

COVID-19 Vaccination Program Nevada's Playbook for Statewide Operations V2

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, 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 tiered 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. States now await formal critical population and related vaccine administration recommendations from the CDC's Advisory Committee on Immunization Practices; 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. 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, military facilities, and residential schools (e.g., Universities and Colleges with dormitories).

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.

Development of the Nevada COVID-19 Vaccination Program Playbook included review and alignment with the Centers for Disease Control and Prevention *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.

Section 1: Public Health Preparedness Planning

Pandemic vaccination response planning requires collaboration among a wide range of publicand 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 providers¹ 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. The Division of Public and Behavioral Health, 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. 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 <u>COVID-19 Vaccination Planning Assumptions for Jurisdictions</u> issued by the Centers for Disease Control and Prevention (CDC) which assisted staff with early planning efforts (<u>Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions</u> (<u>revised 10/29/2020</u>)).

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.

In addition to current situational awareness, there is much to learn from Nevada's past experiences. To prepare for the COVID-19 vaccine response, Nevada State Immunization Program (NSIP) and Public Health 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, Nevada expects to enough vaccine in its federal allocation to get through Tier 1 by the end of January 2021 and move quickly into Tier 2 during January and fully into Tier 2 by the end of February 2021 (federal allocation amounts have not been released and are subject to change).

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.

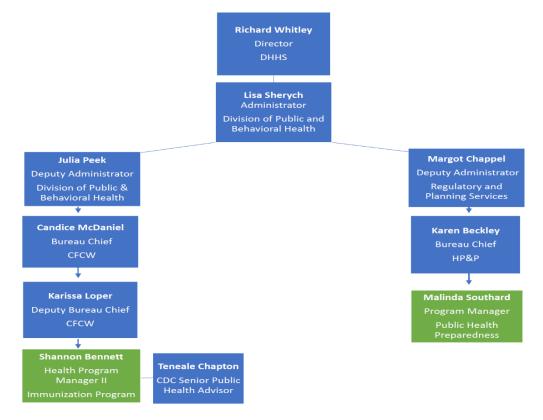
NSIP and partners have implemented new and innovative vaccination strategies to reach vulnerable Nevadans, as well as safely host satellite, temporary, or off-site vaccination events, and solidified new partnerships. The work being accomplished for the 2020-2021 flu season is serving as a real-time, 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. The Federal Emergency Management Agency (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. Public Health Preparedness (PHP) and NSIP 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 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 IHS	on Choice State
Pyramid Lake Tribal Health Clinic	Washoe	WCHD	X	State
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 Division of Public and Behavioral Health (DPBH) Administrator meets with Bureau and NSIP leadership weekly and has reviewed and confirmed the priority group tiers 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 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), 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),
 Department of Public Safety (DPS), 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, Nevada Rural Hospital Partners, 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 the Aging and Disability Services Division of Nevada DHHS and the Bureau of Health Care Quality and Compliance
- Nevada Sheriffs and Chiefs Association
- Local Emergency Managers as a group and individually

Partners Nevada is starting to engage in outreach to Tier 2 and later:

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 <u>public health preparedness resources</u> can assist states, local jurisdictions, and tribal organizations with strategic planning to strengthen their public health capabilities.

<u>Pandemic-influenza-specific resources</u> 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 <u>initial</u> 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
- Adults with high-risk medical conditions who possess risk factors for severe COVID-19 illness
- People 65 years of age and older

Nevada's COVID-19 Vaccination Playbook is divided into population-based high-risk Tiers and by 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. Through numerous conversations with local communities, NSIP recognizes that initial vaccine uptake may be much lower than 80%. NSIP is developing a county-level declination process that will officially "unallocate" doses set aside for each county through a formal declination process incorporating Emergency Managers

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.

and the COVID-19 Vaccine Response leads at Carson City Health and Human Services, Washoe County Health District, and Southern Nevada Health District.

Special considerations and adaptability are 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

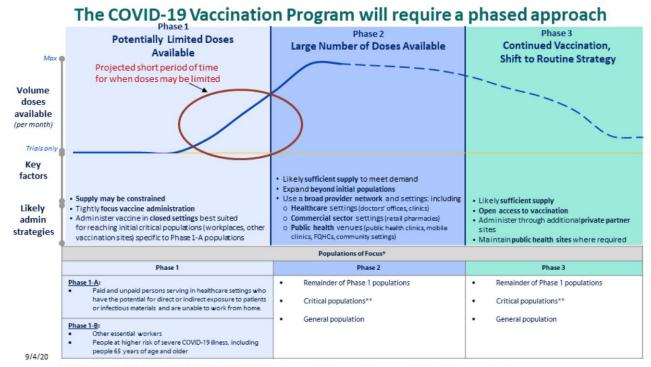
- **a.** Focus on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the general population.
- **b.** Expand the provider network.

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 offsite 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 <u>emergency regulation</u> 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/SNF, 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 approaches to expand access to are reach homebound and similar populations. DPBH

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

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 LCTF 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 is working directly with facilities to ensure they have alternate vaccinating plans. The CDC's Advisory Committee on Immunization Practices (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

Nevada Department of Corrections (NDOC) staff will be invited to closed vaccination events within their community and are included in Tier 1. NDOC inmates will be vaccinated by NDOC.

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 <u>higher risk</u> 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.)
 - o 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 the National Academies of Sciences, Engineering, and Medicine (NASEM) are working to 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 tiered 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)."

The Nevada COVID-19 Vaccination Program Tiers were designed to mitigate as much death and disease to the general population. Priority for limited vaccine supply is being given to those who are put at increased risk of exposure to COVID-19 due to their daily occupational hazards and to those who keep all Nevadans safe by maintaining health, security, law and order, and critical infrastructure for safe living (e.g., energy, water, phone lines, public health, etc.). Tribal communities are not specifically called out in the Tiered 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.

While not specifically identified in the tiered priority lists below, NSIP expects many people with limited access to routine vaccination services, such as people living in rural/frontier communities, people with disabilities, and people who are under- or uninsured will overlap with the occupational groups listed below. As the nation's vaccine supply increases in Phase 3, NSIP will be able to identify vulnerable populations who were not reached in Phases 1 or 2.

A standardized criteria list and current CDC guidance was used to determine the groups populating the tiered priority lists. Data to populate the occupation numbers were provided by Nevada DETR, LHAs, and workforce associations (e.g., Nevada Hospital Association). The estimates identified are as accurate as possible given the dynamic nature of employment data.

- 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)

Using the planning scenarios referenced above, NSIP does not anticipate there will be enough vaccine to serve all Nevadans at increased risk for severe complications from COVID-19 and all Nevadans aged 65 years and older at the beginning of the COVID-19 vaccine response. However, the following Tiered structure ensures those who have an underlying health condition who work in a listed occupation and are unable to work from home, cannot maintain social distancing due to job duties, and therefore have more exposure and a higher risk of contracting COVID-19 will be vaccinated as one of the initial priority populations.

The total number of Nevadans indicated in the lists below is more than the total population of Nevada. This is due to Nevadans being double counted in occupational groups and population groups (i.e., a Nevadan is counted twice when they work in a retail facility and have an underlying health condition). The accuracy of the counts is less important as the response reaches Tiers 3 and 4, because the quantity of COVID-19 vaccine likely available at that time is expected to exceed demand.

FINAL: Tier 1 Critical Infrastructure Workforce by Priority Order

1. General Medical and Surgical Hospital		39,720
2. Long Term Care Facility Staff & Residents		36,751
3. Psychiatric and Substance Abuse Hospitals		1,446
4. Emergency Medical Services Personnel		5,560
5. Frontline Public Health Workforce & Volunteers		1,077
6. Laboratory Workers		2,050
7. Pharmacists and Pharmacy Technicians		7,143
8. Outpatient and Home Health Providers		67,302
9. Nevada Department of Corrections (NDOC) Staff		2,671
10. Law Enforcement and Public Safety		9,350
11. Deployed and mission critical personnel who play essential role in national security		281
12. State and Local Emergency Operations Managers/Staff		100
	Total	173,451 persons
FINAL: Tier 2 Critical Infrastructure Workforce by Priority (Order	
-	<u> </u>	
1. Education and Childcare Staff	<u> </u>	50,558
	<u> </u>	50,558 6,896
1. Education and Childcare Staff	<u> </u>	
 Education and Childcare Staff Nevada System of Higher Education (NSHE) Faculty 	<u> </u>	6,896
 Education and Childcare Staff Nevada System of Higher Education (NSHE) Faculty Essential Public Transportation 		6,896 9,976
 Education and Childcare Staff Nevada System of Higher Education (NSHE) Faculty Essential Public Transportation Agriculture and Food Processing 	, , , , , , , , , , , , , , , , , , ,	6,896 9,976 11,951
 Education and Childcare Staff Nevada System of Higher Education (NSHE) Faculty Essential Public Transportation Agriculture and Food Processing Essential Retail Workers 		6,896 9,976 11,951 67,494
 Education and Childcare Staff Nevada System of Higher Education (NSHE) Faculty Essential Public Transportation Agriculture and Food Processing Essential Retail Workers Logistics and Supply Chain 		6,896 9,976 11,951 67,494 52,843

Community Support (food banks, DETR, WIC)		19,756
. Airport Operations		4,018
. Depository Credit Institution Workforce		8,672
. Mortuary Services		686
. Remaining Public Health Workforce		1,536
. Additional Critical Infrastructure		1,278
. NDOC Inmates		12,500
	Total	270,560 persons
FINAL: Tier 3 People at Increased Risk for Severe Illness or of Acq		•

1. Transitional Housing for Released Offenders	163
2. Homeless	7,554
3. People with Underlying Health Conditions that <i>are</i> at Increased Risk for Severe Illness from COVID-19	909,918
4. People with Underlying Health Conditions that <i>may be</i> at Increased Risk for Severe Illness from COVID-19	916,793
5. Elderly Nevadans Age 65+ without Underlying Health Conditions	207,603
6. Remainder of NSHE Staff	117,110
Total	2,159,141 persons

FINAL: Tier 4 Healthy Adults

1. Healthy Adults, 18-64 years		620,035
	Total	620,035 persons

^{*}Adding the totals from each tier group equals a higher number than Nevada's total population, because some individuals will be counted in both an occupation group and for being at increased risk for severe illness.

Estimating Population Groups for Initial COVID-19 Vaccine Distribution During Phase 1

The Tiers above equate to the CDC's phases:

- Nevada Tier 1 = CDC Phase 1a
- Nevada Tier 2 = CDC Phase 1b
- Nevada Tiers 3-4 = CDC Phase 1c

NSIP and PHP collaborated to create the tiered priority groups and rank the populations in the event Nevada's allocation of COVID-19 vaccine during Phase 1 is insufficient to vaccinate all those included in the Tier 1 Critical Infrastructure Workforce by Priority Order. NSIP and PHP used current ACIP work group considerations and epidemiologic data about COVID-19 illness to develop the prioritizations. If there is insufficient COVID-19 vaccine supply initially to vaccinate all those in Tier 1, then the initial doses will first be distributed to general medical and surgical hospitals to vaccinate frontline healthcare workers, then to the pharmacy partners to vaccinate LTCF staff and residents, followed by psychiatric and substance abuse treatment hospitals, etc.

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 3,080,156⁵ 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.

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

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

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.

NSIP is using CDC guidance to identify specific underlying health conditions causing the person to be at <u>increased risk for severe illness from COVID-19</u>. Population numbers for these Nevadans has been estimated by county. COVID-19 vaccination services for this group are planned to be conducted at the end of Phase 1 or early Phase 2 using closed/private POD sites and pharmacy administration.

Vulnerable 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.

Related Guidance and Reference Materials

The Advisory Committee on Immunization Practices

NASEM Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

<u>Johns Hopkins Center for Health Security Interim Framework for COVID-19 Vaccine Allocation</u> 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)
- <u>BULLETIN</u>: Ensuring the Rights of Persons with Limited English Proficiency in Health Care During COVID-19
- <u>BULLETIN</u>: 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.

<u>Mapping Medicare Disparities Tool</u> 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.

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 and 2 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 the Tier 3 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 <u>people at</u> 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 areas⁶

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 Vaccines for Children (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 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.

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.

- 8. Comply with federal instruction regarding disposal of unused COVID-19 vaccine and adjuvant.
- 9. Report adverse events to the <u>Vaccine Adverse Event Reporting System (VAERS)</u>
- 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 <u>EUA-related requirements</u>, 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 coordinator⁸ 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.

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.

- 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 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.
 - 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 <u>vaccination planning guidance</u> to ensure optimum staffing, layout, <u>supplies</u>, and <u>infection control procedures</u> 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 <u>VaccineFinder</u> (particularly for pharmacies or other high-volume vaccination providers/settings)

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 tiered 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 local health authority/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 Tier 3 groups 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, the Centers for Medicare and Medicaid Services (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.

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 pharmacies⁹ (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 receiving COVID-19 vaccine, the partner must propose, in writing, its minimum capacity for vaccine administration, including:

- 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

⁹ Pharmacy services administrative organizations, or PSAOs

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

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 and 2 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 Tier 2 groups and beyond
- Hospitals NSIP has relationships with the Nevada Hospital Association (NHA), is working to engage Nevada Rural Hospital Partners (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 listsery, 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 <u>state emergency regulation</u> and <u>federal emergency regulation</u> 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 may become available in December 2020. Early dose distribution will be limited; therefore, phased allocation of early doses will be necessary. Populations of focus for initial COVID-19 vaccine doses in Nevada are based on the Priority Tier Groups in Section 4: Critical Populations. This group includes healthcare workers (including ancillary staff, vaccinators, and staff in LTCFs), other essential public safety workers, 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.

Vaccine Allocation

The federal government will determine the amount of COVID-19 vaccine designated for each jurisdiction. 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 based on critical populations recommended for vaccination by ACIP (with input from NASEM), COVID-19 vaccine production and availability, and overall population.

Federal agencies and additional commercial partners will also receive allocations directly from CDC once larger volumes of vaccine are available. 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 tiered allocation methodology for critical populations of focus in earlyand limited-supply scenarios. NSIP will ensure the first providers/settings to be enrolled in the COVID-19 Vaccination Program are based on the capacity of Nevada's Critical Infrastructure Workforce they can serve. Allotments of doses to vaccination providers in Nevada will be based on:

- ACIP recommendations (when available)
- Estimated number of doses allocated to Nevada by the federal government and timing of availability
- Populations served by enrolled vaccination 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

¹⁰ Subject to any vaccine product-specific age restrictions

Nevada Expects Limited Doses of COVID-19 Vaccine

NSIP does not expect to receive enough doses of COVID-19 vaccine to cover all Nevadans at the beginning of the response. A tiered priority list has been developed for a stepped vaccination process, starting with acute care facilities, health care workers, and other critical infrastructure personnel. Eventually, Nevada will be allocated enough COVID-19 vaccine to start vaccinating larger groups of Nevadans, starting with Nevadans 65 years and older, and those with comorbid or underlying health conditions.

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.</p>
- 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.

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 across the entire state before moving to the next priority group. When the next priority group begins, allocation will again start in the county with the highest disease transmission.
- 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, COVID-19 vaccine will be allocated (i.e., ordered on behalf of the provider) by the NSIP Vaccine Manager to those providers serving the Tier 1 and 2 Critical Populations. As vaccine supply increases, COVID-19 vaccination providers enrolled by NSIP will be able to request COVID-19 vaccine 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.

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.

The minimum order size and increment for centrally distributed vaccines is 100 doses per order; though early in the response, some ultra-cold (-60°C to -80°C) vaccine (if authorized for

use or approved) may be shipped directly from the manufacturer in 975-dose minimum quantities.

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 <u>needle guide</u> 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.

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 LHD or CHN POD coordinating authority. If PODs are conducted off-site from the normal physical location, then LHD 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

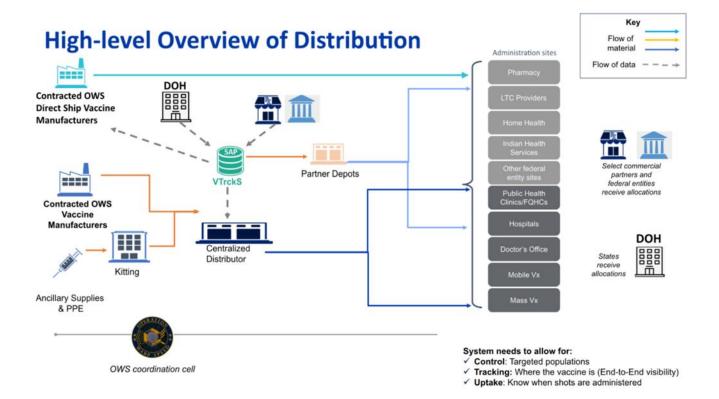
CDC ship-to sites (i.e., for orders smaller than 100 doses for rural providers or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations).

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 shipto location, or for any vaccine-specific portable refrigerators and/or qualified containers and pack-outs.



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* Food and Drug Administration (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.
- 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.

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.

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 <u>Vaccine Storage and Handling Toolkit</u> 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.

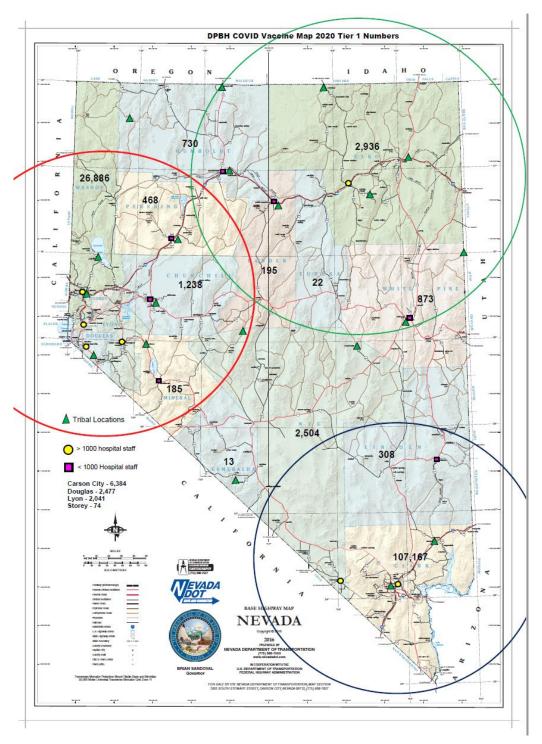
Ultra-Cold Chain Vaccine Management

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.

Ultra-cold 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.



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 <u>Vaccine Storage and Handling Toolkit</u>. 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 excursions¹² 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 <u>Guidance on Planning Vaccination Clinics Held at Satellite,</u>
<u>Temporary, or Off-Site Locations</u> as well as <u>Vaccination Guidance During a Pandemic</u> 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.

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/tier 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 tier to businesses/organizations employing individuals within each tier; 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.

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

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.

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.

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

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

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 handheld 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

 <u>CDC Provider IIS Participation Community of Practice</u>: 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

- <u>IIS Data Quality Blueprint</u>: A guide to help CDC immunization program awardees address and advance data quality within IISs
- <u>Data Quality Assurance in Immunization Information Systems: Incoming Data (2008):</u> 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.
- <u>Consolidating Demographic Records and Vaccination Event Records (2017):</u> Consensusbased 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.

- <u>Decrementing Inventory via Electronic Data Exchange (2016)</u>: Consensus-based best practice recommendations to support the process of decrementing inventory via electronic data exchange.
- <u>Guidance on Unit of Sale/Unit of Use Lot Numbers (2018):</u> Clarifications to the process and expectations for management of vaccine lot numbers.
- <u>Vaccine Code Set Considerations (2020)</u>: 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 <u>Vaccinate with Confidence</u> 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 <u>Vaccinate with Confidence</u> 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 Joint Information Center (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 <u>FDA emergency use authorization</u> and <u>FDA approval</u> (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 tiered 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, local health authorities, 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.

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 <u>CDC COVID-19 Communication Resources</u>. CDC has developed <u>COVID-19 One-Stop Shot Toolkits</u> 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 <u>COVID-19 Communications Plan for Select Non-Healthcare</u> <u>Critical Infrastructure Employers</u> will be helpful for this purpose.

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

The World Health Organization has developed a <u>guide</u> 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 may be authorized for use under an EUA issued by FDA or approved as licensed vaccines.

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 <u>FDA website</u>.

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.

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.

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, coadministered 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 <u>FDA's website</u> 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. <u>VAERS reports</u> can be submitted electronically.

v-safe

CDC will implement **v-safe**, a new 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 <u>Vaccine Safety Datalink (VSD)</u> 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 <u>Clinical Immunization Safety Assessment</u> 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	 REDCap Survey NV WebIZ Profile 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	 REDCap Survey NV WebIZ Profile VTrckS Profile NV WebIZ Vaccine Administration 	Upon enrollment and updated weekly or when the provider experiences significant business changes
	enrolled providers # of zip codes represented by providers enrolled to serve Tier 1	Reports 5. Tiberius GIS data	
Vaccine Access for Tier 2	# of providers serving Tier 2 groups successfully enrolled in Nevada's COVID-19 Vaccination Program	 REDCap Survey NV WebIZ Profile VTrckS Profile 	Upon enrollment and updated weekly or when the provider experiences significant business changes
	# of vaccines that can be administered per hour and/or per day by enrolled providers	4. NV WebIZ Vaccine Administration Reports	
	# of zip codes represented by providers enrolled to serve Tier 2	5. Tiberius GIS data	

	T		T
Vaccine Access for Tier 3	# of providers serving Tier 3 groups successfully enrolled in Nevada's COVID-19 Vaccination Program	 REDCap Survey NV WebIZ Profile VTrckS Profile 	Upon enrollment and updated weekly or when the provider experiences significant business changes
	# of vaccines that can be administered per hour and/or per day by enrolled providers	4. NV WebIZ Vaccine Administration Reports	
	# of zip codes represented by providers enrolled to serve Tier 3	5. Tiberius GIS data	
Vaccine Access for Tier 4	# of providers serving Tier 4 groups successfully enrolled in Nevada's COVID-19 Vaccination Program	 REDCap Survey NV WebIZ Profile VTrckS Profile 	Upon enrollment and updated weekly or when the provider experiences significant business changes
	# of vaccines that can be administered per hour and/or per day by enrolled providers	4. NV WebIZ Vaccine Administration Reports	
	# of zip codes represented by providers enrolled to serve Tier 4	5. Tiberius GIS data	
NV WebIZ Performance	System available for manual entry and electronic (HL7) submission	1. NV WebIZ	24/7 availability Per planned enhancement schedule
	Vaccination data file generates daily		
	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	 REDCap NV WebIZ 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	# and % of first doses administered by tier	1. NV WebIZ	Daily
Coverage, both 1 st and 2 nd doses	group population total # and % of patients with series completion by tier group population total		

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 Operation Warp Speed 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.

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 tiered critical workforces, local Chambers of Commerce, and more.

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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 <u>nationally</u>), but COVID-19 vaccine supply may increase substantially in 2021.
- Initially available COVID-19 vaccines are anticipated to be authorized for use under an <u>Emergency Use Authorization (EUA)</u> 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 <u>initial</u> COVID-19 vaccination may include:

- Healthcare personnel (<u>paid and unpaid</u> 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.
 - o 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 not 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 <u>VaccineFinder</u> daily.
- CDC has prioritized jurisdiction onboarding to the Immunization (IZ) Gateway¹⁵ 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.
- Data Use Agreements (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 <u>VaccineFinder</u>.
- A screening tool on the CDC website will help people determine their own eligibility for COVID-19 vaccine and direct them to <u>VaccineFinder</u>.
- 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 <u>EUA website</u> 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 claimsbased systems (e.g., <u>Vaccine Safety Datalink</u>).

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 Nevada Hospital Association, the Nevada Rural Hospital Partners, 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 Nevada Hospital Association (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 <u>National Healthcare</u>
 <u>Safety Network</u> (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:
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

- o Online/social media advertisements, including on advocacy organization websites
- Mail/postcards
- o 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: Countermeasures Injury Compensation Program

The <u>Public Readiness and Emergency Preparedness Act</u> (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 G: Liability Immunity for Covered Persons

The <u>Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19</u> 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 Advisory Committee on Immunization Practices (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 H: Select Frequently Asked Questions (and Answers from CDC) – October 2, 2020 Edition

Vaccines for Children Program/Routine Vaccination

1) Will Vaccines for Children (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 <u>"Interim Guidance for Immunization Services During the COVID-19</u>
<u>Pandemic"</u> 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 "<u>Vaccination Guidance During a Pandemic</u>" 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 (OWS) 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.

COVID-19 Vaccine Ancillary Kits/Supplies

21) 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.

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

No, the ancillary supplies will not include sharps containers.

23) 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.

24) 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

25) 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.

26) 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.

27) 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.

28) 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.

29) 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.

30) 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

31) 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.

32) 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.

33) 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.

34) 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.

35) 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

36) 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

37) 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.

38) 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.

39) 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.

40) 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.

41) 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.

42) 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.

43) 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.

44) 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.

45) 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.

46) 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.

47) 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.

48) 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.

49) What companies/agencies are considered multijurisdictional providers?

Multijurisdictional vaccination providers include select large drugstore chains, IHS, and other federal entities.