

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

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

Table of Contents

Executive Summary	1
Section 1: Public Health Preparedness Planning	4
Improvement Planning	4
COVID-19 Vaccination Program Planning	4
Section 2: COVID-19 Organizational Structure and Partner Involvement	6
Nevada Planning and Coordination Team (Internal)	6
Roles and Responsibilities	7
State-Local Coordination	7
Tribal Communities	7
COVID-19 Vaccination Program Implementation Committee (Internal and External)	8
Related Guidance and Reference Materials	10
Section 3: Phased Approach to COVID-19 Vaccination	11
Phase 1: Potentially Limited COVID-19 Vaccine Doses Available	12
Point-of-Dispensing (POD) Sites	13
Emergency POD Sites	14
Healthcare Strike Teams	14
Reaching Homebound Nevadans	15
Nursing Homes, Behavioral Health Centers, and Assisted Living Facilities	15
Nevada Department of Corrections	15
Phase 2: Large Number of Doses Available; Supply Likely to Meet Demand	16
Phase 3: Likely Sufficient Supply	16
Related Guidance and Reference Materials	17
Section 4: Critical Populations	
Identifying and Estimating Critical Populations in Nevada	18
Estimating Population Groups for Initial COVID-19 Vaccine Distribution During Phase 1 .	22
Describing and Locating Critical Populations in Nevada	22
People with Underlying Health Conditions	23
Vulnerable Populations	23
Related Guidance and Reference Materials	23
Section 5: COVID-19 Vaccination Provider Recruitment and Enrollment	25
Vaccination Provider Recruitment	25
Vaccination Provider Enrollment	26

COVID-19 Vaccination Provider Training	29
Role of Commercial and Federal Partners	
Pharmacies	
Related Guidance and Reference Materials	
Section 6: Understanding Nevada's COVID-19 Vaccine Administration Capacity	31
Vaccinators in Nevada	32
Related Guidance and Reference Materials	
Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management	34
Vaccine Allocation	34
Nevada Expects Limited Doses of COVID-19 Vaccine	35
Allocation Plan Using County-Level Criteria	35
Next steps moving forward:	
Vaccine Ordering	
Ancillary Supplies	37
Vaccine Distribution	37
Local Health Authorities and Community PODs	
Transportation of Vaccine Between NSIP and Regional Public Health Offices and Local Healt	h Units
Vaccine Inventory Management	
COVID-19 Vaccine Recovery	41
Section 8: COVID-19 Vaccine Storage and Handling	
Vaccine Storage	
Ultra-Cold Chain Vaccine Management	43
Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations	45
Section 9: COVID-19 Vaccine Administration Documentation and Reporting	
Vaccine Data Collection and Management	
COVID-19 Vaccine Data Dashboard	
Inventory Control and Asset Management System	
Section 10: COVID-19 Vaccination Second Dose Reminders	
Section 11: COVID-19 Requirements for Immunization Information Systems	50
System Infrastructure	51
NV WebIZ Mobile/Off-Site Application	51
COVID-19 Vaccination Provider Preparation	52

Data Management	
Vaccine Ordering and Inventory Management	53
Related Guidance and Reference Materials	53
Provider Onboarding	53
Data Quality	53
Immunization Gateway (IZ Gateway)	54
Vaccine Ordering and Inventory Management	54
Section 12: COVID-19 Vaccination Program Communications	55
COVID-19 Vaccination Communication Objectives	55
Key Audiences	
Broad Communication Planning Phases	
Communication Activities	
Messaging Considerations	
Communication Channels	
Partners and Trusted Sources	
Crisis and Risk Communication	
Related Guidance and Reference Materials	
Section 13: Regulatory Considerations for COVID-19 Vaccination	61
Emergency Use Authorization Fact Sheets	61
Vaccine Information Statements	61
Section 14: COVID-19 Vaccine Safety Monitoring	62
Vaccine Adverse Event Reporting System	62
Vaccine Safety Datalink	62
Clinical Immunization Safety Assessment Project	63
Section 15: COVID-19 Vaccination Program Monitoring	64
CDC Data Dashboards	64
Resources	64
Staffing	64
Inventory	65
Messaging	65
Local Jurisdictions	65
Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions (revised 9/15/2020 b	y CDC) 66
COVID-19 Vaccine	66

COVID-19 Vaccine Allocation	66
COVID-19 Vaccination Provider Outreach and Enrollment	67
COVID-19 Vaccine Ordering and Distribution	68
COVID-19 Vaccine Administration Data Reporting	69
Communication	69
COVID-19 Vaccine Safety	70
Appendix B: Considerations for Frontline Health Care Workers	71
Appendix C: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring	74
CDC IIS Data Requirements for COVID-19 Vaccine Administration	74
Background and Purpose	74
CDC COVID-19 Vaccination Reporting Specifications (CVRS)	74
Appendix D: Countermeasures Injury Compensation Program	83
Appendix E: Liability Immunity for Covered Persons	84
Appendix F: Select Frequently Asked Questions (and Answers from CDC) – October 2, 2020 Ed	dition86
Vaccines for Children Program/Routine Vaccination	86
Pandemic Influenza Preparedness/COVID-19 Vaccine	86
COVID-19 Vaccine	88
COVID-19 Vaccine Allocation and Supply	
COVID-19 Vaccine Ancillary Kits/Supplies	90
COVID-19 Vaccine Distribution	91
COVID-19 Vaccine Storage and Handling	93
Critical Populations	94
COVID-19 Vaccination Providers	94

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 Program (NSIP) will assign 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 privatesector 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

Last updated 10/16/2020 1:38 PM

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.

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 <u>critical infrastructure sectors</u>, 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 will use 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

There are many unknowns and unanswered questions at this time regarding the COVID-19 vaccine response in the United States and Nevada. It is important for Nevada and local jurisdictions to have full situational awareness. For example, it is not yet known which vaccines will be available, in what volumes, at what time, with what efficacy, and with what storage and

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.

handling requirements. However, Nevada has reviewed and is following the <u>COVID-19</u> <u>Vaccination Planning Assumptions for Jurisdictions</u> issued by the Centers for Disease Control and Prevention (CDC) which is assisting with early planning efforts (*Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions (revised 9/15/2020)*).

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

After the initial draft plan was written, Nevada has continuously worked to identify any weaknesses by conducting exercises, including workshops/tabletops, and numerous partner conversations. Further functional or full-scale exercises will be considered if time allows.

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 mass 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 mass 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 <u>Homeland</u> <u>Security Exercise and Evaluation</u> 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.

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 now held regularly and will continue throughout the COVID-19 vaccine response.

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 and tribal organizations in COVID-19 vaccine planning efforts. 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 will need to work through NSIP to receive vaccine. It is also critical for NSIP and the LHAs to reach out to any non-federally recognized tribes in Nevada to ensure they have access to vaccination services, since these groups will likely not be served by IHS.

NSIP is engaging individually with all tribal communities across Nevada. Some tribes have requested their own allocation of vaccine to administer within their community. Individualized allocation plans will be developed for each tribe pending receipt of population numbers requested by NSIP. NSIP and PHP are engaged with numerous tribal 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 the vaccine planning. Efforts will 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	Country	Public Health	Allocation Choice	
	County	Jurisdiction	Federal	State
Pyramid Lake Tribal Health Clinic	Washoe	WCHD		
Reno-Sparks Tribal Health Center	Washoe	WCHD		
Nevada Urban Indians, Inc.	Washoe	WCHD		
Washoe Tribal Health Clinic	Douglas	CCHHS		
Yerington Tribal Health Clinic	Lyon	CCHHS		
Las Vegas Clinic	Clark	SNHD		
Irene Benn Medical Center (Moapa)	Clark	SNHD		
Southern Bands Health Center	Elko	NV DPBH		
Owyhee Community Health Facility	Elko	NV DPBH		
Battle Mountain Band Clinic	Lander	NV DPBH		
Duckwater Health Clinic	Nye	NV DPBH		
Ely Shoshone Tribal Clinic	White Pine	NV DPBH		
Fallon Tribal Health Clinic	Churchill	NV DPBH		
Ft. McDermitt Health Clinic	Humboldt	NV DPBH		
Walker River Tribal Health Clinic	Mineral	NV DPBH		

Some Nevada tribal communities are served by IHS; as stated above, those communities are expected to receive a direct allocation of COVID-19 vaccine from the federal government.

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 will require 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 and every Nevada acute care hospital, psychiatric hospital, and limited large-scale inpatient/outpatient medical practice.

Other partners NSIP plans to engage or message to include:

- Additional health systems
- Nevada Rural Hospital Partners
- Federally Qualified Health Centers (FQHC)
- 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)
- Businesses and occupational health organizations
- Faith-based organizations or local religious leaders and trusted institutions
- 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 all parties will be necessary in advocating for and developing strategies to ensure equitable access to COVID-19 vaccination services. If necessary, DPBH/NSIP will consider executing 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 will be set up for enrolled providers to obtain and share timely information regarding COVID-19 vaccine and the response in Nevada. The calls will initially be held with enrolled hospitals, LHAs, and the rural community health nursing (CHN) offices, as these facilities will be prioritized to receive the initial doses of COVID-19 vaccine allocated to Nevada, as they will be in the closest proximity to the Tier 1, highest-priority Critical Infrastructure Workforce.

The Bureau of Child, Family and Community Wellness and NSIP will host 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.

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 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 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 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
- Other essential workers

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 Nevada's vaccination goal is to reach 80% of the Tier 1 critical infrastructure workforce by priority groups with two doses of COVID-19 vaccine within 60 days. One exception is made for General Medicine and Surgical Hospitals; special considerations and adaptability are necessary when allocating COVID-19 vaccine to cover this workforce (Appendix B).

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 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.

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 considering ways to obtain feedback on vaccine acceptance and uptake and how these elements will impact the COVID-19 vaccine allocation process.

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



The COVID-19 Vaccination Program will require a phased approach

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

Phase 1: Potentially Limited COVID-19 Vaccine Doses Available

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

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

Nevada will employ the following strategies to address these constraints:

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

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

As NSIP is performing Phase 1 activities, staffs 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 will be 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 will be 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.

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

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 mass vaccination events for their populations. Nevada's three LHAs, and each county's Emergency Manager, have mass 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 for reaching isolated community members living in Nevada's long-term care facilities, skilled nursing facilities, to reach people who are homeless, or 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.

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

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 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

Staff at these facilities will be invited to a closed/private POD hosted by the LHA or local CHN.

Facility administrators will be given a choice from the federal government for coordinating vaccination of facility residents:

- 1. Facilities can request a pharmacy contracted by the federal government to visit the facility and coordinate all elements of the mass vaccination event, including data reporting; or
- 2. Facilities can request another mass vaccination option from NSIP, using the state's vaccine allocation; LHAs have been engaged in this discussion and a plan is being established for each long-term care facility in Nevada.

Some LHAs have the capacity to use nurse strike teams to visit facilities that opt not to have a pharmacy vaccinate the facility. NSIP will also consider enrolling vaccinating nursing companies which facilities can hire to come in to complete the mass vaccination event and related data reporting. Special considerations are being taken for rural Nevada towns which often do not have large chain pharmacies that may be contracted by the federal government. Further, Immunize Nevada is hiring a deployable nurse strike team to assist in places where there are limited options.

Nevada Department of Corrections

NSIP has developed a plan with the Nevada Department of Corrections for correctional facilities to provide vaccination services to staff and inmates in the event of a pandemic. Most correctional facilities with medical staff are trained and competent in providing care to the inmates in their charge, including immunizations. COVID-19 vaccine for correctional facilities will be directly shipped to a facility's pharmacy.

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:

- 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, mass vaccination events, etc.)
 - Pharmacies not already enrolled by the federal government
 - Public health sites (mobile or drive-through vaccination events, FQHCs, Rural Health Centers (RHCs), LHA vaccine clinics, temporary/off-site clinics, etc.)

Phase 3: Likely Sufficient Supply

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

The key considerations in planning for Phase 3 are:

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

Through Phase 3, Nevada will:

• Continue to focus on equitable access to vaccination services

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

Related Guidance and Reference Materials

<u>CDC's Roadmap to Implementing Pandemic Influenza Vaccination of Critical Workforce</u> provides additional information and tools for state and local planners on how to operationalize and implement 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. Though currently specific to an influenza pandemic, it may help to inform the approach for COVID-19 vaccination planning for the critical workforce.

Section 4: Critical Populations

CDC's Advisory Committee on Immunization Practices (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 will likely 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 identified in the CDC's *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations – September 16, 2020.*

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 will be 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.).

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. 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.

1. General Medical and Surgical Hospital	39,720
2. Long Term Care Facility Staff	18,459
3. Psychiatric and Substance Abuse Hospitals	1,446
4. Emergency Medical Services Personnel	5,560
5. Frontline Public Health Workforce	577
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 Staff	2,671
10. Law Enforcement and Public Safety	9,350
Total	154,503 persons

FINAL: Tier 1 Critical Infrastructure Workforce by Priority Order

FINAL: Tier 2 Critical Infrastructure Workforce by Priority Order	
1. Deployed and mission critical personnel who play essential role in national security	281
2. State Emergency Operations Center	54
3. POD Volunteers	500
4. Education and Childcare Staff	50,558
5. Nevada System of Higher Education (NSHE) Faculty	6,896
6. Essential Public Transportation	9,976
7. Agriculture and Food Processing	11,951
8. Essential Retail Workers	67,494
9. Logistics and Supply Chain	52,843
10. Utilities and Communications Infrastructure	19,565

11. NDOT and Local Emergency Road Personnel	2,831
12. Community Support (food banks, DETR, WIC)	19,756
13. Airport Operations	4,018
14. Depository Credit Institution Workforce	8,672
15. Mortuary Services	686
16. Remaining Public Health Workforce	1,536
17. Additional Critical Infrastructure	1,278
Tota	l 369,778 persons

FINAL: Tier 3 People at Increased Risk for Severe Illness or of Acquiring/Transmitting COVID-19

1. Long Term Care Facility Residents	18,292
2. NDOC Inmates	12,500
3. Transitional Housing for Released Offenders	163
4. Homeless	7,554
5. People with Underlying Health Conditions that <i>are</i> at Increased Risk for Severe Illness from COVID-19	909,918
6. People with Underlying Health Conditions that <i>may be</i> at Increased Risk for Severe Illness from COVID-19	916,793
7. Elderly Nevadans Age 65+ without Underlying Health Conditions	207,603
8. Remainder of NSHE Staff	117,110
То	tal 2,288,751 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

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 LTCF staff, psychiatric and substance abuse treatment hospitals, etc.

For example, if Nevada is allocated an initial 100,000 doses, which is enough to vaccinate 50,000 Nevadans because most COVID-19 vaccine will require two doses, then NSIP could ensure vaccine for Tier 1 group 1 and part of group 2 (i.e., general medical and surgical hospital staff and some LTCF staff).

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 will mean NSIP needs to expand communication and coordination logistics.

NSIP has many points of contact (POCs) in various healthcare and ancillary organizations and will leverage established relationships to enroll providers serving the critical population groups. These partners include all FQHCs, RHCs, all acute care and critical access hospitals, and many adult and pediatric healthcare providers. NSIP is working with Nevada DETR leadership to obtain POCs at the organizations and businesses that employ the non-healthcare critical workforce contained within the priority groups.

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.

⁵ <u>https://www.census.gov/quickfacts/NV</u>

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 will be 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

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

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

- <u>BULLETIN</u>: 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, "CDC is working to engage large pharmacy partners to assist with on-site vaccination in LTCFs. These partners have existing distribution and administration infrastructure (including cold chain) and relationships with some LTCFs to provide medication and, in some cases, vaccination services (e.g., seasonal influenza) for staff and residents in LTCFs; 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 will begin with the state's hospitals and other self-prophylactic organizations and progress to community POD organizers, FQHCs, RHCs, individual doctors' offices and so forth. NSIP partnerships with acute care and critical access hospitals will be key to vaccinating Phase 1 populations in rural/frontier counties.

Weekly calls will be set up for enrolled providers to obtain and share timely information regarding COVID-19 vaccine and the response in Nevada. The calls will start with hospitals, LHAs, and rural CHNs as these facilities will be prioritized to receive the initial doses of COVID-19 vaccine allocated to Nevada, as they will be in the closest proximity to the Tier 1, highest-priority Critical Infrastructure Workforce. The Bureau of Child, Family and Community Wellness and NSIP will host 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.*

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. Enrollment activities will be tracked in NV WebIZ and the federal vaccine tracking system, VTrckS, so providers are not approached multiple times. NSIP will build upon established relationships with community partners, and collaborating with medical societies, HCQC, Nevada Medicaid, the CHNs, and tribal health entities will 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> <u>higher risk for severe illness from COVID-19</u>
- 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

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. <u>https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf</u>

Program coordinated through NSIP. 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*. These conditions are detailed in the agreement itself:

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

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.

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

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 <u>each location</u>:

- 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 offsite 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).

Provider enrollment activities which must be completed by NSIP:

- Ensure provider agreement, profile form, and redistribution agreement (if applicable) are thoroughly and accurately completed by each enrolled provider, retained on file for at least 3 years, and made available to CDC upon request.
- Verify COVID-19 vaccination providers (prescribers only, e.g., MD, DO, RPh, NP, PA) have active, valid licensure/credentials to possess and administer vaccine.
- Onboard COVID-19 vaccination providers to NV WebIZ:
 - All vaccination providers currently report to NV WebIZ per Nevada Revised Statute (NRS) 439.265 and associated Nevada Administrative Code (NAC). Existing provider profiles must be reviewed and updated as appropriate to facilitate COVID-19 vaccine ordering and documentation, and additional user training will likely be necessary. Successful onboarding requires coordination between IIS, Vaccine Management, and provider staff.

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.

- NV WebIZ staff must 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 or extensible XML information set (ExIS).
- 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 and have the appropriate equipment at their location to manage any serious adverse events.
 - 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.

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. 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
- COVID-19 vaccine storage and handling (including transport requirements/restrictions)
- 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 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. 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 as well as vaccinating LTCF residents and staff. NSIP is also engaging health insurance issuers and plans statewide regarding reaching their members with chronic conditions. Health insurance plans can also be helpful partners to assist in informing their enrollees about local vaccination efforts.

Pharmacies

As stated above, COVID-19 vaccine is expected to be directly shipped to large drugstore chains (e.g., CVS, Walgreens) beginning in early 2021 (Phase 2). NSIP will be able to track their allocations, but it is still unclear if NSIP will have allocating authority, or oversight, on which locations the vaccine doses are allocated to within Nevada. It is unclear what level of oversight or responsibility NSIP will have for COVID-19 vaccine doses directly allocated and shipped to these chain pharmacies. 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.

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.

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 will need to begin collecting COVID-19 Provider Profiles to determine this number
- Estimated vaccination provider participation rate in the COVID-19 Vaccination Program

NSIP continuously assesses the state's vaccine administration capacity and will be conducting outreach 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 can partner with 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 will work with Immunize Nevada, NOMHE, and other community partners to engage with and understand these settings
- 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, other important factors NSIP must consider include:

- 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)
- Existing vaccine administration capacity during seasonal influenza or other high vaccination periods (e.g., back-to-school)
- Current provider/setting staffing levels
- Routine immunization programs being conducted simultaneously that may affect throughput for COVID-19 vaccination in certain vaccination provider settings
- 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 from a variety of COVID-19 vaccination providers to inform this process. Previous vaccination exercises or campaigns, 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</u> <u>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 <u>PanVax Tool for Pandemic Vaccination Planning</u>, 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 be available as early as late October, early November 2020. Early dose distribution will be limited; therefore, phased allocation of early doses will likely 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 workers, and people at higher risk for severe COVID-19 illness.⁹ 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

⁹ 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 have 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 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:

- 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.
- 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.

DRAFT: Last updated 10/16/2020 1:38 PM

- Each county priority population will be allocated to 80% before moving to the next county.
- 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, the 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 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 will be 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. CDC will share more information with jurisdictions on these shipments as it becomes available.

Ancillary Supplies

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:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 105 per kit
- 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

For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will also be included.

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 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 (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.

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. 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 coldchain 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.

Transportation of Vaccine Between NSIP and Regional Public Health Offices and Local Health Units

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 COVID-19 vaccine, 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. These entities 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.

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, and NSIP must ensure this inventory information is submitted with each order. 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.

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.

Nevada COVID-19 Vaccination Playbook

DRAFT: Last updated 10/16/2020 1:38 PM

Vaccine inventory management and accountability will be 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. Vaccines *authorized* under an EUA will contain slight variations from *approved* Food and Drug Administration (FDA) products, including:

- Expiration Date: The vaccine vials and cartons will 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. Current expiration dates by vaccine lots for *all authorized* COVID-19 vaccines will be posted on a US Department of Health and Human Services (HHS) website (*weblink pending*), accessible to all COVID-19 vaccination providers. 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 a placeholder expiration date of 12/31/9999 to be read by a scanner. The placeholder 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 12/31/9999.
- **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 with product was received). Ongoing stability testing may impact these requirements.¹⁰

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. When redistributing vaccine is required, NSIP will adhere to all cold chain requirements, will not redistribute or ship vaccine, and will limit any transport of frozen or ultra-cold vaccine products.

An addendum to the <u>Vaccine Storage and Handling Toolkit</u> that specifically addresses COVID-19 vaccines is currently being developed by CDC in addition to other training materials.

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,

¹⁰ These temperatures are based on information available as of 9/4/2020. Updated information will be provided as it becomes available.

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. 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 to the hospitals/counties as necessary to vaccinate people who are in the initial phase.

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 as they 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 offsite COVID-19 vaccination clinic settings using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's <u>Vaccine Storage and Handling</u> <u>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.
- 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 excursions¹¹ 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 will use 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>. These resources provide information on additional considerations necessary during the COVID-19 pandemic, including social distancing, PPE use, and enhanced sanitation efforts.

¹¹ 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. (See *Appendix C: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring*). 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 located on the ISD Awardees SharePoint site and will be communicated with 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. If data will be entered off-site, then vaccination providers must ensure the required data are reported to NV WebIZ within 24 hours. Reporting data may be transitioned daily from NV WebIZ to the CDC via the IZ Gateway¹², or other reporting method specified by CDC. CDC encourages 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.

In addition to reporting vaccine administration, NSIP is developing and putting processes in place to match first and second doses including addressing the need to conduct centralized reminder/recall projects, exchange data with or query other state's/jurisdiction's systems and/or the Immunization Data Lake¹³ to obtain immunization history, if applicable.

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; planning activities underway include leveraging the IZ Gateway Connect and

¹² The Immunization Gateway (IZ Gateway) facilitates electronic messaging of vaccination records in a secure infrastructure allowing IIS systems across the nation to share vaccine administration data not only between jurisdictions, but also with provider organizations (e.g., Department of Defense, Federal Bureau of Prisons, IHS, Department of Veterans Affairs) that do not exchange data with the IIS today.

¹³ The Immunization Data Lake is a cloud-hosted repository to receive, store, and manage COVID-19 vaccination data for doses administered, vaccination coverage, ordering, inventory, and distribution. The Data Lake will provide a catalogue of different COVID-19 vaccine-related data sources that can be used to aid in monitoring COVID-19 vaccine ordering, distribution, coverage, and uptake. Data streams currently being onboarded to the Data Lake include provider enrollment data, VTrckS, and VaccineFinder.

Share components (if feasible)¹⁴; plans for exchanging data with other jurisdictions through the IZ Gateway; generating coverage reports for use within Nevada; and providing data to CDC that meets defined standards.

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.

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 will be developed and made available to COVID-19 vaccine providers to facilitate weekly reporting of aggregate priority group/tier counts vaccinated as well as aggregate patient age, 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 mass 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

¹⁴ 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.

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 will not be 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. While not required to be used, NSIP will strongly encourage 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 should 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 will work with occupational health providers and other partners to decide upon the most appropriate and effective method of issuing second-dose reminders to their clients/patients.

NV WebIZ is also a very useful tool for centralized reminder/recall efforts conducted by NSIP (see Section 11: COVID-19 Requirements for IIS or Other External Systems). NSIP will explore the use and cost of automated patient phone calls ("robocalls"), emails, and SMS text message-based systems. 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 highquality 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 through a uni- or bidirectional data exchange

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

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 ACIP-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 will also develop 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 will be critical to ensuring recipients complete the COVID-19 vaccine series. NSIP will explore the use and cost of automated patient phone calls ("robocalls"), emails, and SMS text message-based systems.

NV WebIZ Mobile/Off-Site Application

NSIP is pursuing the purchase and implementation 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 the use of QR code scanners and hand-held printers, and the entire module is flexible enough to support various POD stations. Hardware units (e.g., specialized iPads) will be purchased by the end of 2020 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 establishing protocols and processes to ensure provider reporting within 24 hours of COVID-19 vaccine administration. NSIP will explore the feasibility of and consider 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, jurisdictions (i.e., Nevada) will need to execute a DUA with CDC to facilitate the reporting of COVID-19 vaccination data. CDC has not yet released the DUA template.

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
- <u>American Immunization Registry Association (AIRA) Data Validation Guide for the IIS</u> <u>Onboarding Process (2017):</u> A guide with recommendations on the data validation process within onboarding
- <u>Onboarding Consensus-Based Recommendations (2018)</u>: 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
- <u>IIS Data Quality Practices to Monitor and Evaluate Data at Rest (2018)</u>: 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

- <u>IIS Inventory Management Operations (2012)</u>: 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. Public education and a detailed communication plan for COVID-19 vaccination providers will be critical components for the success of the vaccine response.

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 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 will develop vaccine confidence messaging in collaboration with the Joint Information Center (JIC) beginning with a flu vaccine confidence campaign in September 2020. Many partners can help share vaccine confidence messaging and resources. A coordinated approach will be adopted by partners statewide in cooperation with the JIC. NSIP will act 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 mass 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 should be 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)
- Health insurance issuers and plans (coverage for vaccine, in-network providers, etc.)
- Employers
- Local government
- Community partners and stakeholders
- Public/consumers
 - o Essential workers
 - 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

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 will provide no benefit if they are not received by the intended audience. NSIP will explore 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.

DRAFT: Last updated 10/16/2020 1:38 PM

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 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.

Vaccine Information Statements

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

Section 14: COVID-19 Vaccine Safety Monitoring

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

Vaccine Adverse Event Reporting System

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

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

Per the *CDC COVID-19 Vaccination Program Provider Agreement*, COVID-19 vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the event. Vaccine manufacturers are required to report to VAERS all adverse events that come to 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.

The following two programs require no actions from states/jurisdictions 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 and assesses complex adverse events following vaccination. Healthcare providers can request a consultation for a complex vaccine safety issue with an individual patient at <u>CISAeval@cdc.gov</u>.

Section 15: COVID-19 Vaccination Program Monitoring

Continuous monitoring for situational awareness throughout the COVID-19 Vaccination Program is crucial for a successful outcome. Prior to receiving COVID-19 vaccine allocations, NSIP must establish procedures for monitoring various critical program planning and implementation elements, including performance targets, resources, staffing, and activities.

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) and new (IQVIA) data sources. Data and estimates from additional sources will be added, as available.

The COVID-19 Vaccination Response Dashboard will include:

- Data for planning (e.g., estimates of critical population categories, number and attributes of healthcare providers and facilities)
- Implementation data (e.g., number of enrolled COVID-19 vaccination providers, COVID-19 vaccine supply and distribution, COVID-19 vaccine administration locations)
- COVID-19 vaccine administration data

The COVID-19 Vaccination Response Dashboard will be implemented in stages based on data availability and shareability. Both dashboards will include a view tailored for states and jurisdictions, available through SAMS, and a view for the general public on CDC's website.

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.

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 alljurisdiction calls, regular e-mail communication, and website updates. NSIP staff will routinely monitor both CDC and local-level messaging to inform Nevada's communications efforts. Variations in messaging can create confusion and hamper the effective implementation of the vaccination program. Messaging must be clear, current, and received as intended by the audience. Monitoring social media can be helpful in assessing message delivery and reception and dispelling inaccurate information.

Local Jurisdictions

Constant communication and coordination with local jurisdictions and tribal organizations will be instrumental during all phases of the COVID-19 Vaccination Program in Nevada. NSIP will work 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 will help ensure local jurisdictions and providers adhere to recommendations and guidance from CDC and Nevada authorities.

Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions (revised 9/15/2020 by CDC)

Many COVID-19 vaccine candidates are in development, and clinical trials are being conducted simultaneously with large-scale manufacturing. It is not known which vaccines may be approved or authorized for use by FDA or when such authorizations or approvals will take place. 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 early November 2020 if a COVID-19 vaccine is authorized or licensed by FDA by that time, but COVID-19 vaccine supply may increase substantially in 2021.
- Initially available COVID-19 vaccines will either be approved as licensed vaccines or 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 September 15, 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 or mixing adjuvant 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 ay include:

- Healthcare personnel 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 conditions and people 65 years of age and older
- Other essential workers

DRAFT: Last updated 10/16/2020 1:38 PM

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 large drugstore chains, the Indian Health Service, other federal providers) 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.

To be determined:

• Specific multijurisdictional providers to be served directly by CDC
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 adjuvant or diluent, if required) will be shipped to provider sites within 48 hours of order approval by the immunization program, if supply is available. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but shipment will be timed to arrive with or before the vaccine.
- Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators.
 - Each kit will include supplies needed to administer 100 doses of vaccine.
 - Jurisdictions may need to plan for additional PPE, depending on vaccination site needs.
 - For COVID-19 vaccines that require reconstitution with diluent or mixing adjuvant 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 may be much larger (expected to be 1,000 dose minimum); 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 and repacked again within 5 days.

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 on CDC's <u>VaccineFinder</u>.
- 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.

To be determined:

- Jurisdiction responsibility/involvement concerning reporting of data from multijurisdictional providers
- Method and frequency for vaccination providers to report information to VaccineFinder

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

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.

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., reconstitution, adjuvant use, 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, 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

- Clinically important adverse events following any vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- Adverse events will also be monitored through electronic health record- and claimsbased systems (e.g., <u>Vaccine Safety Datalink</u>).
- Additional vaccine safety monitoring may be required under the EUA.

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

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 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.

COVID-19 vaccine allocation priority should be given to hospitals in Nevada counties experiencing the highest COVID-19 case positivity rate at the time the first COVID-19 vaccine doses arrive in Nevada. The situation requires constant, consistent, and open communication between NSIP, OPHIE, the Nevada Hospital Association, and the individual hospital's leadership teams before and during the vaccine allocation process. The Nevada State Epidemiologist will assist NSIP and OPHIE to make decisions regarding which facilities should receive vaccine if initial supplies are severely limited.

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:

- 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.
- 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. Health care 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.

If limited vaccine allocations are made to hospitals which cannot cover all staff, it should be left up to each hospital, via their leadership or a Board/Committee of their choosing, to determine which staff receive the first doses of the available vaccine product. A guiding document has been created by NSIP for hospitals if this situation occurs.



Priority use of the initial COVID-19 vaccine allocation within the Inpatient Healthcare Setting. Prioritization is based on a risk assessment from both the patient and employee perspectives. Key areas prioritized for vaccination under a limited supply scenario should be those professionals working in the COVID-19 Intensive Care Unit (ICU) and Emergency Department (ED), including, but may not be limited to:

ICU Nurses

ED Physician and Nursing staff

Anesthetists

Respiratory Therapists Attending Pulmonologists Hospitalists Other staff in direct contact with COVID-19 patients Trauma Surgeons Operating Room Nurses and Technicians Orthopedic Surgeons

Once the highest risk areas are immunized, healthcare workers at high risk due to age or comorbidities¹⁶ will receive the next vaccine allocation.

¹⁶ The most current comorbidities are described by CDC at: <u>https://www.cdc.gov/coronavirus/2019-ncov/need-</u> <u>extra-precautions/groups-at-higher-risk.html</u>

Appendix C: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring

CDC IIS Data Requirements for COVID-19 Vaccine Administration

Background and Purpose

The ongoing, rapid monitoring of COVID-19 vaccine uptake will be a critical part of the nation's COVID-19 response efforts. Immunization programs and immunization information systems (IIS) will play a critical role in vaccine delivery, the monitoring of vaccine doses administered, and generation of vaccination coverage estimates among several different population groups.

A strong, nationally coordinated approach is critical to collecting, tracking, and analyzing vaccination data, especially in early phases of vaccine administration, which is expected to occur in non-traditional settings. This document outlines the anticipated vaccine administration data elements IIS will report to CDC. The required data elements in this document represent demographic and vaccination information routinely captured by an IIS during a vaccination event. In addition to the ability to collect and report these data elements, IIS will also be required to report information from these data elements 1) in a timely fashion (within 24 hours of administration) and 2) through a connection to the Immunization Gateway (IZ Gateway) or data lake. This will enable CDC to reliably track COVID-19 vaccinations and analyze vaccination coverage by demographic factors once vaccine supplies are available. The vaccine administration data elements in this document will continue to evolve to include inventory and distribution elements as those parameters are finalized.

CDC COVID-19 Vaccination Reporting Specifications (CVRS)

The table below defines the COVID-19 vaccination data elements required for reporting to CDC's Immunization Data Clearinghouse (DCH). Currently, this specification supports the submission of de-identified case-level data. It includes reference to identified data elements, but these elements may be populated with "Redacted" or an appropriate code value. In the future, this specification will be expanded to include two additional models for reporting.

All models of reporting will use the same file format but will vary in what identifying information is provided. The specification allows for submission of three different types of events: (1) vaccination events, (2) vaccine refusals, and (3) missed appointments. Each has unique requirements and is defined in the "Deidentified Extract Format."

Only vaccination events are required to be reported at this time.

FIELD DEFINITIONS			DATA POPULATION REQUIREMENTS			
Field	COVID-19 Data	Variable	Data Element	Vaccination Event	Vaccination	Missed
Number	Element	Name	Description and	Data Population	Refusal Data	Appointment Data
			Extract Guidance	Requirements	Population	Population
					Requirements	Requirements
1	Extract type	ext_type	Extract type	Required. Set to	Required. Set	Required. Set to
			defines whether	the value 'D'	to the value 'D'	the value 'D'
			this file contains			
			completely de-			
			identified data,			
			PPRL ID, or fully			
			identifiable data.			
2	PPRL	pprl_id	Privacy Preserving	Do not populate	Do not	Do not populate
	generated ID		Record Linkage ID.		populate	
3	Recipient ID	recip_id	Unique ID for this	Required	Required	Required
			recipient. This can			
			be the ID used by			
			your system or a			
			randomly			
			assigned unique			
			identifier.			
			However, the ID			
			must be			
			consistent across			
			reports to allow			
			linking doses to			
			the same recipient			
Λ	Paciniant	racin first	ID. Recipient's first	Pequired Set to	Pequired Set	Pequired Set to
-	name: first	name	name	the value	to the value	the value
	name. mse	name	name	"Redacted"	"Redacted"	"Redacted"
5	Recipient	recip middl	Recipient's middle	Required Set to	Required Set	Required Set to
5	name: middle	e name	name	the value	to the value	the value
		o		"Redacted"	"Redacted"	"Redacted"
6	Recipient	recip last n	Recipient's last	Required. Set to	Required. Set	Required. Set to
-	name: last	ame	name	the value	to the value	the value
				"Redacted"	"Redacted"	"Redacted"
7	Recipient date	recip dob	Recipient's date of	Required	Required	Required
	of birth		birth			·
8	Recipient sex	recip_sex	Recipient sex	Required	Required	Required
9	Recipient	recip_addre	The street	Required. Set to	Required. Set	Required. Set to
	address: street	ss_street	component of the	the value	to the value	the value
			recipient's address	"Redacted"	"Redacted"	"Redacted"
10	Recipient	recip_addre	The steet 2	Required. Set to	Required. Set	Required. Set to
	address: street	ss_street_2	component of the	the value	to the value	the value
	2		recipient's address	"Redacted"	"Redacted"	"Redacted"

11	Recipient	recip addre	The city	Required. Set to	Required. Set	Required. Set to
	address: city	ss city	component of the	the value	to the value	the value
		ss_ency	recinient's address	"Redacted"	"Redacted"	"Redacted"
12	Recipient	recip addre	The county	Required if known	Required if	Required if known
12	address	ss county	component of the	for this recipient	known for this	for this recipient
	county	35_county	recipient's address	for this recipient	recipient	
12	Bosiniant	racia addra	The state	Poquirad if known	Required if	Boguirod if known
12			ine sidle	for this reginient	keyuneu n	for this reginight
	address: state	ss_state	component of the	for this recipient	KNOWN IOF LINS	for this recipient
	De state et					Described (filles and
14	Recipient	recip_addre	The zip code of	Required if known	Required if	Required if known
	address: zip	ss_zıp	the recipient's	for this recipient	known for this	for this recipient
	code		address (5 digit or		recipient	
			10 digits, with			
			hyphen, are			
			acceptable)			
15	Recipient race	recip_race_	Patient's race	Required	Required	Required
	1	1				
16	Recipient race	recip_race_	Patient's race.	Required if known	Required if	Required if known
	2	2	Fields recipient	for this recipient	known for this	for this recipient
			race 2-6 support		recipient	
			recipients with			
			more than 1 race.			
			(Skip if only one			
			race reported).			
17	Recipient race	recip_race_	Patient's race.	Required if known	Required if	Required if known
	3	3	Fields recipient	for this recipient	known for this	for this recipient
			race 2-6 support		recipient	
			recipients with			
			more than 1 race.			
			(Skip if only one			
			race reported).			
18	Recipient race	recip race	Patient's race.	Required if known	Required if	Required if known
	4	4	Fields recipient	for this recipient	known for this	for this recipient
			race 2-6 support		recipient	
			recipients with		•	
			more than 1 race.			
			(Skip if only one			
			race reported).			
19	Recipient race	recip race	Patient's race.	Required if known	Required if	Required if known
	5	5	Fields recipient	for this recipient	known for this	for this recipient
			race 2-6 support		recipient	
			recipients with			
			more than 1 race			
			(Skip if only one			
			race reported).			

20 Recipient race recip_race_ Patient's race. Required if known Required if Required	ed if known
6 6 Fields recipient for this recipient known for this for this	recipient
race 2-6 support recipient	·
recipients with	
more than 1 race.	
(Skip if only one	
race reported).	
21 Recipient recip ethnic The ancestry of Required Required Required	ed
ethnicity ity the patient	
22 Vaccination vax event i The vaccination Required Required Required	ed
event ID d event's unique	
identifier within	
the system.	
23 admin_date The date the Required Required. This Require	ed. This will
Administration vaccination event will represent repres	ent the date
date occurred (or was the date the of the	nissed
intended to occur) vaccine was appoir	tment.
refused.	
24 CVX cvx The vaccine type Required Required Do not	populate
that was	
administered.	
25NDCndcThe vaccineRequired if knownDo notDo not	populate
product that was for this populate	
administered. Unit vaccination event	
of Use (UoU) is	
preferred if both	
UoU and Unit of	
Sale (UoS) are	
available.	
26 MVX mvx The manufacturer Required if known Do not Do not	populate
of the vaccine for this populate	
administered vaccination event	
27 Lot number lot_number The lot number of Required if known Do not Do not	populate
the vaccine for this populate	
administered: Unit Vaccination event	
of Use (UOU) is	
preferred if both	
dvdildUle. 29 Vaccine Danot Danot	nonulato
20 Vaculie Vax_expiration the expiration Required in knowing Do not Do not	populate
expiration date i on i date of the i tor this i populate	
expiration date on date of the for this populate	
expiration date on date of the for this populate vaccine vaccination event administered. This	
expiration date on date of the for this populate vaccine vaccination event administered. This can either be	
expiration date on date of the for this populate vaccine vaccination event administered. This can either be vaccination event	

29	Vaccine	vax admin	The body site of	Required if known	Do not	Do not populate
	administering	site	vaccine	for this	populate	
	site		administration.	vaccination event		
30	Vaccine route	vax_route	The route of	Required if known	Do not	Do not populate
	of	_	vaccine	for this	populate	
	administration		administration	vaccination event		
			(e.g., oral,			
			subcutaneous)			
31	Dose number	dose_num	Dose # in	Required	Do not	Do not populate
			vaccination series		populate	
			provided dose is			
			considered valid			
			(e.g., counts			
			towards			
			immunity).			
32	Vaccination	vax_series_	Report if the	Required	Do not	Do not populate
	series	complete	vaccination series		populate	
	complete		is complete. Select			
			"YES" when the			
			recipient has			
			completed the			
			the specific			
			vaccine product. If			
			more deses are			
			required select			
			"NO " If unknown			
			or cannot be			
			calculated select			
			"UNK."			
33	Responsible	responsible	The name of the	Required	Required	Required
	organization	_org	parent			
			organization or			
			health system that			
			originated and is			
			accountable for			
			the content of the			
			record. If an			
			organization has			
			several clinics or			
			facilities, this			
			would be the			
			organization that			
			reprsents all of			
			tne			
			clinics/facilities.			
			(IIIE "Administered at			
		1	Administered at		1	

			location" field is			
			the name of			
			individual physical			
			location)			
24	Advainiatorod	admin nam	The name of the	Doguirod	Doguirod	Doguirod
54	Administered	admin_nam	ne name of the	Required	Required	Required
	at location	e	for sility that			
			Idenity that			
			reported the			
			vaccination,			
			refusal, or missed			
			appointment. In a			
			small practice			
			setting, this could			
			be the same as			
			the responsible			
25)/Tral/C	saturaliza interes	organization.	Deguined	Domuino -	Deguined
35	VIICKS	vtrcks_prov	This is the 6-digit	Required	Required	Required
	provider Pliv	_pin				
			VIICKS. FOR VEC			
			the VEC DIN. This			
			Ine VFC PIN. This			
			for linking across			
			data sources			
26	Administered	admin type	The characteristic	Pequired	Pequired	Required if known
30	at location.	admin_type	of the provider	Required	Nequired	for this missed
	type		site that reported			annointment
	type		the vaccination			appointment
			refusal, or missed			
			appointment			
37		admin addr	The street	Required if known	Required if	Required if known
	Administration	ess street	component of	for this	known for this	for this missed
	address: street	_	where the vaccine	vaccination event	refusal	appointment
			is being			
			administered/plan			
			ned to be			
			administered.			
			Exception for			
			mobile clinics.			
38		admin_addr	The street 2	Required if known	Required if	Required if known
	Administration	ess_street_	component of	for this	known for this	for this missed
	address: street	2	where the vaccine	vaccination event	refusal	appointment
	2		is being			
			administered/plan			
			ned to be			
			administered.			

			Exception for			
			mobile clinics.			
39		admin_addr	The city	Required if known	Required if	Required if known
	Administration	ess_city	component of	for this	known for this	for this missed
	address: city		where the vaccine	vaccination event	refusal	appointment
			is being			
			administered/plan			
			ned to be			
			administered.			
			Exception for			
			mobile clinics.			
40		admin addr	The county	Required if known	Required if	Required if known
	Administration	ess county	component of	for this	known for this	for this missed
	address:	,	where the vaccine	vaccination event	refusal	annointment
	county		is heing	Vaccination event	rerusur	appointment
	county		administered/plan			
			add to bo			
			neu lo be			
			auministered.			
			Exception for			
			mobile clinics.			
41		admin_addr	The state	Required if known	Required if	Required if known
	Administration	ess_state	component of	for this	known for this	for this missed
	address: state		where the vaccine	vaccination event	refusal	appointment
			is being			
			administered/plan			
			ned to be			
			administered.			
			Exception for			
			mobile clinics.			
42		admin_addr	The zip code	Required if known	Required if	Required if known
	Administration	ess_zip	component of	for this	known for this	for this missed
	address: zip		where the vaccine	vaccination event	refusal	appointment
	code		is being			
			administered/plan			
			ned to be			
			administered.			
			Exception for			
			mobile clinics.			
43	Vaccine	vax prov s	The professional	Required	Do not	Do not populate
	administering	uffix	designation of the		populate	
	nrovider suffix	AIIIY	nerson		populate	
			administering the			
			vaccination lo a			
			IVID, LPIN, KIN).			
			iviay also be			
			reterenced as			
			vaccination			

			administering			
			provider type.			
44	Vaccination	vax refusal	Vaccination was	Required. Set to	Required. Set	Required. Set to
	refusal	—	refused, select	the value 'No'	to the value	the value 'No'
			'Yes'. If the		'Yes'	
			vaccine was			
			administered.			
			select 'No'			
45	Comorbidity	cmorbid st	Report if the	Required	Required	Required
-	status	atus	recipient has a			
			comorbidity.			
			Comorbid			
			conditions are			
			coexisting or co-			
			occurring			
			conditions and			
			sometimes also			
			"multimorbidity"			
			or "multiple			
			chronic			
			conditions".			
			If the recipient has			
			at least one of the			
			below options,			
			select Yes. If they			
			do not have any of			
			the following			
			comorbidities or			
			have "No Existing			
			Conditions" then			
			select No.			
			-Asthma			
			-Serious Heart			
			Condition			
			-Liver Disease			
			-Chronic Lung			
			Disease			
			-Chronic Kidney			
			Disease			
			-Diabetes			
			-Severe Obesity			
			-			
			animunocompromi			
			Seu			
			lf unknown or you			
			do not collect this			

DRAFT: Last updated 10/16/2020 1:38 PM

			information, please select "UNK"			
46	Recipient missed vaccination appointment	recip_misse d_appt	Report if the patient missed their vaccination appointment	Required. Set to the value 'No'	Required. Set to the value 'No'	Required. Set the value to 'Yes'
47	Serology results	serology	Report if there was a positive Serology (Antibody test) result If you do not collect, please populate with UNK	Required	Required	Required

Appendix D: 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 <u>www.hrsa.gov/cicp</u>, email <u>cicp@hrsa.gov</u>, or call 1-855-266-CICP (1-855-266-2427).

Appendix E: Liability Immunity for Covered Persons

The <u>Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for</u> <u>Medical Countermeasures Against COVID-19</u> provides liability immunity to covered persons. The <u>third amendment</u> 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 F: 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 <u>PREP Act declaration for medical countermeasures against COVID-19</u> 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 <u>http://www.hrsa.gov/cicp/</u>.

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 <u>https://www.cdc.gov/hcp/admin/mass-clinic-activities/index.html</u>. 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 <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-</u> <u>ppe.html</u>. 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 hightemperature 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 Program Provider 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.