process and expectations for management of vaccine lot numbers.
- Vaccine Code Set Considerations (2020): A general overview of vaccine code sets and brief description of how code sets support multiple and varied IIS functions, including electronic data exchange with EHRs and other health information systems and vaccine ordering and inventory management.

Section 12: COVID-19 Vaccination Program Communications

Starting before COVID-19 vaccines are available, clear, effective communication will be essential to implementing a successful COVID-19 Vaccination Program. Building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation, are critical to ensure vaccine uptake.

A successful COVID-19 Vaccination Program will have lasting effects on the nation's immunization system and overall vaccination efforts in the future. Using risk communication principles along with the CDC's recently developed Vaccinate with Confidence framework, NSIP and partners will develop and implement timely, evolving plans as the foundation for the state's overall COVID-19 vaccination communication efforts. Limited funding for the statewide COVID-19 vaccine response is being awarded to NSIP by CDC; the proposed budget includes funds for Immunize Nevada to assist in organizing and implementing a statewide media campaign to promote and inform about the COVID-19 vaccine and where it is available throughout each Phase.

Vaccine hesitancy is expected to be a significant issue, especially among Black, Indigenous and Persons of Color (BIPOC) communities. The CDC's Vaccinate with Confidence framework and the results of various local and statewide vaccine attitudes surveys will be used to develop and inform Nevada's vaccination messaging campaign. Adopting innovative methods to reach BIPOC communities will help ensure high vaccine uptake among high-risk and disproportionately impacted communities. NSIP is developing vaccine confidence messaging in collaboration with the JIC beginning with a flu vaccine confidence campaign in September 2020. Many Nevada partners can help share vaccine confidence messaging and resources. A coordinated approach has been adopted by partners statewide in cooperation with the JIC. NSIP acts as the liaison bringing partners to the JIC for input and message distribution.

Nevada does have active groups opposed to immunizations. These groups are expected to remain active and potentially ramp up statewide activities during the COVID-19 vaccine response. NSIP is encouraging POD sites to consider the possibility of protests/demonstrations and plan for legal protestors to be present during satellite/temporary/off-site vaccination clinics. State and local government and community leaders, Nevada legislators, and other key stakeholders are expected to be targeted with vaccine misinformation regarding the COVID-19 vaccine and vaccines/vaccine science generally.

COVID-19 Vaccination Communication Objectives

- Educate Nevadans about the development, authorization, distribution, and execution of COVID-19 vaccines and that situations are continually evolving.
- Ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines.

- Help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure).
- Engage in dialogue with internal and external partners to understand their key considerations and needs related to COVID-19 vaccine program implementation.
- Ensure active, timely, accessible, and effective public health and safety messaging along with outreach to key stakeholders and the public about COVID-19 vaccines.
- Provide guidance to local health departments, clinicians, and other hosts of COVID-19 vaccination provider locations.
- Track and monitor public receptiveness to COVID-19 vaccination messaging.

Key Audiences

Messaging is being tailored for each audience to ensure communication is effective:

- Healthcare personnel (i.e., organizations and clinicians who will receive information about receiving and administering vaccine)
- Law Enforcement and Public Safety
- Health insurance issuers and plans (coverage for vaccine, in-network providers, etc.)
- Employers
- Unions and Associations representing Nevada's essential workers
- Local government
- Community partners and stakeholders
- Public/consumers
    - Those in groups at risk for severe outcomes from COVID-19 infection
    - Those in groups at increased risk of acquiring or transmitting COVID-19
    - Those with limited access to vaccination services

Broad Communication Planning Phases

Messaging will be timely and applicable for the current phase of the COVID-19 Vaccination Program:

- Before vaccine is available
- When vaccine is available in limited supply for certain populations of early focus (Phase 1)
- When vaccine supply is increasing and available for other critical populations and the general public (Phase 2)
- When vaccine widely available (Phase 3)

Communication Activities

NSIP and funded partners will:

- Communicate early about 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
- Engage and use a wide range of partners, collaborations, and communication and news media channels to achieve communication goals, understanding that channel preferences and credible sources vary among audiences and people at higher risk for severe illness and critical populations, and channels vary in their capacity to achieve different communication objectives
- Communicate proactively whenever possible, anticipating issues and forecasting possible problems before they reach broad awareness
- Ensure that communications meet the requirements of the Americans with Disabilities Act, the Rehabilitation Act, the Patient Protection and Affordable Care Act, the Plain Language Act, and other applicable disability rights laws for accessibility
- Use information and education campaigns to extend reach and increase visibility of vaccine recommendations and resources
- Work closely with partner agencies, representatives of local communities with critical populations, and intermediaries to achieve consensus on actions, consistency in messages, and coordinated communication activities
- Communicate transparently about COVID-19 vaccine risks and recommendations, immunization recommendations, public health recommendations, and prevention measures

NSIP staff routinely monitor both CDC and local-level messaging to inform Nevada's communications efforts. NSIP staff receive daily emails directly from the CDC which are monitored for important information which can be shared rapidly with other staff via email or through an internal directly messaging platform.

NSIP is also collaborating with multiple groups on messaging and/or survey campaigns. Two such collaborations are described below; NSIP and the Bureau of Child, Family and Community Wellness leadership continue to cultivate additional relationships to build vaccine confidence and secure a broad messaging base, including with NOMHE, the Nevada Sheriffs and Chiefs Association, Nevada DEM and local emergency managers, business associations representing the various critical workforces, local Chambers of Commerce, and more.

NSIP will be learning about COVID-19 disease and vaccine attitudes from a study developed and championed by the Associate Dean for Clinical Research at the University of Nevada, Reno School of Medicine. The intent of this study is to conduct ongoing assessment of both public and health care provider attitudes in Nevada to provide timely data to inform education,

communication and messaging in communities statewide to increase COVID-19 vaccine awareness and uptake in Nevada. Results from the study will be shared regularly with key institutions and stakeholders to develop/target consistent messaging. In order to achieve this intent, UNR is conducting two parallel surveys to:

- Describe attitudes of COVID-19 vaccine acceptance, sources of knowledge and utilization among citizens of Nevada
- Describe attitudes of COVID-19 vaccine recommendations from health care providers, students and trainees in Nevada

Immunize Nevada is adapting its current flu media campaign to message vaccine confidence to Nevadans. The goal will be to empower families, combat myths and misinformation, and protect Nevada's communities as we wait for a COVID-19 vaccine, while continuing to encourage Nevadans to roll up their sleeves for flu shots. This campaign and the methods utilized will be leveraged and enhanced with upcoming CDC funding in December 2020 to focus solely on messaging vaccine confidence and the logistics of who can get the vaccine "now" and how to do so for the COVID-19 vaccine.

The campaign will use the following channels to reach Las Vegas, Reno, and rural Nevada residents.

· Digital outdoor boards

· Cable TV - Cox (includes a sports schedule as well)

· All digital capabilities from Spectrum Statewide (display, video, etc.)

· Streaming TV

· Social media - Facebook, Instagram)

Variations in messaging can create confusion and hamper the effective implementation of the vaccination program. Messaging from all stakeholders (e.g., government, LHAs, trusted community partners, etc.) be clear, current, consistent, and received as intended by the audience. Monitoring social media engagement metrics and survey responses will allow NSIP, UNR, and Immunize Nevada to assess message delivery and reception and dispel inaccurate information.

To review some COVID-19 communication resources circulating in Nevada, including the CDC's COVID-19 Vaccination Communication Toolkit, Immunize Nevada's new "I Got My COVID-19 Vaccine For ____" sign for posting in your workplace, and the "I Got My COVID-19 Vaccine" social media profile image, please make sure to visit Immunize Nevada's COVID-19 Vaccine Planning Page.

Messaging Considerations

Nevada's COVID-19 vaccine messages and products will be tailored to reach different audiences and developed with consideration for health equity. NSIP and partners will use consistent and plain language that is easily understood. Information will be presented in culturally responsive language and available in languages representing Nevada's communities. NSIP will address all people inclusively, with respect, using non-stigmatizing, bias-free language; insufficient consideration of culture in developing materials may unintentionally result in misinformation, errors, confusion, and/or loss of credibility. When developing/using communications materials, Nevada will check for the following:

- Are there words, phrases, or images that could be offensive to or stereotypical of the cultural or religious traditions, practices, or beliefs of the intended audiences?
- Are there words, phrases, or images that may be confusing, misleading, or have a different meaning for the intended audience (e.g., if abstract images are used, will the audience interpret them as intended)?
- Are there images that do not reflect the look or lifestyle of the intended audience or the places where they live, work, or worship?
- Are there health recommendations that may be inappropriate or prohibited for the social, economic, cultural, or religious context of the intended audience?
- Are any toll-free numbers or reference web pages in the message in the language of the intended audience?

These considerations and any others that emerge during message development and deployment will be reviewed again when materials are translated.

Communication Channels

Even perfectly developed messages and materials provide no benefit if they are not received by the intended audience. NSIP is working with trusted community partner to understand how specific audiences are most likely to access information with the communication methods available to them. Feedback mechanisms such as a web page or e-mail account to allow the audience to express concerns, ask questions, and request assistance will be extremely important. NSIP is exploring such mechanisms for Nevada, as CDC considers this a priority of the COVID-19 vaccine response messaging campaign.

Traditional Media Channels

- Print
- Radio
- TV

Digital Media

- Internet ads
- Social media
- Text messaging

Partners and Trusted Sources

Engaging and empowering partners is critical to reinforcing COVID-19 vaccination messages. Efforts with partners and trusted sources, such as Immunize Nevada, will be integrated into other channels in addition to programmatic and community engagement efforts. These partners include:

- Other state agencies
- Local government agencies
- Employers and Businesses
- Healthcare providers
- Community coalitions
- Health insurance issuers and plans
- Educators
- Unions and professional organizations
- Organizations serving BIPOC communities
- Organizations serving people with disabilities
- Community and faith-based groups

Crisis and Risk Communication

Crisis and emergency risk communication (CERC) is the application of evidence-based principles to effectively communicate during emergencies. These principles are used by public health professionals and public information officers to provide information that helps people, stakeholders, and entire communities make the best possible decisions for themselves and their loved ones. CERC recognizes that during emergencies, we work under impossible time constraints and must accept the nature of our choices.

CERC principles include:

- Be First
- Be Right
- Be Credible
- Express Empathy
- Show Respect

Nevada will have communication messaging before, during, and after COVID-19 vaccine is available to help communities understand the importance of vaccination as well as the benefits

and risks. Communicating what is currently known, regularly updating this information, and continuing dialogue with trusted community partners and the media throughout the vaccine distribution and administration process in Nevada is essential to establishing and maintaining credibility and the public's trust.

Related Guidance and Reference Materials

NSIP will regularly review available CDC COVID-19 Communication Resources. CDC has developed COVID-19 One-Stop Shot Toolkits for communication, including toolkits tailored for different populations as well as a social media toolkit. To reach essential workers for vaccination, NSIP may need to assist industry and businesses in communicating with employees about vaccination clinics. CDC's COVID-19 Communications Plan for Select Non-Healthcare Critical Infrastructure Employers will be helpful for this purpose.

Immunize Nevada is also hosting a comprehensive COVID-19 vaccine website with target pages for providers, the public, businesses, etc. at nvcovidfighter.org.

The Nevada Health Response website now has a vaccine page with great information and will be updated regularly.

COVID-19 Vaccination Toolkits | CDC

- COVID-19 Vaccination Communication Toolkit for Health Systems and Clinics | CDC
- FAQs about COVID-19 Vaccination in Long-Term Care Facilities (cdc.gov)
- Recipient Education | COVID-19 Vaccination | CDC

Immunize Nevada's COVID-19 Vaccine Frequently Asked Questions printable resource will be updated regularly.

American Association of Pediatrics (AAP): Countering Vaccine Hesitancy is a broad resource for clinicians.

Voices for Vaccines: Talking to Your Vaccine-Hesitant Loved Ones with Compassion and Confidence is helpful for learning to talk with friends and family who might have questions or concerns.

Alison Singer from the Autism Science Foundation has a presentation on the CASE approach that's a step-by-step guide for one-on-one discussions about vaccines.

World Health Organization (WHO): How to respond to vocal vaccine deniers in public is a good resource for spokespeople representing organizations.

CDC's CERC manual is available online, including more trainings, and example of how CERC is applied during emergencies.

WHO has developed a guide that provides strategies and tools to support effective communication planning and management in response to vaccine safety events.

Section 13: Regulatory Considerations for COVID-19 Vaccination

Initially available COVID-19 vaccines have been authorized for use under EUAs issued by FDA.

Emergency Use Authorization Fact Sheets

The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. FDA will coordinate with CDC to confirm these "conditions of authorization." Vaccine conditions of authorization are expected to include distribution requirements, reporting requirements, and safety and monitoring requirements. The EUA will be authorized for a specific time period to meet response needs (i.e., for the duration of the COVID-19 pandemic). Additional information on EUAs, including guidance and frequently asked questions, is located on the FDA website.

Product-specific EUA fact sheet for COVID-19 vaccination providers will be made available that will include information on the specific vaccine product and instructions for its use. An **EUA fact sheet for vaccine recipients** will also be developed, and both will likely be made available on the FDA website and through the CDC website.

EUA Overview Table: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs

NSIP provider management staff will ensure providers know where to find both the provider and recipient fact sheets, have read and understand them, and are clear on the requirement to provide the recipient fact sheet to each client/patient prior to administering vaccine. NSIP staff can do this via the program's email listserv for all Vaccine Coordinators and Backup Coordinators. Additionally, every provider will have a main NSIP staff contact who will be monitoring the provider's activities and progress as a COVID-19 vaccination provider.

FDA issued Emergency Use Authorization for the Pfizer BioNTech COVID-19 vaccine on Friday December 11, 2020. Information regarding that vaccine as well as the EUA Provider Fact Sheet and the EUA Recipient and Caregiver Fact Sheets are available on FDA web page (or at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine).

EUA Recipient Caregiver Fact Sheet Codes

To help facilitate documentation of having provided the EUA Recipient Caregiver Fact Sheet in electronic medical records/immunization information systems, the CDC is leveraging the existing Vaccine Information Statement (VIS) Code Set infrastructure, including barcoding, and URLs to provide the information needed for various systems, analogous to electronic system and workflow documentation of VIS.

Codes can be downloaded from the CDC IIS Vaccine Code Sets web pages https://www.cdc.gov/vaccines/programs/iis/code-sets.html

Moderna EUA Fact Sheets

- **Letter of Authorization: https://www.fda.gov/media/144636/download**
- **Fact sheet for healthcare providers: https://www.fda.gov/media/144637/download**
- **Fact sheet for recipients and caregivers: https://www.fda.gov/media/144638/download**

FDA is also hosting a FAQ page for the Moderna vaccine: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine.

COVID-19 Vaccine Emergency Use Authorization FAQs

1. **Will a prescription be necessary for a vaccine under an EUA?**
   It is expected the COVID-19 vaccines issued EUAs may be administered without the requirement for an individual prescription for each vaccine recipient from an authorized healthcare provider. Under an EUA, FDA has an option to waive prescription requirements, if appropriate, depending on the authorized product specifics, authorized use, and/or emergency circumstances. In addition to an EUA, other legal authorities and/or plans may apply to vaccine administration:
   - Legal authorities for relevant emergency response agencies (e.g., state, local, tribal and territorial health departments, healthcare professional licensing boards);
   - Standing orders issued by a state health officer or applicable medical control officials or an executive order issued by a governor to authorize certain healthcare providers (e.g., nurses, pharmacists) to administer COVID-19 vaccine;
   - State COVID-19 vaccination and emergency response plans; and
   - CDC's COVID-19 Vaccination Program.

2. **Does an EUA have any impact on standing orders?**
   Standing orders are a type of medical order authorized or allowed under state laws. They permit the delegation and delivery of healthcare services through standardized criteria and procedures. Standing orders are one mechanism to enable non-physician healthcare providers (e.g., nurses, pharmacists) to assess and vaccinate persons who meet the criteria for vaccination without requiring a direct, individual order each time.

   During emergencies, states might use other legal mechanisms to facilitate vaccine administration, such as executive orders, emergency regulations, or position statements from licensing boards. FDA does not issue standing orders. However, it is expected that EUAs for COVID-19 vaccines would allow flexibility so that states could use their own mechanisms, like standing orders, to authorize appropriate healthcare providers to administer COVID-19 vaccine(s). States should review any applicable authorizations of

certain healthcare providers to administer COVID-19 vaccine under the Public Readiness and Emergency Preparedness (PREP) Act Declaration for Medical Countermeasures against COVID-19 (e.g., qualified pharmacy technicians and state-authorized pharmacy interns acting under the supervision of a qualified pharmacist). It is also expected that vaccine administration would be in accordance with the stakeholder's official COVID-19 vaccination and emergency response plans and that vaccination providers would be enrolled in the CDC COVID-19 Vaccination Program.

Statutes and regulations regarding the use of standing orders (or similar mechanisms) vary by state. States should review their statutory and regulatory language to ensure standing orders can cover the administration of an unlicensed vaccine that has been authorized by FDA for emergency use under an EUA. Specifically, states should ensure that state law does not preclude the use of standing orders for an investigational product authorized under an EUA. States should also ensure their state laws permit the administration of COVID-19 vaccines intended to be used under EUAs (i.e., the language of the state's laws is either broad enough to include COVID-19 vaccines or specifically lists the COVID-19 vaccines, depending on how the state's laws are written) and that COVID-19 vaccines are administered within the scope of authorized use under the applicable EUA.

3. **Can a COVID-19 vaccine be administered to populations not included in the authorized use of the vaccine under its EUA?**
   No. Use of any vaccine in populations outside the scope of its EUA would be an unauthorized use of the vaccine. Each EUA issued by FDA will describe the scope of the vaccine's authorized use, including populations (e.g., age groups) to which the vaccine may be administered. The scope of what is authorized under each EUA will be based on the available safety and efficacy data from populations studied in clinical trials. In order for liability protections under the Public Readiness and Emergency Preparedness (PREP) Act to apply, the use of the vaccine must be under an appropriate regulatory mechanism (e.g., an EUA, investigational new drug application, or approved biologics license application). Therefore, if a vaccine is authorized for use under an EUA, any use beyond the scope of what is described in the EUA would not be eligible for applicable liability protections under the PREP Act or injury compensation available under the Countermeasures Injury Compensation Program.

Vaccine Information Statements

VISs are required by law for licensed vaccines and only if a vaccine is added to the Vaccine Injury Table. Optional VISs may be produced, but only after a vaccine has been licensed. Plans for developing a VIS for COVID-19 vaccine are not known at this time but will be communicated as additional information becomes available.

Section 14: COVID-19 Vaccine Safety Monitoring

An "adverse event following immunization" is an adverse health problem or condition that happens after vaccination (i.e., a temporally associated event). It might be truly caused by the vaccine or it might be purely coincidental and not related to vaccination. CDC continuously monitors the safety of vaccines given to children and adults in the United States. VAERS, co-administered by CDC and FDA, is the national frontline monitoring system for vaccine safety.

Vaccine Adverse Event Reporting System

COVID-19 vaccination providers should report clinically important adverse events following COVID-19 vaccination to VAERS. VAERS is a national early warning system to detect possible safety problems with vaccines. Anyone—a doctor, nurse, pharmacist, or any member of the general public—can submit a report to VAERS. *VAERS is not designed to detect whether a vaccine caused an adverse event, but it can identify "signals" that might indicate possible safety problems requiring additional investigation.* The main goals of VAERS are to:

- Detect new, unusual, or rare adverse events that happen after vaccination
- Monitor for increases in known side effects
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Assess the safety of newly licensed vaccines
- Detect unexpected or unusual patterns in adverse event reports

Per the *CDC COVID-19 Vaccination Program Provider Agreement*, COVID-19 vaccination providers are required to report the following to VAERS:

- Vaccine administration errors (whether associated with an adverse event or not),
- Serious adverse events (even if they are not sure the vaccination caused the event),[14]
- Multisystem inflammatory syndrome (MIS) in children or adults, and
- Cases of COVID-19 that result in hospitalization or death

Vaccination providers are also required to report to VAERS any additional adverse events and/or adhere to any revised safety reporting requirements per FDA's conditions of authorized vaccine use posted on FDA's website throughout the duration of the EUA, as applicable. Vaccination providers should also report any additional clinically significant adverse events following COVID-19 vaccination to VAERS, even if they are not sure the vaccination caused the event. Vaccine manufacturers are required to report to VAERS all adverse events that come to

[14] Serious adverse events are defined as: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly/birth defect, or an important medical event that may not result in death, be life-threatening, or require hospitalization when, based upon appropriate medical judgment, it may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above. Serious adverse events should be reported regardless of causality.

their attention. VAERS data-sharing agreements with Department of Defense and IHS healthcare facilities are being coordinated through the federal government. NSIP will ensure enrolled COVID-19 vaccination providers understand the procedures for reporting adverse events to VAERS. VAERS reports can be submitted electronically.

v-safe

CDC has launched the new **v-safe** after vaccination health checker**. V-safe** web pages feature information on how to register and complete a **v-safe** health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources. **V-safe** will be available in a Spanish version in January 2021, with Korean, Vietnamese, and Simplified Chinese versions following shortly.

Healthcare providers have a vital role in encouraging COVID-19 vaccine recipients to participate; please see recommended provider/patient script below and reach out to NSIP staff to obtain posters with the QR code to display in your office.

Suggested healthcare provider script for encouraging patients to participate in **v-safe:**
*"CDC has created a way for you to report how you feel after COVID-19 vaccination through a smartphone-based tool that uses text messaging and web surveys to check in with you. Here (or in your packet) is a **v-safe** information sheet with more details and simple instructions to sign up."*

v-safe is a smartphone-based tool that uses text messaging and web surveys to check in with vaccinated individuals for adverse events after a COVID-19 vaccination. **v-safe** asks questions that will help CDC monitor the safety of COVID-19 vaccines. Medically significant events will be identified if the vaccinated individual reports that they missed work, were unable to complete normal daily activities, or had to seek care from a health provider or healthcare professional. The information will be sued to analyze common side effects (soreness in the arm, muscle aches, etc.) and to detect unexpected, serious health problems if they occur.

The following two programs require no actions but are provided for informational purposes to help in fielding questions about COVID-19 vaccine safety monitoring.

Vaccine Safety Datalink

The Vaccine Safety Datalink (VSD) is a collaboration between CDC's Immunization Safety Office and nine healthcare organizations. This active surveillance system monitors electronic health data on vaccination and medical illnesses diagnosed in various healthcare settings and conducts vaccine safety studies based on questions or concerns raised from medical literature and VAERS reports.

Clinical Immunization Safety Assessment Project

CDC's Clinical Immunization Safety Assessment Project is a national network of vaccine safety experts from CDC's Immunization Safety Office and seven medical research centers. This project conducts clinical research, assesses events following vaccination, and provides consultations to U.S. healthcare providers and public health partners.

Healthcare providers or health departments in the U.S. can request a consultation from CISA for a complex COVID-19 vaccine safety question that is a) about an individual patient residing in the U.S. or vaccine safety issue and b) not readily addressed by CDC or ACIP guidelines. CISA consultations can be requested by calling CDC-INFO at 1-800-CDC-INFO (1-800-232-4636) or using the CDC-INFO webform. Please indicate that the request is for a CISA evaluation. The request will be forwarded to the CISA Project clinicians for review.

Section 15: COVID-19 Vaccination Program Monitoring

Continuous monitoring for situational awareness throughout the COVID-19 Vaccination Program is crucial for a successful outcome. NSIP has established procedures for monitoring various critical program planning and implementation elements, including performance targets, resources, staffing, and activities.

NSIP Performance Measures

Key Plan Area	Performance Measure	Data Source	How Often Data is Collected
Provider Enrollment	# of providers successfully enrolled in Nevada's COVID-19 Vaccination Program	1. REDCap Survey 2. NV WebIZ Profile 3. VTrckS Profile	Weekly
Vaccine Access for Tier 1	# of providers serving Tier 1 groups successfully enrolled in Nevada's COVID-19 Vaccination Program \# of vaccines that can be administered per hour and/or per day by enrolled providers # of zip codes represented by providers enrolled to serve Tier 1	1. REDCap Survey 2. NV WebIZ Profile 3. VTrckS Profile 4. NV WebIZ Vaccine Administration Reports 5. Tiberius GIS data	Upon enrollment and updated weekly or when the provider experiences significant business changes
Vaccine Access for Frontline Critical Workers	# of providers serving frontline occupational groups successfully enrolled in Nevada's COVID-19 Vaccination Program \# of vaccines that can be administered per hour and/or per day by enrolled providers # of zip codes represented by providers	1. REDCap Survey 2. NV WebIZ Profile 3. VTrckS Profile 4. NV WebIZ Vaccine Administration Reports 5. Tiberius GIS data	Upon enrollment and updated weekly or when the provider experiences significant business changes

	enrolled to serve frontline occupational groups		
Vaccine Access for Other Critical Workforce	# of providers serving other critical occupational groups successfully enrolled in Nevada's COVID-19 Vaccination Program # of vaccines that can be administered per hour and/or per day by enrolled providers # of zip codes represented by providers enrolled to serve other critical occupational groups	1. REDCap Survey 2. NV WebIZ Profile 3. VTrckS Profile 4. NV WebIZ Vaccine Administration Reports 5. Tiberius GIS data	Upon enrollment and updated weekly or when the provider experiences significant business changes
Vaccine Access for the General Population	# of providers serving general population groups successfully enrolled in Nevada's COVID-19 Vaccination Program # of vaccines that can be administered per hour and/or per day by enrolled providers # of zip codes represented by providers enrolled to serve the general population	1. REDCap Survey 2. NV WebIZ Profile 3. VTrckS Profile 4. NV WebIZ Vaccine Administration Reports 5. Tiberius GIS data	Upon enrollment and updated weekly or when the provider experiences significant business changes
NV WebIZ Performance	System available for manual entry and electronic (HL7) submission Vaccination data file generates daily	1. NV WebIZ	24/7 availability Per planned enhancement schedule

	COVID-19 vaccination support functionality deployed		
Provider Data Reporting	100% of doses reported to NV WebIZ 100% of patients served reported in weekly aggregate REDCap survey Successful monthly reconciliation of COVID-19 vaccine inventory	1. NV WebIZ Vaccine Administration Report 2. NV WebIZ 3. REDCap	Daily (NV WebIZ) Weekly (REDCap) Monthly (Reconciliation)
Reporting to CDC	100% of uploads of enrollment data accomplished every Monday and Thursday by 3:00pm PST Vaccination data file generated and uploaded daily	1. REDCap 2. NV WebIZ 3. Immunization Clearinghouse	Twice Weekly Daily (vaccination data)
Vaccine Ordering and Distribution	# of Pfizer vaccines ordered # of Pfizer vaccines redistributed by facility name, geographic location, and population(s) served # of Moderna vaccines ordered # of Moderna vaccines distributed (via McKesson) by facility name, geographic location and population(s) served	1. VTrckS 2. NSIP internal records	Daily

COVID-19 Vaccine Coverage, both 1st and 2nd doses	# and % of first doses administered by prioritized group population total # and % of patients with series completion by prioritized group population total	1. NV WebIZ	Daily

CDC Data Dashboards

To provide situational awareness for states/jurisdictions and the general public throughout the COVID-19 vaccination response, CDC will have two dashboards available.

The **Weekly Flu Vaccination Dashboard** will include weekly estimates of influenza vaccination for adults, children, and pregnant women (when approved for these groups) using existing (National Immunization Survey [NIS]-Flu) data sources. Data and estimates from additional sources will be added, as available.

An additional dashboard, the OWS Tiberius platform, is a COVID-19 vaccine distribution planning, tracking, modeling, and analysis application that provides flexible, real-time, data-backed processes so users of all types can make data-driven decisions. Tiberius will integrate data sources from federal agencies, state and local partners, private-sector partners, and other data providers to create a comprehensive common operating picture for the COVID-19 vaccine planning, distribution, and administration effort that awardees can use to support the COVID-19 vaccine response. NSIP has access to Tiberius and is incorporating this application into program workflows as appropriate.

On Sunday, December 20, 2020, the CDC posted online the cumulative, national number of COVID-19 vaccine doses distributed and administered. This data will be updated daily after 3pm ET with data from the previous day. Starting December 21, 2020, the data will move to CDC's COVID Data Tracker at https://covid.cdc.gov/covid-data-tracker.

Resources

NSIP will regularly monitor program resources to avoid unexpected obstacles to the progress of Nevada's COVID-19 Vaccination Program.

Staffing

Having enough adequately trained staff with current situational awareness is key to implementing a successful COVID-19 Vaccination Program. Specialized expertise is required, and it is important to have backups in each specialty area to guard against interruption of activities because of illness or other personal situations. For example, if staff are supporting

temporary or off-site COVID-19 vaccination clinics, the hours are likely to be long and physically taxing. Managers and supervisors need to regularly check in with and support assigned staff's wellness and overall resilience to perform the assigned tasks.

As of November 30, 2020, NSIP is fully staffed to implement the COVID-19 Vaccination Program in Nevada. In addition to NSIP permanent state FTEs, the COVID-19 vaccine funding supplement from CDC in September allowed the NSIP to bring on a Public Health Nurse, two Project Coordinator leads, two Provider Enrollment Specialists, and four NV WebIZ Data Quality Specialists. NSIP will maintain this surge staffing level throughout the response, or until June 30, 2022 using supplemental CDC funding.

Inventory

Important activities during the implementation of Nevada's COVID-19 Vaccination Program might be halted if certain supplies are depleted without replenishment. NSIP is developing a list and is tracking supplies and inventory needs for various program components (e.g., temporary/off-site clinics, vaccination provider enrollment and training, vaccine management, etc.). NSIP will regularly monitor these records to prompt support staff to order and replenish supplies and ensure availability as needed. For example, NSIP is working to project and monitor use of PPE throughout the response and will work with PHP and DPBH Administration to have ordering and procurement protocols in place for securing additional supplies as needed.

Messaging

CDC will provide timely messaging throughout the COVID-19 vaccination response via all-jurisdiction calls, regular e-mail communication, and website updates. NSIP staff routinely monitor both CDC and local-level messaging to inform Nevada's communications efforts. NSIP staff receive daily emails directly from the CDC which are monitored for important information which can be shared rapidly with other staff via email or through an internal directly messaging platform.

NSIP is also collaborating with multiple groups on messaging and/or survey campaigns. Two such collaborations are described below; NSIP and the Bureau of Child, Family and Community Wellness leadership continue to cultivate additional relationships to build vaccine confidence and secure a broad messaging base, including with NOMHE, the Nevada Sheriffs and Chiefs Association, Nevada DEM and local emergency managers, business associations representing the various prioritized critical workforces, local Chambers of Commerce, and more.

NSIP will be learning about COVID-19 disease and vaccine attitudes from a study developed and championed by the Associate Dean for Clinical Research at the University of Nevada, Reno School of Medicine. The intent of this study is to conduct ongoing assessment of both public and health care provider attitudes in Nevada to provide timely data to inform education, communication and messaging in communities statewide to increase COVID-19 vaccine awareness and uptake in Nevada. Results from the study will be shared regularly with key

institutions and stakeholders to develop/target consistent messaging. In order to achieve this intent, UNR is conducting two parallel surveys to:

- Describe attitudes of COVID-19 vaccine acceptance, sources of knowledge and utilization among citizens of Nevada
- Describe attitudes of COVID-19 vaccine recommendations from health care providers, students and trainees in Nevada

Immunize Nevada is adapting its current flu media campaign to message vaccine confidence to Nevadans. The goal is to empower families, combat myths and misinformation, and protect Nevada's communities as we wait for a COVID-19 vaccine, while continuing to encourage Nevadans to roll up their sleeves for flu shots. This campaign and the methods utilized will be leveraged and enhanced with upcoming CDC funding in December 2020 to focus solely on messaging vaccine confidence and the logistics of who can get the vaccine "now" and how to do so for the COVID-19 vaccine.

The campaign will use the following channels to reach Las Vegas, Reno, and rural Nevada residents.

· Digital outdoor boards

· Cable TV - Cox (includes a sports schedule as well)

· All digital capabilities from Spectrum Statewide (display, video, etc.)

· Streaming TV

· Social media - Facebook, Instagram)

Variations in messaging can create confusion and hamper the effective implementation of the vaccination program. Messaging from all stakeholders (e.g., government, LHAs, trusted community partners, etc.) be clear, current, consistent, and received as intended by the audience. Monitoring social media engagement metrics and survey responses will allow NSIP, UNR, and Immunize Nevada to assess message delivery and reception and dispel inaccurate information.

Local Jurisdictions

Constant communication and coordination with local jurisdictions and tribal organizations is instrumental during all phases of the COVID-19 Vaccination Program in Nevada. NSIP is actively working with DPBH Administration, the DHHS Director's Office, and the Governor's Office to establish roles and responsibilities at all levels. This will help avoid misperceptions as well as gaps in planning and implementation. Throughout the COVID-19 Vaccination Program, NSIP will monitor and maintain awareness of local-level strategies and activities, providing technical assistance as needed. This visibility ensures local jurisdictions and providers adhere to recommendations and guidance from CDC and Nevada authorities.

Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions (revised 10/29/2020 by CDC)

Many COVID-19 vaccine candidates are in development, and clinical trials are being conducted simultaneously with large-scale manufacturing. COVID-19 Vaccination Program plans must be flexible and accommodate multiple scenarios. For the purpose of initial planning, Nevada will consider the following assumptions outlined by the CDC.

COVID-19 Vaccine

- Limited COVID-19 vaccine doses may be available by mid-December 2020 (an estimated 22.5 million doses nationally), but COVID-19 vaccine supply may increase substantially in 2021.
- Initially available COVID-19 vaccines are anticipated to be authorized for use under an Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration.
- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C) temperatures, and ongoing stability testing may impact these requirements. *Note: These temperatures are based on information available as of October 29, 2020. Updated information will be provided as it becomes available.*
- Jurisdictions should develop strategies to ensure the correct match of COVID-19 vaccine products and dosing intervals. Once authorized or approved by the FDA, two doses of COVID-19 vaccine, separated by either 21 or 28 days, will be needed for most COVID-19 vaccine products, and second-dose reminders for patients will be necessary. Both doses will need to match each other (i.e., be the same vaccine product).
- Some COVID-19 vaccine products will likely require reconstitution with diluent at the point of administration.

COVID-19 Vaccine Allocation

Final decisions are being made about use of initially available supplies of COVID-19 vaccines. These decisions will be partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination may include:

- Healthcare personnel (paid and unpaid people serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home)
- Non-healthcare essential workers
- Adults with underlying medical conditions that are risk factors for severe COVID-19 illness
- People 65 years of age or older

Allocation of COVID-19 vaccine to jurisdictions will be based on multiple factors, including:

- Critical populations recommended by the Advisory Committee on Immunization Practices (with input from the National Academies of Sciences, Engineering, and Medicine)
- Current local spread/prevalence of COVID-19
- COVID-19 vaccine production and availability

Jurisdictions should anticipate that allocations may shift during the response based on supply, demand, and risk. Each jurisdiction should plan for high-demand and low-demand scenarios.

COVID-19 Vaccination Provider Outreach and Enrollment

- To receive and administer COVID-19 vaccine and ancillary supplies, vaccination providers must enroll in the United States Government (USG) COVID-19 Vaccination Program, coordinated through their jurisdiction's immunization program, by signing and agreeing to conditions outlined in the *CDC COVID-19 Vaccination Program Provider Agreement.*
- CDC will make this agreement available to each jurisdiction's immunization program for use in conducting outreach and enrolling vaccination providers. Jurisdictions will be required to maintain these agreements on file for a minimum of 3 years.
- Jurisdictions will be required to collect and submit to CDC information on each enrolled vaccination provider/site, including provider type and setting, patient population, (i.e., number and type of patients served), refrigerated/frozen/ultra-cold temperature storage capacity, and logistical information for receiving COVID-19 vaccine shipments.
- Some multijurisdictional vaccination providers (e.g., select retail pharmacy chains, the Indian Health Service, other federal entities) will enroll directly with CDC to order and receive COVID-19 vaccine. These direct partners will be required to report vaccine supply and uptake information back to each respective jurisdiction. CDC will share additional information when available on these procedures to ensure jurisdictions have full visibility for planning and documentation purposes.
- Jurisdictions may choose to partner with commercial entities to reach the initial populations of focus.
- Routine immunization programs will continue.

COVID-19 Vaccine Ordering and Distribution

- **COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will share more information about reimbursement claims for administration fees as it becomes available.**
- CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine

products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer (*as opposed to by the centralized distributor).*

- Jurisdiction-enrolled vaccination providers will follow the jurisdiction's vaccine ordering procedures.
- COVID-19 vaccination providers will be required to report COVID-19 vaccine inventory each time a COVID-19 vaccine order is placed.
- Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS) by jurisdiction immunization programs for vaccination providers they enroll.
- Vaccine (and diluent, if required) will be shipped to provider sites within 48 hours of order approval by the immunization program, if supply is available. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but shipment will be timed to arrive with or before the vaccine.
- Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators.
    - Each kit will include supplies needed to administer 100 doses of vaccine.
    - Jurisdictions may need to plan for additional PPE, depending on vaccination site needs.
    - For COVID-19 vaccines that require mixing with diluent at the point of administration, these ancillary supply kits will include additional necessary syringes, needles, and other supplies for this purpose.
    - *Sharps containers, gloves, bandages, and other supplies will <u>not</u> be included.*
- Minimum order size for CDC centrally distributed vaccines will be 100 doses per order for most vaccines. Minimum order size for direct-ship vaccines will be 975 doses. CDC will provide more detail as it becomes available.
- Vaccine will be sent directly to vaccination provider locations for administration or designated depots for secondary distribution to administration sites (e.g., chain drugstores' central distribution).
- Once vaccine products have been shipped to a provider site, the federal government will not redistribute product.
- Jurisdictions will be allowed to redistribute vaccines while maintaining the cold chain. However, with the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, jurisdictions should be judicious in their use of redistribution and limit any redistribution to refrigerated vaccines only.
- Jurisdictions are **<u>not</u>** advised to purchase ultra-cold storage equipment at this time. Ultra-cold vaccine may be shipped from the manufacturer in coolers packed with dry ice. These coolers should be repacked with dry ice within 24 hours of receipt of shipment (day 0) and repacked again every 5 days to maintain required temperature. On day 15, the vaccine should be moved into the refrigerator, stored at 2°C to 8°C, and used within 5 days (120 hours).

To be determined:

- *Vaccine disposal/recovery procedures*

COVID-19 Vaccine Administration Data Reporting

- Jurisdictions 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 to jurisdictions.
- All vaccination providers may be required to report and maintain their COVID-19 vaccination information in CDC's VaccineFinder daily.
- CDC has prioritized jurisdiction onboarding to the Immunization (IZ) Gateway[15] to allow Immunization Information Systems (IISs) to receive data directly from national providers, nontraditional vaccination providers, and other external systems, as well as to report vaccine administration data to CDC.
- DUAs will be required for data sharing via the IZ Gateway and other methods of vaccine administration data sharing with CDC and will be coordinated by each jurisdiction's immunization program.

Communication

- CDC will develop communication resources for jurisdictions and tribal organizations to use with key audiences. These resources will be available on a public-facing website currently under development, but jurisdictions and tribal organizations will likely need to tailor messaging and resources specific to special populations in their communities.
- CDC will work with national organizations to disseminate key messages.
- Communication and educational materials about COVID-19 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., mixing with diluent, administration techniques), etc. will be available in a variety of formats.
- When vaccine supply is available for expanded groups among the general population, a national COVID-19 vaccine finder will be available on the public-facing VaccineFinder.
- A screening tool on the CDC website will help people determine their own eligibility for COVID-19 vaccine and direct them to VaccineFinder.
- Transparent communication with Nevadans will be essential in proper execution of this vaccine distribution strategy. Clear and concise information on vaccine clinical trials,

[15] The IZ Gateway is a portfolio of project components that share a common IT infrastructure. The IZ Gateway aims to rapidly onboard IISs to provide readiness for COVID-19 vaccine response through data exchange, both among IIS and between IIS and federal providers, mass vaccination reporting, and consumer access tools. The IZ Gateway aims to increase the availability and volume of complete and accurate immunization data stored within IIS and available to providers and consumers regardless of their jurisdictional boundaries.

phased population groups, among others are being considered to ensure Nevadans are informed.

- Nevada's 2020-2021 influenza campaign can and will be leveraged for COVID-19 communication when appropriate.

COVID-19 Vaccine Safety

- Vaccine safety monitoring is required under the EUA(s) for COVID-19 vaccines. Select adverse events are required to be reported to the Vaccine Adverse Event Reporting System (VAERS) (i.e., vaccine administration errors, serious adverse events, multisystem inflammatory syndrome (MIS) in children or adults, and cases of COVID-19 that result in hospitalization or death). Any revised safety reporting requirements should also be adhered to. FDA's EUA website containing letter(s) of authorization and fact sheets should be checked for any updates that may occur.
- Any additional clinically significant adverse events following vaccination should be reported to the VAERS.
- Adverse events will also be monitored through electronic health record- and claims-based systems (e.g., Vaccine Safety Datalink).

Appendix B: Considerations for Frontline Health Care Workers

Frontline healthcare workers should be the first population vaccinated in Nevada. Ensuring frontline health care workers are protected from SARS-CoV-2 (the virus which causes COVID-19) protects all Nevadans and visitors by ensuring there will be adequate staffing within the state's hospital systems to care for patients with COVID-19 and all other hospital patients whose needs can be just as serious.

Key Considerations

For hospital allocation, NSIP will use methodology collaboratively created and approved by the local health authorities, the NHA, NRHP, and Immunize Nevada.

Hospitalizations. Hospital vaccine disbursement will be prioritized based upon prevalence of hospitalized COVID-19 patients. Prevalence of hospitalized COVID-19 patients will be defined as *the average number of suspected and positive COVID-19 patients currently admitted within the hospital.* A 30-day period will be used to determine the daily average based on numbers reported to the NHA via the daily hospital survey. The hospital with the highest daily average of patients currently admitted will be placed first to receive vaccine followed by the rest of the hospitals in descending order as vaccine supply allows.

Using this established criterion, NSIP will determine which counties are experiencing elevated COVID-19 related hospitalizations. Based upon real-time analyses, NSIP can allocate vaccine to hospitals in those counties using a data-driven, targeted approach. Initial vaccine allocation will account for 80 percent of known number of staff in each facility until all facilities have received an allocation. This allocation methodology should cover vaccine refusals and staffing fluidity to ensure vaccine doses are not unnecessarily wasted. If more vaccine is needed at a certain facility, the facility will be able to request additional vaccine from NSIP. The NSIP Vaccine Manager and Vaccine Coordinator will work to fill those requests as quickly as possible every weekday.

Due to the anticipated small amount of initial vaccine allocation, hospitals will likely be allocated COVID-19 vaccine in multiple rounds. The first round will be for frontline healthcare workers, followed by additional rounds for the remaining staff. This will be a fluid situation as initial vaccine allocation amounts remain unknown.

After hospitals have received enough allocation to vaccinate all staff, NSIP will use the methodology approved by the Governor's COVID-19 Mitigation and Management Task Force to monitor county-level disease transmission. A county is flagged for elevated disease transmission if it meets two of the three criteria:

1. Average number of tests per day (per 100,000) < 100. The average number of molecular tests conducted in the most recent complete two-week period in a county, divided by the number of people living in the county. This number is then multiplied by 100,000 to

control for varying populations in counties. Due to reporting delay, this is reported over a 14-day period with a 7-day lag. Counties that average fewer than 100 tests per day will meet this criterion.

2. Case rate (per 100,000) > 200. The total number of cases diagnosed and reported over a 30-day period divided by the number of people living in the county. This number is then multiplied by 100,000 to control for varying populations in counties. Counties with a case rate greater than 200 per 100,000 will meet this criterion.
3. Case rate (per 100,000) > 50 AND testing positivity > 8.0%. The total number of positive molecular tests divided by the total number of molecular tests conducted. This number is then multiplied by 100 to get a percentage. Due to reporting delay (which may be different between positive and negative tests), this is reported over a 14-day period with a 7-day lag. Counties with a test positivity > 8.0% paired with case rate greater than 50 per 100,000 will meet this criterion.

Using these established criteria, NSIP will determine which counties are experiencing elevated disease transmission. Based upon real-time analyses, NSIP can allocate vaccine to those counties using a data-driven, targeted approach. Healthcare workers and other critical infrastructure personnel within the counties determined to have elevated disease transmission are likely at greater risk of exposure and development of COVID-19 and becoming too ill to work. This allocation strategy will be used until the COVID-19 vaccine allocation from the federal government meets the need of the vaccine in Nevada.

Each hospital will have frontline healthcare workers defined and enumerated. Rural and frontier hospitals prefer all staff to be vaccinated as frontline healthcare workers because staff within these facilities do many duties across the hospital. Frontline healthcare workers will be vaccinated in all hospitals throughout the state as priority. After frontline healthcare workers in hospitals are vaccinated, the rest of the hospital staff will be prioritized and vaccinated throughout the state before vaccinating the rest of Tier 1.

It is the responsibility of hospital decision-makers to ensure their workforce is appropriately prioritized based on these guiding principles. Healthcare staff and practitioners providing direct patient care or services to confirmed and suspected COVID-19 patients, including inpatient services and ED/Trauma, should be offered the vaccine as a priority. This includes staff, employees and practitioners who are routinely assigned activities within the following hospital inpatient areas:

- Intensive Care Units caring for COVID-19 Patients
- Hospital floors or wards designated to care for COVID-19 patients
- Emergency/ Trauma Department
- Respiratory care services who routinely care for COVID-19 patients
- Housekeeping, janitorial, etc. staff who work near COVID-19 patients

Appendix C: Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination

The United States Department of Health and Human Services is partnering with **CVS and Walgreens** to offer on-site COVID-19 vaccination services for residents of nursing homes and assisted living facilities once vaccination is recommended for them.

The **Pharmacy Partnership for Long-term Care (LTC) Program** provides end-to-end management of the COVID-19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this patient population, while reducing burden on LTC facilities and jurisdictional health departments. LTCF staff who have not received COVID-19 vaccine can also be vaccinated as part of the program. This program provides critical vaccination services and is free of charge to facilities. This effort will require extensive coordination with jurisdictions, long-term care facilities (LTCFs), federal partners, including the Centers for Medicare and Medicaid Services (CMS), and professional organizations, including American Health Care Association (AHCA) and Leading Age, which include members across both nursing homes and assisted living facilities.

As part of this program, which 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 will likely be needed to administer both doses of vaccine and vaccinate any new residents and staff.
- Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
- Ensure cold chain management for vaccine.
- Provide on-site administration of vaccine.
- Report required vaccination data (approximately 20 data fields) to the local, state/territorial, and federal jurisdictions within 72 hours of administering each dose.
- Adhere to all applicable Centers for Medicare & Medicaid (CMS) COVID-19 testing requirements for LTCF staff.

If interested in participating, LTCFs should sign up (or opt out) starting October 19. Sign up will remain open for two weeks.

- Skilled nursing facilities (SNFs) will make their selection through the National Healthcare Safety Network (NHSN). An “alert” will be incorporated into the NHSN LTCF COVID-19 module to guide users to the form.
- Assisted living facilities (ALFs) will make their selection via an online REDCap (https://redcap.link/LTCF) sign-up form.
- Facilities will indicate which pharmacy partner (CVS or Walgreens or an existing LTC pharmacy) they prefer to have on site.

- Online sign-up information will be distributed through ALF and SNF partner communication channels (email, social media, web).
- Indicating interest in participating is non-binding and facilities may change their selection or opt in or out via email after the online survey closes.

Once the sign-up period has closed, no changes can be made via the online form, and the facility must coordinate directly with the selected pharmacy provider to change any requested vaccination supplies and services.

HHS will communicate preferences to CVS and Walgreens and will try to honor facility preferences but may reassign facilities depending on vaccine availability and distribution considerations and to minimize vaccine wastage.

HHS expects the program services to continue on-site at participating facilities for approximately two months. After the initial phase of vaccinations, each facility can choose to continue working with CVS or Walgreens or can work with a pharmacy provider of its choice.

Appendix D: Vaccination Implementation Strategies to Consider for Critical Populations

Vaccinating the critical infrastructure workforce, people at increased risk for severe COVID-19 illness, people at increased risk of acquiring or transmitting COVID-19, and people with limited access to routine vaccination services may be challenging for several reasons. Various strategies, some with commonality across groups and others unique to certain populations, will be considered in Nevada to reach these critical populations for COVID-19 vaccination.

Provider Recruitment and Enrollment	• **Communicate vaccination provider requirements and enrollment procedures widely throughout jurisdiction**, including to long-term care and correctional/detention facilities. • **Enroll a variety of providers throughout jurisdiction**, especially those serving critical populations, such as: ○ Health Departments ○ Health Clinics (including FQHCs and Community Health Centers) ○ Health Care for Homeless Clinics ○ Physicians' Offices ○ Home healthcare providers ○ Employers/occupational health clinics ○ College/university health services/clinics that serve young adults ○ Pharmacies ○ Long-term care facilities ○ Correctional/detention facilities ○ Mobile clinics ○ Points of Dispensing Events (PODs)
Enumerating and Locating Populations	• **Map distribution of critical populations** or the facilities/locations they live or work in (e.g., long-term care facilities, correctional/detention facilities, homeless shelters or encampments, colleges, and universities) • **Map location of enrolled providers and their capacity** • **Compile and maintain critical points of contact** for reaching critical populations, for example: ○ Large healthcare systems ○ Large retail pharmacies

	○ Large employers of critical workers within the jurisdiction ○ Home healthcare providers ○ Correctional/detention facilities ○ College and University Presidents ○ Tribal leaders and local Indian Health Service Administrators ○ Homeless shelters, community kitchens, syringe service programs, and Continuum of Care Homeless Assistance Programs ○ Intermediate care facilities, group homes, and paratransit services for people with disabilities • **Utilize electronic health records or administrative data** for estimating critical population size/location (e.g., CMS, trade group databases, point-in-time estimates and housing inventory count data, college/university student enrollment records).
Vaccine Administration	• **Ensure social distancing, mask use, and/or other preventive measures by enrolled providers** • Encourage vaccination providers to **schedule clinic visits** to prevent people from congregating • Consider utilizing **risk-specific vaccination options/events** (e.g., events specifically and only for people 65 years of age and older, etc.) • Consider establishing **institutional standing orders** where possible • **Ensure consent is obtained ahead of time if medical proxy is in place** • For people living in institutions, consider **vaccinating at intake**; for people attending colleges/universities, **vaccinate at enrollment** • **Engage community members from the critical populations** for planning (e.g., people with disabilities) • **Engage trusted sources** to educate about vaccine recommendations and availability and to address hesitancy, for example: ○ Professional organizations, state licensure boards, and healthcare coalitions ○ Critical workforce employers and union representatives ○ Specific critical populations health advocacy organizations ○ College/University Presidents, athletic coaches, and other student/campus organizations ○ Homeless shelter, community kitchen, and syringe service program managers ○ Social workers ○ Faith leaders

	• Ensure vaccination clinics are available during different times of day/evening to **accommodate different schedules**
	• **Conduct mobile clinics in multiple locations at non-traditional sites**, such as:
	  ○ Small health clinics not enrolled as providers
	  ○ Intermediate care facilities and group homes for people with disabilities
	  ○ Long-term care facilities
	  ○ Correctional/detention facilities
	  ○ Employers and job fairs
	  ○ College/University parking lots, gyms, dining halls, faculty buildings, and residence halls
	  ○ Homeless shelters, community kitchens, syringe service programs, and homeless encampments
	  ○ Faith-based organizations
	  ○ Public libraries, public parks
	  ○ Community fairs
	• **Leverage ongoing seasonal influenza clinics**

Second-Dose Reminders	• **Use a variety of methods to send second-dose reminders to recipients and/or medical proxies, including:**
	  ○ Vaccination cards
	  ○ Electronic health records/patient portals
	  ○ Text messaging
	  ○ Phone calls
	  ○ Email
	  ○ Mail
	  ○ Peer Navigators/Community Health Workers/Promatoras
	• For people living in institutions who are moved after receipt of first dose, **link them to vaccination providers in the community or send reminders to the receiving facility.**

Documentation and Reporting	• Provide training to qualified vaccination providers on use of the jurisdiction's **immunization information system (IIS)** or other external tracking system • Leverage various **other administrative systems**, as able (e.g., employer systems, Homeless Management Information System, etc.)

Provider/ Administrator Communications	• Education healthcare providers throughout jurisdiction about recommendations to vaccinate critical populations and, if not an enrolled provider, **where to refer patients for free vaccination**
	• **Educate nonclinical facility administrators** about recommendations to vaccinate critical populations, such as:
	  ○ Employer human resource staff
	  ○ Correctional/detention facility wardens, leadership, and health services
	  ○ College/University administrators, faculty, and staff
	  ○ Homeless shelter staff
	• **Ensure providers have information needed on vaccine recommendations to counsel patients**, including relevant contraindications or potential lower efficacy in certain groups
	• For people in institutions, train providers to ensure **transfer of vaccination records** to receiving facility or request vaccination records from previous facility
	• **Message directly to caretakers, medical proxies, or parents of college/university students to encourage uptake**

Critical Population Communications	• Develop **diverse communication materials** on vaccine recommendations and where to get vaccinated for people in critical population groups, such as:
	  ○ Flyers/posters at:
	  ▪ Healthcare provider facilities (e.g., physicians' offices, health centers, hospital emergency departments)
	  ▪ Large employers
	  ▪ Pharmacies
	  ▪ Long-term care facilities
	  ▪ Correctional/detention facilities
	  ▪ College/University campuses
	  ▪ Homeless shelters, homeless encampments, community kitchens, and syringe service programs
	  ▪ Retail stores
	  ▪ Bus stations
	  ▪ Public parks and libraries
	  ○ Newspaper (print and online) advertisements

	○ Online/social media advertisements, including on advocacy organization websites ○ Mail/postcards ○ Population-specific communications (e.g., employer communications, trade magazines, senior-focused publications, college/university newspapers, or other communications) • Ensure all communication materials are **culturally and linguistically appropriate**, including messaging with American Sign Language, large print, and braille • **Create low-literacy messages**, including those for people with severe intellectual disabilities • Ensure all messaging **complies with ADA regulations**

Appendix E: Federal Pharmacy Partnership for COVID-19 Vaccination Program

The United States Department of Health and Human Services is partnering with pharmacies to increase access to COVID-19 vaccine once a vaccine is authorized or approved and recommended for use in the U.S. Through the **Federal Pharmacy Partnership Strategy for COVID-19 Vaccination**, select pharmacy partners will receive a direct allocation of COVID-19 vaccine. This will help jurisdictions augment access to vaccine when supply increases and vaccine is recommended beyond the initial critical populations. With more than 86% of people living within five miles of a community pharmacy, pharmacies have unique reach and ability to provide access to COVID-19 vaccine and support broad vaccination efforts. This program will provide critical vaccination services for the U.S. population, with vaccine administered at retail locations at no cost to recipients. The program will be implemented in close coordination with jurisdictions to ensure optimal COVID-19 vaccination coverage and vaccine access nationwide.

The federal allocation to pharmacies will not cover every pharmacy in the United States. Pharmacies not included in the federal allocation program are still encouraged to be part of the vaccination program and should coordinate with their jurisdictions to become COVID-19 vaccination providers.

Program Benefits

Once there is an adequate supply of COVID-19 vaccine to support broader vaccination efforts, it will be important to swiftly increase access to COVID-19 vaccine for the general population. Partnerships with retail chain pharmacies and networks of community pharmacists across the U.S. will increase the general population's access to COVID-19 vaccine. Pharmacists can be crucial public health partners to increase access and convenience of COVID-19 vaccines.

- Pharmacists are trained to provide vaccinations and are important immunizers in their communities.
- Pharmacists are a trusted health resource in their communities and play a vital role in the public health response to COVID-19 by counseling patients and administering tests.
- Pharmacies have the capability to quickly surge and meet demand nationwide because of existing infrastructure and the large number of pharmacists who can administer vaccines.
- CDC has worked extensively with pharmacy chains to improve pandemic preparedness, conduct vaccine throughput exercises, and assess store and organizational response capabilities.

Program Participants

Retail chain pharmacies and networks of community pharmacists are also being considered for this program. As of Monday, October 29, 2020, the following pharmacy partners have signed on to participate in this program with the federal government:

- Walgreens
- CVS Health Corporation
- Walmart Stores (including Sam's)
- Rite Aid Corp
- The Kroger Co. (i.e., Krogers, Harris Teeter, Fred Meyer, Frys, Ralphs, King Soopers, Smiths, City Market, Dillons, Marianos, Pick-n-Save, Copps, Metro Market)
- Publix
- Costco
- Albertson's Companies (i.e., Osco, Jewel-Osco, Albertsons, Albertsons Market, Safeway, Tom Thumb, Star Market, Shaws, Haggen, Acme, Randalls, Carrs, Market Street, United, Vons, Pavilions, Amigos, Lucky's, Pak n Save, Sav-On)
- Hy-Vee
- Meijer
- H-E-B
- Retail Business Services (i.e., Food Lion, Giant Food, The Giant Company, Hannaford Bros Co, Stop & Shop)

Together, these pharmacy partners will extend the COVID-19 vaccination provider network to over 35,000 store locations. Store lists for each of these partners will be shared with jurisdictions. Additional partners are also expected to sign on, further expanding the program. Details on additional partners will be shared with jurisdictions as soon as they are available.

Based on their 1) size and reach, 2) capability to store vaccines and ensure cold chain management, 3) ability to meet data reporting requirements to jurisdictions and CDC, and 4) estimated daily number of doses each facility is able to administer, these partners stand ready to assist jurisdictions in COVID-19 vaccination efforts.

Program Implementation

Pharmacy partners must sign a COVID-19 Pharmacy Partner Agreement to Participate. Before receiving COVID-19 vaccine, the partner must propose, in writing, its minimum capacity for vaccine administration, including a) the number and location of facilities that will administer COVID-19 vaccine, b) the estimated number of COVID-19 vaccine doses that each facility will be able to administer within defined periods, and c) estimated cold chain storage capacity.

- Pharmacy partners will directly order and receive allocation of COVID-19 vaccine from the federal government.

- Vaccine will be provided at no cost to the pharmacy chain and will be administered at retail locations at no cost to vaccine recipients.
- On a daily basis, pharmacy partners must report to CDC the number of doses of COVID-19 vaccine a) ordered by store location in VTrcks and b) on hand in each store reported through VaccineFinder. Pharmacy providers will also be required to report CDC-defined data elements related to vaccine administration to jurisdiction IISs or through other agreed upon methods (e.g., formatted data extracts) to jurisdictions if IIS reporting is not available.
- Pharmacy partners will provide a point of contact for reach jurisdiction for questions related to allocation of vaccine in store locations in their jurisdiction area.
- Jurisdictions may opt out of having pharmacies in their area receive allocations through this program.

Appendix F: Nevada Licensed Facilities Descriptions

CREDENTIAL TYPE	DESCRIPTION PER DHHS/DPBH LICENSURE	ACIP MORBIDITY AND MORTALITY CONSIDERATIONS	SUGGESTED PHASE AND RATIONALLE
Facility for Skilled Nursing (SNF)	Provides **continuous skilled nursing (24 hr.)** and related care as prescribed by a physician to a patient in the facility who is not in an acute episode of illness and whose primary need is the availability of such care on a continuous basis	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living** • **Rotating Staff**	**1a Staff** **1a Residents** -Most enrolled in Pharmacy Partnership Program (**PPP Part A**) -Vaccinate staff and residents in same visits -Partnered with a CVS or Walgreens -Vaccinations began 12/21/20
Skilled Nursing Facility (SNF) – Distinct Part of Hospital	Provides **continuous skilled nursing (24 hr.)** and related care as prescribed by a physician to a patient in the facility who is not in an acute episode of illness and whose primary need is the availability of such care on a continuous basis -Attached to or distinct part of a hospital -Most SNF staff shared and vaccinated along with hospital personnel	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living** • **Rotating Staff**	**1a Staff** **1a Residents** -Most enrolled in Pharmacy Partnership Program (**PPP Part A**) -Vaccinate staff and residents in same visits -Partnered with a CVS or Walgreens -Vaccinations began 12/21/20
Residential Facility for Groups Type of Assisted Living (AL)	Adult Group Care/Assisted Living (AL) Facility: Establishments that furnish food, shelter, assistance and limited supervision to a person with an intellectual disability or with a physical disability or a person who is aged or infirm.	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living** • **Rotating Staff**	**1a Staff** **1a Residents** -Most enrolled in Pharmacy Partnership Program (**PPP Part B**) -Vaccinate staff and residents in same visits -Partnered with a CVS or Walgreens -Vaccinations began 1/4/21
Facility for Intermediate Care (ICF) **-Includes Desert Regional Center**	-Operated and maintained to **provide 24-hour personal and medical supervision** for a person who does not have illness, disease, or injury or other condition that would require the degree of care and treatment which a hospital or facility for skilled nursing is designed to provide	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living** • **Rotating Staff**	**1a Staff** **1a Residents** -Similar to Skilled Nursing Facility (PPP Part A) -Vaccinate staff and residents in same visits -Vaccinations may begin 12/21/20

Facility for Intermediate Care ICF/IID	Intermediate Care Facility for Individuals with Intellectual Disabilities -Operated and maintained to **provide 24-hour personal and medical supervision** for a person who does not have illness, disease, or injury or other condition that would require the degree of care and treatment which a hospital or facility for skilled nursing is designed to provide (ICF/IID)	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living** • **Rotating Staff**	**1a Staff** **1a Residents** -Similar to Skilled Nursing Facility (PPP Part A) -Vaccinate staff and residents in same visits -Vaccinations may begin 12/21/20
Community Based Living Arrangement (CBLA) Services	Service Only Provider: Provides behavioral health-type services listed below in client's home	• **Rotating Staff**	**1a Staff** -Vaccinate staff first to cocoon residents
Community Based Living Arrangement Services-Residential CBLA Facility	Residential CBLA Facility: -Provider owned and operated -Flexible, individualized services, including training and habilitation services, provided in the home to persons with mental illness or developmental disabilities, designed to assist persons in maximizing their independence	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living**	**1a Staff** **1a Residents** -Similar to Assisted Living Facility (PPP Part B) -Vaccinate staff and residents in same visits -Vaccinations may begin 1/4/21
Intensive Supported Living Arrangement (ISLA)	Intensive supported living arrangement services with **24-hour care** means flexible, individualized services **provided in the home** to a person with an intellectual disability or a person with a developmental disability who is served by the Division that are designed and coordinated to assist the person in maximizing the person's independence, including, without limitation, training and habilitation services **Not HCQC licensed – not on HCQC or DTER databases/separate spreadsheet delivered to counties**	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living** • **Rotating Staff**	**1a Staff** **1a Residents** -Similar to Skilled Nursing Facility (PPP Part A) -Vaccinate staff and residents in same visits -Vaccinations may begin 12/21/20
Supported Living Arrangement (SLA)	Supported living arrangement services means flexible, individualized **services provided in the home** to a person with an intellectual disability or a person with a developmental disability who is served by the Division that are designed and coordinated to assist the person in maximizing the	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living**	**1a Staff** **1a Residents** -Similar to Assisted Living Facility -Vaccinate staff and residents in same visits -Vaccinations may begin 1/4/21

	person's independence, including, without limitation, training and habilitation services **Not HCQC licensed – not on HCQC or DTER databases/separate spreadsheet delivered to counties**		
Agency to Provide Nursing in the Home	Provides skilled nursing and assistance and training in health and housekeeping in the home -Includes Home Health Aide, Medical Social Worker, Occupational/Physical/Speech Therapy, Skilled Nursing, Nutritional Guidance	• **Rotating Staff**	**1a Staff** -Vaccinate staff first to cocoon residents
Agency to Provide Nursing in the Home	Branch Office – description as above	• **Rotating Staff**	**1a Staff** -Vaccinate staff first to cocoon residents
Agency to Provide Nursing in the Home	Sub Unit – description as above	• **Rotating Staff**	**1a Staff** -Vaccinate staff first to cocoon residents
Agency to Provide Personal Care Services in the Home	Any person who is employed by an agency to provide **personal care services in the home**, a community health worker pool or a peer support recovery organization -Has successfully completed a course in cardiopulmonary resuscitation, basic emergency care to an elderly person or a person with a disability	• **Rotating Staff**	**1a Staff** -Vaccinate staff first to cocoon residents
Personal Care Agency that is also ISO Certified	Any person who is employed by an agency to provide **personal care services in the home**, a community health worker pool or a peer support recovery organization -Has successfully completed a course in cardiopulmonary resuscitation, basic emergency care to an elderly person or a person with a disability -Extra training in International Organization for Standardization (ISO)	• **Rotating Staff**	**1a Staff** -Vaccinate staff first to cocoon residents

Home for Individual Residential Care (HIRC)	-**Home** in which a natural person furnishes food, shelter, assistance and limited supervision to not more than two persons with intellectual disabilities or with physical disabilities or who are aged or infirm, unless the persons receiving those services are related within the third degree of consanguinity or affinity to the person providing those services	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living**	**1b Staff** **1b Residents**
Facility for Hospice Care	**Facility** operated to provide hospice care: -Includes the provision of physical, psychological, custodial and spiritual care for persons who are terminally ill and their families	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living** • **Rotating Staff**	**1a Staff** **1a Residents**
Hospice Care – Program of Care	Centrally administered program of palliative services and supportive services provided by an interdisciplinary team directed by a physician -**Care may be provided in the home, at any time, 24/7**	• **Rotating Staff**	**1a Staff**
Facility for Care of Adults During the Day	Adult Day Care: -Establishment operated and maintained to **provide care during the day on a temporary or permanent basis** for aged or infirm persons	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Setting** • **Rotating Staff**	**1b Staff** **1b Attendees** -Vaccinate staff first to cocoon residents
Jobs – Day Training (JDT)	Jobs and **Day Training** (JDT) assists individuals in obtaining meaningful employment and living skills to help them achieve community inclusion, independence, and productivity. -Program serves individuals 18 years old or older who have who have an open case with Developmental Services and indicate a desire for the service. **Not HCQC licensed – not on HCQC or DTER databases/separate spreadsheet delivered to counties**	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Setting** • **Rotating Staff**	**1b Staff** **1b Attendees** -Vaccinate staff first to cocoon residents

Psychiatric Residential Treatment Facility	A **hospital** for the diagnosis, care and treatment of mental illness which **provides 24-hour care.**	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living** • **Rotating Staff**	**1a Staff** **1a Residents** -Similar to Skilled Nursing Facility (PPP Part A) -Vaccinate staff and residents in same visits -Vaccinations may begin 12/21/20
Facility for Modified Medical Detoxification	Facility that **provides 24-hour medical monitoring** of treatment and detoxification in a manner which does not require that the service be provided in a licensed hospital	May include: • **Aged 75 +** • **Aged 65 – 74** • **Aged 16 – 64 with Underlying Conditions** • **Congregate Living** • **Rotating Staff**	**1a Staff** **1a Residents** -Similar to Skilled Nursing Facility (PPP Part A) -Vaccinate staff and residents in same visits -Vaccinations may begin 12/21/20
Department of Child and Family Services (DCFS)	Facilities provide 24-hour monitoring of children	• **Rotating Staff** • **Residents aged 16 -17?**	**1a Staff** **1a Residents**
Rural, Sierra and Desert Regional Centers Aging and Disability Services Division (ADSD) Staff (not Desert Regional ICF)	-Rural & Sierra Regional Centers do not operate any direct care programs -Employ Developmental Specialists, Nurses, Psychologists, Mental Health Counselors and various other staff. -Staff typically have to complete home & work visits (though most have been suspended during this PHE).	• **Rotating Staff**	**1b Staff** -Vaccinate staff first to cocoon attendees
Other Aging and Disability Services Division (ADSD) Staff	Adult Protective Services, Early Intervention (OT, PT and SPT staff and doctors that perform hands-on patient evaluations), Community Based Care, Autism Treatment and Assistance Program, Long Term Care Ombudsman (investigate complaints and perform unannounced visits to licensed facilities)	• **Rotating Staff**	**1b Staff**

Appendix G: COVID-19 Vaccine Distribution FAQs

Allocations to Nevada

1. **Are allocations provided to federal partners part of jurisdiction allocations or are they separate?**
   Allocations for federal agencies will be separate from the jurisdiction's allocations. There are five federal agencies to receive an allocation: Indian Health Services, Department of Defense, Department of State, Veteran's Health Administration, and Bureau of Prisons.

2. **When will information be available on initial jurisdiction allocation and follow-up interval? Is there a timeline?**
   Jurisdictions should anticipate receiving pro rata allocations of vaccine doses when product becomes available. At the onset of the vaccination program, allocations will be updated each week on Tuesdays as additional vaccine doses become available.

3. **How often will the allocation (ordering cap) shift, and will second doses be added to the ordering cap?**
   The ordering cap will be updated weekly on Tuesdays. Jurisdictions will be notified when second doses are available and are being included in their weekly allocation. The ordering cap will roll over from week to week. Jurisdictions should plan for pro-rata allocations (e.g., based on adult population).

Data Systems

1. **For ordering COVID-19 vaccines, does a hard copy of information need to be provided or just an electronic version?**
   Hard copy information is not required for ordering COVID-19 vaccines. Jurisdictions and their enrolled provider sites will place orders in the same way they do for routine publicly supplied vaccines.

Vaccine Redistribution

1. **Can CDC clarify the distinction between redistribution and repositioning (transfer) of vaccine?**
   If the public health agency or external entity is moving vaccine and the new facility is responsible for vaccine administration, then that would be considered **redistribution**. If the public health agency or external entity is moving vaccine and is responsible for its administration in another location, then that would be considered **repositioning (transfer)**.

2. **What is the requirement for redistribution agreements as they relate to local, short-distance transfer?**
   Distance is not a factor in determining if a redistribution agreement must be signed:
   - If the public health agency is moving the vaccine to a location where it will be responsible for vaccine storage/handling/administration, then this can be handled as **repositioning (transfer)**.
   - If another entity is responsible for the redistribution, then the redistribution agreement must be signed regardless of the distance.
   - If the public health agency has a depot and will be moving vaccine to sites that will assume responsibility for vaccine storage/handling/administration, then there should be a signed redistribution agreement for the public health depot location. (Note: Depot sites must also have signed Provider Agreements and completed provider profiles. CDC Project Officers can assist with the completion of the provider profile for these sites if needed.)

3. **Is there guidance available for redistribution of Pfizer's ultracold vaccine?**
   While CDC does not recommend transporting ultracold vaccine, if necessary, this vaccine may be transported in its original shipping container with dry ice or in a portable ultracold freezer than can maintain a temperature of -80°C. Refrigerated vaccine may also be transported following storage and handling transport guidelines at 2°C - 8°C. However, note this vaccine, once thawed and refrigerated, is only viable for up to 120 hours (five days), at which point it must be used or discarded. **Any hours used for transport count against the 120-hour limit.**

4. **What restrictions are there, if any, on redistribution?**
   The redistributing entity is responsible for ensuring every receiving provider is covered by a provider agreement and adheres to the requirements in the agreement.

5. **If a redistribution form is completed by an enrolled provider, can they redistribute vaccine to affiliated sites, or do all sites receiving the vaccine need to complete the provider enrollment forms as well?**
   If vaccines are redistributed, then all receiving sites need to be covered by Section A in the signed Redistribution Agreement. If the redistributing entity is a parent company, then they can sign Section A on behalf of the receiving sites, but all receiving sites must sign Section B.

6. **If a provider site cannot use all 975 doses of the Pfizer COVID-19 vaccine and is unable to take on the responsibility outlined in the redistribution agreement, then can the jurisdiction (e.g., NSIP) take on that responsibility?**
   Yes. When orders are reviewed and approved, the jurisdiction should evaluate the provider's ability to administer the minimum order (975 doses) for the Pfizer COVID-19 vaccine. Jurisdictions can help with repositioning vaccine if the provider is not able to administer the minimum order of doses.

7. **What legal considerations should a provider site take into account before transferring vaccine to a non-affiliated organization?**
   The redistribution agreement states that the redistributing entity must "ensure secondary locations receiving redistributed COVID-19 vaccine, constituent products, or ancillary supplies also sign and comply with all conditions in the CDC COVID-19 Vaccination Program Provider Agreement." The redistributing entity's ability to meet that requirement may be impacted by the ability to enforce it, which could be limited by the lack of legal affiliation. The redistributing entity's legal advisors should determine this prior to taking on the responsibility of redistribution.

Vaccine Storage, Handling, and Shipping

1. **Is there any guidance on temperature monitoring and reporting for sites? For instance, frequency of reporting?**
   Vaccine storage and handling guidance will be vaccine specific. Final guidance will be provided as an addendum to the Vaccine Storage and Handling Toolkit.

2. **What size of dry ice pellets should be used to recharge the thermal shipping containers?**
   Use 10-16mm dry ice pellets to recharge the thermal shipping containers. Dry ice for the first recharge will be provided by the U.S. government. Jurisdictions should not have to recharge the shipping container again unless the shipping container is used for more than 5 days. When placing your order, you will be able to indicate if the site does not need dry ice for the first recharge.

3. **Can provider sites order amounts of the Pfizer COVID-19 vaccine in less than 975-dose increments?**
   No, the minimum order volume is 975 doses (1 tray).

4. **For the Pfizer COVID-19 vaccine, will there be more than one tray per thermal shipping container? Or is a single tray of 975 doses the only way it will be shipped?**
   The minimum order size is 975 doses, the amount of doses in a single tray. Each thermal shipping container can hold up to 5 trays (4,875 doses). There is no maximum number of

doses of Pfizer's vaccine that can be ordered as long as the jurisdiction does not exceed their allocation, but providers are encouraged to order only the number of doses that a site is able to administer.

5. **Is Pfizer's COVID-19 vaccine sensitive to vibrations?**
   CDC is in the process of acquiring information on implications for moving and transporting both Pfizer's and Moderna's COVID-19 vaccines. Information will be shared as soon as it is available.

6. **Are there specifications for digital data loggers (DDLs) beyond being able to log ultracold temperatures? Are there manufacturer recommendations?**
   For Pfizer's COVID-19 vaccine, a temperature monitoring device is included with the thermal shipping container. CDC is finalizing an option that allows the provider site to use that device to monitor temperature if the thermal shipping container is being used to store vaccine. Guidance for reactivating this temperature monitoring device will be provided shortly. If you have ultracold temperature storage units, a DDL that monitors the appropriate temperature will be needed.

7. **Are there any training resources available for cold chain management?**
   There are training materials available on general principles of cold chain management (listed below). Both training programs and clinical materials will be available to support vaccine storage at ultracold temperatures.
   - You Call the Shots: Vaccine Storage and Handling – an interactive, web-based immunization training course on storage and handling best practices and principles
   - "Keys to Storing and Handling Your Vaccine Supply" Video – this video is designed to decrease vaccine storage and handling errors by demonstrating recommended best practices and addressing FAQs
   - Vaccine Storage and Handling Toolkit – a comprehensive guide that reflects best practices for vaccine storage and handling from ACIP recommendations, product information from vaccine manufacturers, and scientific studies
   - Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum – this addendum provides information, recommendations, and resources on storage and handling best practices to help safeguard the COVID-19 vaccine supply and ensure patients receive safe and effective vaccines
   - Epidemiology and Prevention of Vaccine-Preventable Diseases – comprehensive information on routinely used vaccines and the diseases they prevent; chapter 5 is dedicated to vaccine storage and handling (updated 2020)
   - Vaccine Storage and Handling and Vaccine Administration webinar

8. **Are dry ice contracts available?**
   The federal government will provide dry ice for the first recharge. Jurisdictions/provider sites will be responsible for acquiring dry ice needed for additional recharges.

9. **Will DDLs be required for redistribution of vaccine at refrigerated temperatures?**
   Yes, DDLs should be used based on vaccine storage and handling best practices to monitor temperatures when redistributing vaccine at refrigerated temperatures.

10. **Will thermal shipping containers have to be returned before ordering more vaccine?**
    No, but there are a limited number of thermal shipping containers. Pfizer is requesting thermal shipping containers be returned within 20 days of receipt. Jurisdictions and provider sites are strongly encouraged to return thermal shipping containers within the 20-day window.

11. **Do provider sites have to replace the temperature monitoring device in the thermal shipping container?**
    No. CDC is finalizing an option to use the temperature monitoring device that comes with the thermal shipping container to monitor vaccine temperatures during storage. Guidance for reactivating this device will be provided as soon as possible.

12. **Are DDLs available that can be moved from thermal shipping containers to freezers?**
    No, the temperature monitoring device included in the thermal shipping container cannot be moved, and the device will deactivate when it arrives at a site. Instructions will be provided on how to turn the device back on if you are storing the vaccine in the thermal shipping container. If the vaccine is moved to an ultracold freezer for storage, then a different temperature monitoring device will be needed.

13. **What days will sites receive vaccine?**
    CDC anticipates shipments will arrive Mondays – Fridays, unless a special expedited order is needed.

Miscellaneous

1. **Is there written guidance for returning expired vaccine and inputting wastage data?**
   Written guidance is being finalized and will be provided as soon as it is available.

2. **What are the dimensions of the ancillary supply kits, number of kits in a shipping box, and dimensions of the shipping box?**
   The dimensions of the kit that will accompany Pfizer's COVID-19 vaccine are 24 in x 20 in x 24 in. This kit provides supplies needed to administer 975 doses of vaccine. The

dimensions of the kit that will accompany Moderna's COVID-19 vaccine are 14 in x 13 in x 9 in. This kit provides supplies needed to administer 100 doses of vaccine.

3. **Is an informed consent form required for administration of vaccine under an EUA?**
   Written informed consent is not required for administration of vaccine authorized under an EUA. As part of the enrollment process (e.g., through NV WebIZ's text-based system), vaccine recipients provide permission or agreement to enroll in a registration system (e.g., privacy terms for use of personally identifiable information); this is separate from documenting informed consent for access to and administration of vaccine. However, jurisdictions/institutions/facilities may require informed consent for vaccination. An EUA does not prohibit those informed consent requirements.

4. **For pharmacies working with LTCFs, what happens if the LTCF is experiencing an outbreak of COVID-19?**
   Guidance will be developed and will be shared when it is available.

5. **When will vaccine storage and handling educational resources be available?**
   A COVID-19 vaccine addendum to CDC's Vaccine Storage and Handling Toolkit is now available. CDC is also developing supplemental guidance for each COVID-19 vaccine, including vaccine storage, handling and administration information. Vaccine manufacturers are also developing materials. All materials will be distributed when they become available.

Appendix H: Countermeasures Injury Compensation Program

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under a PREP Act declaration. The CICP also may provide benefits to certain survivors of individuals who die as a direct result of the administration or use of such covered countermeasures. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are:

- Any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used:
    - To treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or
    - To limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause; or
- Any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the Federal Food, Drug, and Cosmetic Act (FD&C Act), and the Public Health Service Act, or a respiratory protective device approved by National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary of the Department of Health and Human Services determines to be a priority for use during a public health emergency declared under section 319 of the Public Health Service Act.

For more information about the CICP, visit the program's website at www.hrsa.gov/cicp, email cicp@hrsa.gov, or call 1-855-266-CICP (1-855-266-2427).

Appendix I: Liability Immunity for Covered Persons

The Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19 provides liability immunity to covered persons. The third amendment to the declaration defines "covered persons" as follows:

"V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)
Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I [the Secretary] have determined that the following additional persons are qualified persons:

> (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency;
>
> (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;
>
> (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act; and
>
> (d) a State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy), vaccines that the ACIP recommends to persons ages three through 18 according to ACIP's standard immunization schedule.

Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

- The vaccine must be FDA authorized or FDA-approved.
- The vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of

indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.

- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.

- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.

- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

- Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 et seq. are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures."

Appendix J: Select Frequently Asked Questions (and Answers from CDC) – October 2, 2020 Edition

Vaccines for Children Program/Routine Vaccination

1) **Will VFC Program providers need to have a COVID-19 agreement signed as well as their VFC agreement or will the VFC agreement supersede a pandemic agreement?**

   Any provider receiving and administering COVID-19 vaccine will need to sign the COVID-19 agreement.

2) **Will [COVID-19] vaccine be available for children and adolescents in the initial phase?**

   At first, COVID-19 vaccines may not be recommended for children. The groups recommended to receive the vaccines could change in the future.

3) **Is there a tip sheet to resume routine [pediatric] vaccinations in development?**

   Yes, the full set of recommendations can be found at https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Pandemic Influenza Preparedness/COVID-19 Vaccine

4) **Will any new COVID-19 vaccine be covered by the National Vaccine Injury Compensation Program?**

   No, COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program.

   The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who die as a direct result of the administration or use of covered countermeasures identified in a PREP Act declaration. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are any antiviral medication, any other drug, any biologic, and diagnostic, any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, the transmission of SARS-CoV-2 or a virus mutating from SARS-CoV-2, or any device used in the administration of and all components and constituent materials of any such product.

   The CICP is administered by the Health Resources and Services Administration within the Department of Health and Human Services. Information about the CICP and filing a claim is available by calling 1-855-266-2427 or visiting http://www.hrsa.gov/cicp/.

5) **In pandemic influenza planning, jurisdictions have been expected to vaccinate 80% of the population. Will the same apply to COVID-19 vaccination? If not, what percentage should jurisdictions strive to achieve?**

   CDC does not currently have population-level targets for COVID-19 vaccination, but jurisdiction's should prepare to have capacity to vaccinate all persons in the jurisdiction who may want to get fully vaccinated with two doses of COVID-19 vaccines, as approved or authorized by FDA and recommended by ACIP. More information will be provided as it becomes available.

6) **Will there be guidance for mass vaccination clinics?**

   Yes. CDC has updated guidance for satellite, temporary, and off-site clinics and it is available at https://www.cdc.gov/hcp/admin/mass-clinic-activities/index.html. The guidance provides information on procedures for protecting patients and staff during the COVID-19 pandemic. However, programs will need to keep in mind recommendations for social distancing and considerations for events and gatherings during the COVID-19 pandemic and ensure mitigation strategies are in place to the extent possible. In many instances, curbside or drive-through clinics may be the best options.

7) **What are the PPE requirements when administering vaccines during the COVID-19 pandemic?**

   CDC has issued "Interim Guidance for Immunization Services During the COVID-19 Pandemic" to help immunization providers in a variety of clinical settings plan for safe vaccine administration during the COVID-19 pandemic. For information on PPE for healthcare workers, see https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html. Additional guidance will be provided as needed when COVID-19 vaccine is available.

8) **Can COVID-19 and influenza vaccines be administered at the same time on the same day?**

   Once COVID-19 vaccine(s) are authorized or approved by FDA, CDC will provide administration guidance.

COVID-19 Vaccine

9) Does CDC recommend an observation period after vaccination?

ACIP currently recommends that providers should consider observing patients for 15 minutes after receipt of a vaccine.

10) Are data available on the efficacy of the COVID-19 candidate vaccines?

Efficacy data are being collected as part of the Phase 3 clinical trials in the U.S. and other countries.

11) Is social distancing necessary when an individual receives their second dose of vaccine?

CDC recommends following the "Vaccination Guidance During a Pandemic" for all routine vaccination as well as for planning for COVID-19 vaccination clinics [including second-dose recall].

COVID-19 Vaccine Allocation and Supply

12) Will Indian Health Services (IHS) receive its own vaccine allocation for distribution to tribes in areas it serves? Or will IHS and tribes receive vaccine through state or local jurisdictions?

Tribal Nations are being offered a choice for how they wish to receive vaccine. They can choose between receiving vaccine through the state allocation or through their IHS allocation. States should engage with the Tribal Nations located in their area to discuss their preferred option. States should include documentation of Tribal preference in the plans they submit to CDC (See *Section 2, Tribal Communities, page 4 of the Nevada COVID-19 Vaccination Playbook).*

13) CDC expects there will be limited vaccine supply in the initial phase. What does "limited" mean?

CDC doesn't know when a vaccine(s) will be available or how many doses may be available. The COVID-19 Vaccination Scenarios for Jurisdictional Planning document, provided by CDC to jurisdictions, should be used by state and local jurisdictions to develop operation plans for early COVID-19 vaccination when vaccine supply may be constrained. The scenarios describe potential COVID-19 vaccine requirements, early supply estimates in the event that a vaccine is authorized under EUA, and populations that may be recommended for vaccination during this early period. These scenarios are designed to support jurisdictional, federal, and partner planning, but they are still

considered hypothetical. The COVID-19 vaccine landscape is evolving and uncertain, and these scenarios may evolve as more information is available.

14) In the phased approach to COVID-19 vaccination, what are the phases and who will get the vaccine first?

Jurisdictions should anticipate that allocations may shift during the response based on supply, demand, and risk. Each jurisdiction should plan for high-demand and low-demand scenarios and should be planning in terms of three phases:

- Phase 1: Potentially limited supply of COVID-19 vaccine doses available. Focus initial efforts on reaching the critical populations listed above. Ensure vaccination locations selected can reach populations, manage cold chain requirements, and meet reporting requirements for vaccine supply and uptake.

- Phase 2: Large number of vaccine doses available. Focus on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the general population; expand provider network.

- Phase 3: Sufficient supply of vaccine doses for entire population (surplus of doses). Focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.

Additional planning details are available in the *COVID-19 Vaccination Interim Playbook for Jurisdiction Operations (pgs. 10-13)*.

15) How long after the initial phase will additional vaccine be available?

CDC does not know yet which of the vaccines will be available or how quickly vaccine supply will be scaled up to meet demand after the initial allocation. More information will be provided as it becomes available.

16) Will jurisdictions be notified of the number of doses each facility receives? Is the jurisdiction responsible for timely data on doses administered for doses that are not processed through the jurisdiction's immunization program?

Jurisdictions are only responsible for doses that are directly assigned for them to manage. CDC is working closely with commercial partners that may receive direct

allocations to ensure that information on supply and dose administration is shared with each jurisdiction.

17) **Will the Department of Defense (DOD) receive its own vaccine allocation? Will DOD or the jurisdiction be responsible for vaccine distribution/coverage for federal employees?**

    Federal agencies (VA, DOD, BOP, IHS) are in the process of developing their COVID-19 vaccination plans and some decisions are still pending. The agencies have requested that their allocation provide for their workforce and patient population. More information will be shared as soon as it is available.

18) **How much space will be needed to store COVID-19 vaccines in the refrigerator or freezer?**

    Vaccine storage and handling guidance will vary by vaccine manufacturer. More information will be shared as soon as it is available.

19) **When will jurisdiction awardees get their vaccine allocations?**

    Operation Warp Speed is making allocation decisions. More information will be shared as soon as it is available.

20) **Will CDC or OWS have a public-facing vaccine locator at the national level?**

    As COVID-19 vaccine becomes available, providers will self-report to the website www.vaccinefinder.org.

21) **What is the process for jurisdictions for ordering second doses in VTrckS? Will second doses be shipped automatically to the initial providers sites who received the first round of Pfizer doses*?**

    Pfizer second doses will not be shipped automatically. The second dose allocations will be added to the jurisdiction's weekly Pfizer allocation (showing a breakdown for what is a first dose 'round' and what is the second dose 'round' of doses). Vaccine orders will have to be placed for those doses following the jurisdiction's processes. Jurisdictions will need to explain to providers how much of their Pfizer vaccine shipments are intended to be for the Pfizer second dose administration.
    **This question was asked by NSIP staff and answered by the CDC Project Officer on 12/17/20.*

COVID-19 Vaccine Ancillary Kits/Supplies

22) What supplies will be provided with the COVID-19 vaccine?

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. Each kit will contain supplies to administer 100 doses of vaccine, including 105 needles (various sizes for the population served by the ordering vaccination provider), 105 syringes, 210 alcohol prep pads, four surgical masks and two face shields for vaccinators, and 100 COVID-19 vaccination record cards for vaccine recipients.

23) Will the ancillary supplies in the shipments include sharps containers?

No, the ancillary supplies will not include sharps containers.

24) Are more details (brand, type, etc.) available about the supplies to be provided with COVID-19 vaccine?

CDC will provide the brand information when it is available.

25) When COVID-19 vaccine is available to the general public, will the vaccine be kitted with supplies, similar to what is being done in the initial phase?

Yes, ancillary kits will ship to coincide or arrive just before shipments of vaccine throughout the response.

COVID-19 Vaccine Distribution

26) How will COVID-19 vaccine be ordered?

Vaccination providers will follow their jurisdiction's vaccine ordering procedures. Vaccine orders will be approved and transmitted in CDC's VTrckS by jurisdiction immunization programs for vaccination providers they enroll.

27) Will vaccine orders go to McKesson and be sent directly to providers?

CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.

28) How many vaccine doses will each shipment contain in the initial phase?

Vaccine shipment amounts will vary based on the vaccine. The minimum order size and increment for centrally distributed vaccines will be 100 doses per order; though early in the response, some ultra-cold vaccine, if authorized for use or approved, may be shipped directly from the manufacturer in larger quantities. CDC will share more information on these shipments as it becomes available.

29) What assistance will jurisdictions receive to ensure the same vaccine is administered for the first and second doses? How will the type of vaccine and intervals between doses be tracked?

COVID-19 vaccination record cards will be provided as part of the vaccine ancillary kits. In addition to recording information in the IIS, EHR, and /or Vaccine Administration Management System (VAMS), vaccination providers are required to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second-dose reminders to vaccine recipients.

Several of the vaccines in clinical trials will require 2 doses, separated by 21 or 28 days. Immunization information systems (IISs) will be critical for reporting and tracking intervals. Jurisdictions should also be planning for redundant methods of providing second-dose reminder to vaccine recipients.

Vaccination providers should be highly encouraged to complete the vaccination cards and give them to each patient who receives vaccine to ensure a basic vaccination record is provided and to keep the card in case the IIS or other system is not available when they return for their second dose.

30) Are there planning considerations for distributing ultra-cold vaccines to high-temperature areas?

Ultracold vaccines will ship to the vaccination provider location directly from the manufacturer in a pack-out that contains dry ice. CDC will confirm with the manufacturer about the ambient temperature conditions under which the packout was qualified to determine if there are specific considerations for jurisdictions. The thermal shipper is the way to get vaccine to clinics/sites with temperature extremes.

31) Will McKesson be shipping COVID-19 vaccine 7 days a week, or only during business hours Monday-Friday?

COVID-19 vaccine shipments are planned for Monday-Friday. In the event of an urgent situation, Saturday shipments can be arranged on case by case basis. In those circumstances, provider locations would need to be available on Saturday during the timeframe in which the shipment is expected to arrive.

COVID-19 Vaccine Storage and Handling

32) Will there be different storage and handling requirements for COVID-19 vaccine?

Yes, at least one vaccine requires ultra-cold storage conditions. CDC is working on ways to support ultra-cold chain vaccine storage and handling needs. CDC will provide more information and guidance as they become available.

33) Should jurisdictions invest in ultra-cold storage units at this time?

Jurisdictions are not advised to purchase ultra-cold storage equipment at this time. Ultra-cold vaccine may be shipped from the manufacturer in coolers packed with dry ice. Storage and handling instructions for ultra-cold vaccine will address repacking these coolers for extended storage.

34) Will there be additional funding for jurisdictions to purchase ultra-cold storage units?

Because CDC does not recommend jurisdictions invest in ultra-cold storage units at this time, there will be no additional funding made available.

35) What are the on-site storage requirements and warm-up protocols for vaccine that must be stored at ultra-cold temperatures?

CDC anticipates jurisdictions will receive direct shipment to the vaccination provider site on a real-time, day-to-day basis. Currently, one vaccine candidate requires storage at -60°C to -80°C or at 2-8°C for up to 5 days (i.e., 120 hours). Once reconstituted, the vaccine can be at room temperature for up to six hours. However, stability testing is still ongoing and storage temperatures may change. CDC understands and appreciates the operational complexities ultra-cold storage poses at the vaccination provider site. Some COVID-19 vaccine products will require a very different storage and handling approach than normal cold-state vaccine.

36) Does CDC know what percentage of the vaccine will require ultra-cold storage?

CDC does not currently have this information. However, at least one vaccine candidate requires ultra-cold vaccine storage.

Critical Populations

37) How should jurisdictions define the priority workforce for early COVID-19 vaccination?

The ACIP, with input from the NASEM, is considering recommendations for who should receive early doses of COVID-19 vaccine when supply may be limited. With assistance and input from NASEM, ACIP will advise the CDC on which people should receive vaccine when supply is limited. As more vaccine quickly becomes available, the goal is to provide easy access to vaccination for everyone who wants to be vaccinated. More information will be shared as soon as it is available. Jurisdictions will be asked to identify additional methods for reaching critical population groups (e.g., identifying and planning with employers of essential workers).

COVID-19 Vaccination Providers

38) How can providers enroll to administer COVID-19 vaccine?

To receive and administer COVID-19 vaccine, vaccination providers must enroll in the COVID-19 Vaccination Program through their jurisdiction's immunization program. Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement. (Note: Federal clinicians working in federal facilities may have professional licensure from a different jurisdiction.) Enrolled COVID-19 vaccination provider must also fully complete the CDC COVID-19 Vaccination Provider Profile form for each location where COVID-19 vaccine will be administered. Some national pharmacy chains and federal entities will be instructed to enroll directly with CDC.

39) Should jurisdictions onboard any provider who is not currently enrolled with the jurisdiction's immunization program but who is willing to give COVID-19 vaccine and just restrict their ability to order to COVID-19 vaccine only?

Immunization programs should make early efforts to recruit providers who are essential to reaching critical populations for the COVID-19 Vaccination Program. Decisions on whom to enroll to provide broad access to vaccination are made at the immunization program's discretion as long as providers sign and agree to the requirements in the federal COVID-19 Vaccination Program Provider Agreement.

40) Is there a tip sheet to support COVID-19 vaccine confidence for providers to use when talking with patients?

Focus groups are being conducted and materials will be developed. More information will be shared as soon as it is available.

41) Who will pay for COVID-19 vaccine? Can it be ordered privately?

COVID-19 vaccine will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. More information will be shared as soon as it is available.

42) Will provider be able to charge a COVID-19 vaccine administration fee?

CDC will share more information about reimbursement claims for administration fees as it becomes available.

43) Can providers enroll in the COVID-19 Vaccination Program directly with CDC or do they have to enroll through their jurisdiction's immunization program?

To receive and administer COVID-19 vaccine, vaccination providers must enroll in the COVID-19 Vaccination Program through their jurisdiction's immunization program. CDC is exploring coordination with some multijurisdictional entities (e.g., certain federal entities and national chain pharmacies) to receive vaccine outside of this process. CDC is working to ensure jurisdictions have full visibility of this process.

44) Will private providers have access to COVID-19 vaccine?

Public and private providers enrolled in the COVID-19 Vaccination Program will have access to vaccine, based on supply, state and local need, and their jurisdiction's enrollment procedures.

45) Will CDC provide a vaccine administration agreement that jurisdictions should use to register providers interested in enrolling to administer COVID-19 vaccine?

Yes, the CDC COVID-19 Vaccination Program Provider Agreement package was shared with jurisdictions on September 14, 2020. Immunization programs are responsible for enrolling providers.

46) Will immunization programs need to conduct site visits with providers who are administering only COVID-19 vaccine?

Immunization programs will not be required to conduct site visits with COVID-19 vaccination providers. However, programs will be responsible for ensuring the provider agreement and profile forms are fully completed and that the provider has appropriate storage and temperature monitoring equipment to maintain the required temperature range for the vaccine product(s) the provider receives. Programs will also be responsible for ensuring providers are familiar with the ACIP recommendations and trained in key areas:

- COVID-19 vaccine administration, storage, and handling requirements
- Documenting and reporting wastage and temperature excursions
- Reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Providing Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs)
- Reporting information to the IIS and/or other vaccine administration reporting systems

CDC will provide materials jurisdictions can use in training efforts.

47) To what extent will the immunization program be accountable for storage and handling for providers who receive only COVID-19 vaccine?

Immunization programs must ensure providers have appropriate storage and continuous temperature monitoring equipment to maintain the required temperature range for the vaccine product(s) the provider receives. Programs should also make sure providers know how to document and report temperature excursions and COVID-19 vaccine spoilage/wastage according to jurisdiction procedures.

48) Will CDC provide a consent form for vaccination?

No, informed consent is not a federal requirement. An Emergency Use Authorization (EUA) vaccine recipient fact sheet will be available online, and providers are required to provide those to vaccine recipients prior to vaccine administration. Immunization programs will be required to ensure providers are aware of the fact sheet requirements.

49) **Does HHS or CDC have Memoranda of Agreement (MOAs) in place with large pharmacy networks? When and how will HHS or CDC share planning assumptions for the large pharmacy chains?**

    CDC is working with OWS and national chain pharmacy organizations on COVID-19 vaccine distribution and administration planning. CDC will share details of the plans and information on coordination with jurisdictions as soon as it is available.

50) **What companies/agencies are considered multijurisdictional providers?**
    Multijurisdictional vaccination providers include select large drugstore chains, IHS, and other federal entities.