State of Nebraska
COVID-19 Vaccination Plan

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December 31, 2020

NEBRASKA COVID-19 VACCINE PLAN (NCVP)

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Section 1. COVID-19 Vaccination Preparedness

Purpose

The purpose of the COVID-19 Vaccine Plan is to assist partners in a shared understanding of pandemic response that includes planning assumptions, roles and responsibilities, ordering and reporting, and mass vaccination tools for local providers to substantially reduce morbidity and mortality from COVID-19.

Scope

The scope of this plan is limited to the distribution and dispensing of COVID-19 vaccine and ancillary supplies to all Nebraskans through vaccine supplied by the federal government to include tribal nations located in the state (unless otherwise directed by federal guidance).

Background

COVID-19 was declared a pandemic in March of 2020. COVID-19 vaccine research and development also began in March 2020. The US Department of Health and Human Services (HHS) is working with partners to determine target populations. Thoughtful allocation of COVID-19 vaccines will be critical to prevent morbidity and mortality and reduce the impact of COVID-19 on society. The first available doses of COVID-19 vaccine are not anticipated to be available on a large scale until spring of 2021 with limited supply potentially available fall of 2020. The Advisory Committee on Immunization Practices (ACIP) will provide recommendations on priority groups and which groups should be vaccinated. Guidance on determining and providing vaccine to priority groups will be based on the principles included in the CDC "*Updated Planning Guidance on Allocating and Targeting Pandemic Influenza Vaccine during an Influenza Pandemic*" and "*COVID-19 Vaccination Program Interim Playbook for Jurisdictional Operations*".

2009 H1N1 pandemic required planning collaboration with a variety of public and private sector providers, including immunizations, preparedness, emergency management, various healthcare groups, critical infrastructure divisions, and community vaccination providers. H1N1 provided lessons learned that offer perspective for future pandemic planning. Lessons learned include: vaccine uptake is not for everyone and some individuals will not want to be vaccinated; supply for vaccine can be variable and insufficient; strive to under promise/over deliver; transparency is imperative; and messaging with two-way communication is essential for enhancing trust and reducing hesitancy.

Lessons learned also offers the opportunity for planning improvement to recognize strengths, identify gaps, unearth unforeseen opportunities, and make correction plans that can be utilized in real-event clinical and non-clinical situations. Nebraska Department of Health and Human Services (NDHHS) Immunization Program will work with various providers, traditional and nontraditional, to explore training opportunities, set goals, evaluate vaccination exercise experiences, and provide collective collaboration that is solution oriented. However, planning improvement will be an on-going process to ensure that Nebraskans are the recipients of the most current, efficient, and effective services. Planning scenarios to be shared with local providers are located in the resources section of this document.

Influenza season will also be occurring when the risk of COVID-19 will likely remain high. The NDHHS Immunization Program is increasing activities to enhance seasonal influenza vaccination to reduce the demands on hospitals, protect healthcare workers, and reduce respiratory diseases among individuals.

Planning assumptions

- Limited COVID-19 vaccine could be available possibly as early November 2020, but COVID-19 vaccine supply will increase substantially in 2021. Current planning is in three phases.
- Initial COVID-19 vaccination efforts should focus on those in the critical workforce who provide healthcare and maintain essential functions of society, as well as those at highest risk of developing complications from COVID-19, depending on supply availability and type.
- Final decisions will be made on the use of initially available supplies of COVID-19 vaccines and partially informed by proven efficacy.
- Initial doses of COVID-19 vaccine may be authorized for use under an "Emergency Use Authorization (EUA)" based upon available safety and efficacy data.
- Two doses of COVID-19 vaccine, separated by $\geq$ 21 or $\geq$ 28 days, will be needed for immunity. Second-dose reminders for patients will be necessary. Both doses will need to be with the same product, which will require strategies to ensure the correct match of COVID-19 vaccine products and dosing intervals such as reminder/recall.
- As vaccine is made available, a reserve will be held at the federal level to ensure access to a second dose.
- Routine immunization programs will continue.
- Recommendations on populations of focus will be based on Federal Drug Administration (FDA), Advisory Committee on Immunization Practices (ACIP), National Academy of Medicine (NAM) current epidemiology, and vaccine production and availability.
- Public demand for COVID-19 vaccination will likely be high, especially when there is limited supply and if there is severe disease in the community.
- Seasonal influenza vaccination will be particularly important for all persons $\geq$ 6 months of age, especially front-line health care providers (HCPs), to limit influenza as another respiratory illness.
- Assuming COVID-19 will continue to spread in the community in the fall of 2020 and into 2021, vaccination plans must ensure vaccine clinics will not put patients at risk for COVID-19, which in the setting of mass vaccination may need to include considerations for personal protective equipment (PPE), social distancing or spacing of persons vaccinated and staff, and scheduling individual vaccination appointment times, among other approaches.
- Some COVID-19 vaccine products will likely require reconstitution with diluent or adjuvant at the point of administration.
- When the COVID-19 vaccine becomes available, distribution will be centralized for most vaccines with at least one vaccine being direct shipped.
- Vaccine orders will be approved and transmitted in the CDC's Vaccine Tracking System (VTrckS) and providers should follow vaccine ordering procedures.
- COVID-19 vaccine providers must complete a COVID-19 Vaccination Program Provider Agreement.
- COVID-19 vaccine will be allocated either proportionally to each state's population size or by the amount of people within the critical population groups in each state. Vaccine will be centrally maintained and directly distributed by CDC's distributor to COVID-19 vaccination providers.

- Additional allocation consideration for COVID-19 vaccine is based on multiple factors, including:
  - Populations recommended by Advisory Committee on Immunization Practices (ACIP) and National Academy of Medicine (NAM)
  - Current spread/prevalence of COVID-19
  - COVID-19 vaccine production and availability
- COVID-19 vaccine, adjuvant, and ancillary kits will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers and their patients.
- Storage and handling requirements will encompass three different vaccine cold chain parameters:
  - Refrigerated (2-8°C): 1-4 vaccine(s)
  - Frozen (-20°C): 1-2 vaccine(s)
  - Ultracold (-80°C): 1 vaccine(s)
- Vaccine orders may have a minimum order size of 100 dose lots to 1000 dose lots.
- Two types of ancillary kits are expected:
  - Administration Kit with needles/syringes/alcohol prep pads/facemasks and faceshields in quantities to support administration of 100 doses (all vaccine types).
  - Mixing kit with needles/mixing syringes to support vaccines that require field mixing (2 vaccine types)
- Once vaccine products have been shipped to a provider site, the federal government will not redistribute product. Given cold chain requirements, jurisdictions should be judicious in redistribution for vaccine below 2-8°C.
- Jurisdictions are not advised to purchase ultra-cold storage equipment at this time; ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice, can store vaccine for an extended period of time, and can be repacked for longer use.

Federal (CDC) Contributions to Preparation

- Provide the Vaccine Administration Management System (VAMS) when available.
  - CDC hosted, web-based system to support mass vaccination operation and data collection/tracking to meet COVID-19 vaccination requirements. State IISs will have access to mass vaccination data from VAMS via the Immunization Gateway (IZ Gateway) (see the next section on Immunization Gateway for more details) and VAMS will be the primary data collection system for the initial phases of the mass vaccination efforts.
  - In general, the patient interface will allow registration and appointment management, the clinic interface will allow clinic management and recording of vaccine administration, and the public health interface will allow data reporting and analysis. A full list of VAMS functionalities will be forthcoming.
  - CDC will develop, present, and provide training on VAMS with select jurisdictions by late August.
  - Training plans for the various VAMS end user groups are currently being developed. In addition, a centralized help desk will be available to help with issues that may arise.
- Work with vaccine companies to secure vaccine and provide supplies.
- Provide vaccination communication and campaigns for key audiences and work with national organization to disseminate key messages.
- Act as a point of contact for Awardee jurisdictions.
- Provide continued and evolving guidance
- Activate the VaccineFinder website.

- Create screening tool to be located on the CDC website that will help individuals determine eligibility for COVID-19 vaccine.
- Provide various templates for jurisdictions to use – Data Use Agreements (DUA), workplans, etc.
- Issue guidance on groups to prioritize for initial COVID-19 vaccination.

Section 2. COIVD-19 Organizational Structure and Partner Involvement

State Responsibilities, Structure, and Partner Involvement

NDHHS is headed by a Chief Executive Officer (CEO) who is appointed by and reports to the Governor. The CEO supervises the Directors of each of the five divisions within NDHHS: Public Health, Children and Family Services, Behavioral Health, Medicaid and Long Term Care, and Developmental Disabilities, as well as Operations and Incident Command. The Incident Commander oversees the Preparedness section, and is acting as the Point of Contact for the Nebraska COVID-19 response.

NDHHS has begun planning for COVID-19 vaccine distribution by bringing together multiple stakeholders to ensure inclusion of a wide array of expertise, perspectives, and reach to critical populations.

The main anticipated roles for the NDHHS Immunization Program will be working to assess priority groups, facilitate vaccine distribution, vaccine tracking and monitoring, documenting doses administered, and reporting on vaccine status. The program is preparing for COVID-19 vaccines implementation by conducting internal planning and coordination that focuses on prevaccination, vaccination, and post-vaccination phases. This planning will include a diverse and varied competencies that include immunization systems, emergency response, clinical, communications, and immunizations. External representatives from Local Health Departments (LHD), the hospital association, Federally Qualified Health Clinics (FQHC), Community Based Clinics (CBC), and health disparity/tribal communities have been included in planning. This collective representation is intended to address preferred levels of vaccination coverage through the development of strategies and plans, setting goals, provider communication, assessing need, advocating inclusion, and implementation.

- NDHHS is preparing for COVID-19 vaccination by increasing influenza vaccination efforts through utilization of approved CDC supplemental funding. These funds allow the NDHHS to partner with Immunization Program subrecipients to:
  - Provide at least 7 mass flu vaccination events
  - Provide Flu and COVID-19 prevention materials
  - Submit quarterly reports
  - Share workplan achievements
  - Increase access to vaccines
    - Vaccinate children and adults
    - Vaccinate regardless of ability to pay

To assist with provider structuring, these subrecipients will be asked to be front line participants in Phase 1 of COVID-19 vaccine distribution.

There are multiple ways that DHHS is ensuring robust communication between stakeholders and involving partners in planning. Multiple internal workgroups include staff from the Immunization, Preparedness, Epidemiology, Communications, and NESIIS teams, as well as leadership. A weekly

meeting includes the DHHS teams mentioned above as well as representatives from external partners such as local health departments (rural and urban), FQHCs, Tribal Health, community-based clinics, Health Equity leadership, and NDHHS leadership.

In addition, the Incident Commander has instituted a Fusion Cell process for the overall COVID-19 response, which includes Lines of Effort for vaccine and influenza activities. The Fusion Cell meets twice per week, and is attended by Executive Leadership, multiple DHHS staff, and external partners. Finally, the Immunization program staff communicate regularly with federal partners and other states in Region 7.

- The COVID-19 Vaccination Plan is enhanced by the involvement of these internal and external work groups, who assist in the following ways:
  - Setting weekly goals and sharing updates
  - Identifying various ways to contribute to vaccine execution
  - Identifying service gaps, areas of concern
  - Offering solution based contributions
  - Serving as POC and conduits of information from state to local level
  - Clarifying roles within programs and with external partners
  - Assisting NDHHS to identify priority populations and partners for the distribution and use of COVID-19 vaccine in Nebraska. See Sections 4 and 5 for population and partner inclusion.

- NDHHS will utilize the following to support partner involvement and organize planning structure
  - CDC guidance
  - ACIP Recommendations,
  - Federal, State, and local epidemiology
  - Ethical and cultural considerations
  - State-level perspectives to identify populations.

- NDHHS Immunization Program currently has strong working relationships with Tribal/Native Health Clinics. This program will continue to support native sovereignty and respect tribal leadership discretion with regards to vaccination efforts. . Tribes have been offered the choice to either partner with the federal Indian Health Services or receive vaccine directly, or to partner with Nebraska and receive vaccine through the state process. At this time, the following Tribes have agreed to partner with Nebraska:
  - Santee Sioux Tribe Health Center
  - Ponca Hills Health and Wellness Center
  - Fred LeRoy Health and Wellness Center
  - Winnebago Hospital
  - Macy/Carl T Curtis Health Center
  - Lincoln Urban Indian Clinic

- NDHHS is participating in various COVID-19 work groups
  - Internal
    - Immunization, NESIIS, Preparedness, and Program Leadership
    - Immunization and DHHS Administration and CEO
    - Immunization staff

        - NESIIS staff
        - Weekly COVID-19 Executive Reporting meeting
            - Chief Medical Officer-weekly COVID-19 numbers shared
            - Lab and Community COVID-19 Testing
            - Community testing locations (open throughout Nebraska)
            - Long Term Care testing
            - Test Nebraska weekly COVID-19 testing completed, Personal Protective Equipment (PPE) counts
            - Contact Tracing
            - Long Term Care facility issues
                - PPE
                - Staffing
                - Testing
                - Containment
            - Immunizations
    - External and Internal
        - Local Health Department bi-weekly calls
        - Weekly calls with CDC Immunization Project Officer
        - Bi-monthly calls with CDC Immunization Project Officer and other Regions
        - Bi-monthly calls with CDC Immunization Project Officer and CDC IIS Project Officer
        - Emergency Response Coordinator (ERC) monthly calls
        - Douglas County Health Department (ERC led) monthly calls with Douglas County Providers/Partners
        - Weekly COVID-19 Vaccine planning meetings that include Immunizations, Communications, NESIIS, Epidemiology, CDC nominees, Preparedness, representatives from local health departments (rural and urban), FQHCs, Native, community based clinics, Health Equity leadership, and NDHHS leadership

- NDHHS Immunization Program will partner with State Corrections and local health departments will work with county/city jails to ensure vaccinations for detained populations.

Identified Local Provider Involvement

NDHHS has identified local providers to work with for COVID-19 vaccine distribution, and has engaged them in planning. These providers have agreed to:

- Concentrate early COVID-19 vaccine administration efforts on the initial critical populations
- Recognize and plan to vaccinate priority populations according to phases and be prepared to make vaccination decisions by vaccine type, dose lot size, and opportunity.
- Identify and locate initial populations of focus for different Phases.
    - Sample worksheet can be found under the resource section of this document.
    - Sample populations data breakdown can be found at COVID-19 Vaccines: Work Group Interpretations pdf icon[2 MB, 26 pages]
- If appropriate, provide COVID-19 vaccination services in closed point-of-dispensing (POD) settings that allow for the maximum number of people to be vaccinated while maintaining social distancing and other infection control procedures.
- Participate in vaccination communication campaign to inform Nebraskans about vaccine availability and to counter vaccine hesitancy.

- Ensure staff are trained on recording data and administering vaccine
  - Doses administered data should include:
    - lot number
    - expiration date of vaccine
    - patient information
- Assist patients with scheduling and provide reminder/recall
- Adhere to cold chain requirements
  - Follow process for storing and handling vaccine
  - Utilize medical grade refrigerators
  - Maintain temperature when or if transported (data loggers)
- Provide consent forms and vaccine information statements (VIS) if available
- Have an operating vaccination procedure that reflects CDC and State of Nebraska guidance and requirements.
- Sign and agree to conditions outlined in the *COVID-19 Vaccination Program Provider Agreement.*
- Agree to provide data:
  - NESIIS
    - data exchange
    - manual entry in real time
    - batch file upload
  - If selected for use, VAMS
- Report any clinically important adverse events following any vaccination to the Vaccine Adverse Event Reporting System (VAERS).

Section 3. Phased Approach to COVID-19 Vaccination Critical Populations and Providers

Nebraska is planning a phased approach to COVID-19 Vaccination distribution, beginning with Phase 1 where the volume of doses is low and supply is constricted. During this phase, vaccines will only be available for Phase 1 providers to order and receive, and only Phase 1 target populations will receive vaccination. Nebraska is additionally breaking Phase 1 into three sections, Phase 1a, 1b, and 1c to provide even greater separation between target populations to ensure that initial doses are given to critical portions of the population. Phase 2 assumes a larger availability of vaccine, likely sufficient to meet demand, and requires expansion of the provider network to vaccinate a larger portion of the population. Finally, Phase 3 represents a shift towards ongoing vaccination where there is open access to the product via the more traditional network of vaccination.

Phase 1 Providers will include current Vaccine for Children (VFC) partners already connected to NESIIS for ordering vaccine and reporting data, and those able to administer vaccine in closed setting specific to Phase 1, such as:

- Local Health Departments
- FQHCs, Community Based Clinics, Tribal Healthcare
- Hospitals – closed settings

Pharmacy Partnership for Long-term Care (LTC) Program

Nebraska plans to participate in the pharmacy partnership for Long-term Care Program coordinated by CDC. This program provides on-site vaccine clinics for residents of long-term care facilities (LTCFs) and any remaining LTCF staff who were not vaccinated in Phase 1a. It also provides end-to-end

management of the COVID-19 vaccination process, including close coordination with jurisdictions, cold chain management, on-site vaccinations, and fulfillment of reporting requirements. The program will facilitate safe and effective vaccination of this prioritized patient population, while reducing burden on facilities and jurisdictional health departments.

This CDC program is free of charge to facilities. The pharmacy will:

- Schedule and coordinate on-site clinic date(s) directly with each facility. Three visits over approximately two months are likely to be needed to administer both doses of vaccine and vaccinate any new residents and staff.
- Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
- Ensure cold chain management for vaccine.
- Provide on-site administration of vaccine.
- Report required vaccination data (approximately 20 data fields) to the local, state/territorial, and federal jurisdictions within 24 hours of administering each dose.
- Adhere to all applicable CMS requirements for COVID-19 testing for LTCF staff.
    - If interested in participating, each facility should sign up and indicate their preferred partner from the available pharmacies.
        - Skilled nursing facilities and assisted living facilities will indicate which pharmacy partner (one of two large retail pharmacies or existing LTC pharmacy) their facility prefers to have on-site (or opt out of the services) between October 19–October 30.
            - SNFs will make their selection through NHSN beginning October 19.
            - An “alert” will be incorporated into the NHSN LTCF COVID-19 module to guide users to the form.
            - ALFs will make their selection via online REDCap sign-up form.
        - The online sign-up information will be distributed through LTCF partner communication channels (email, social media, web).
        - After November 1, 2020, no changes can be made via the online forms, and the facility will have to coordinate directly with the selected pharmacy provider to make any changes in requested vaccination supply and services.
        - Indicating interest in participating is non-binding and facilities may change their selection (opt-out) if needed.
        - CDC will communicate preferences to the pharmacy partners and will attempt to honor facility preferences but may reassign facilities depending on vaccine availability and distribution considerations, and to minimize vaccine wastage.

CDC expects the Pharmacy Partnership for Long-term Care Program services to continue on-site at participating facilities for approximately two months. After the initial phase of vaccinations, the facility can choose to continue working with the pharmacy that provided its initial on-site clinics or can choose to work with a pharmacy provider of its choice. NDHHS Immunization Program is encouraging LTCFs to be aware of the vaccination partnership opportunities and to work with the local health department regardless of what option is selected.

NDHHS and local health departments will adjust to an increase in COVID-19 vaccine supply and expand provider networks, so that Phase 2 Providers will include:

- Pharmacies, doctor’s offices, Urgent Care clinics

- Public health sites such as mobile clinics, public health clinics, temporary /off-site clinics

Federal Direct Allocation to Pharmacy Partners

Nebraska plans to participate in the federal direct allocation to pharmacy partner strategy coordinated by CDC. In this strategy, vaccine will be allocated and distributed directly to select pharmacy partners from the federal government, offering an efficient way for large portions of the population to access vaccine.

- Direct allocation opportunities will be provided to retail chain pharmacies and networks of independent and community pharmacies[1] (those with a minimum of 200 stores). All partners must sign a pharmacy provider agreement with the federal government.
- On a daily basis, pharmacy partners must report to CDC, the number of doses of COVID-19 vaccine a) ordered by store location; b) supply on hand in each store reported through VaccineFinder, and c) number of doses of vaccine administered to individuals in each state, locality, and territory.
- Pharmacy providers will be required to report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC will provide information on these data elements and methods to report if stores are not able to directly provide data to jurisdiction IISs.
- All jurisdictions participating in this program will have visibility on number of doses distributed to and administered by each partner store.
- Jurisdictions will be given contact information for each partner participating in this program if they have any questions or concerns related to distribution of vaccine to stores in their jurisdiction.

Section 4 below details the target populations identified for Phase 1 participation.

Section 4. Critical Populations

Phase 1 - Potentially limited supply of COVID-19 vaccine doses available means that segments of the population must be prioritized to receive the vaccine. Vaccine type, dose lot size, and opportunity should influence local COVID-19 providers when phase population progression is necessary.

- Phase 1 A
  - Healthcare personnel (hospitals, home health care, pharmacies, EMS, outpatient, public health)
  - Long-term Care Facility residents and staff

  Early stages of supply should go ONLY to those staff providing direct patient care AND/OR are exposed to infectious materials. Initial supplies of vaccine should NOT go to:
    - Administrative staff
    - Staff working remotely
    - Staff not in direct contact with COVID patients or infectious materials

[1]Pharmacy services administrative organizations, or PSAOs

- Phase 1 B*
  - Persons 75 years and older
  - First responders
  - Education sector
  - Critical Infrastructure

  *ACIP defines phase 1B as the subset of workers at highest risk for work-related exposure to SARS-CoV-2, the virus that causes COVID-19, because their work-related duties must be performed on-site and involve being in close proximity (<6 feet) to the public or to coworkers.

- Phase 1 C
  - Persons 65 – 74 years of age
  - Persons with high-risk medical conditions
  - Vulnerable populations (disabled, homeless, etc)

Phase 2 – Large number of vaccine doses available, sufficient to meet the demand of general population.

Critical Population Identification

Healthcare personnel and other essential workers

With regard to critical populations in Nebraska, healthcare personnel will include workers serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home. This includes healthcare workers in hospitals, urgent and primary care access points, and long-term care staff. To estimate numbers of healthcare personnel, a combination of data sources will be used, including the U.S. Census Bureau American Community Survey, employment statistics from the U.S. Bureau of Labor Statistics, and employment data from the Nebraska Department of Labor. The NHSN and a supplemental DHHS survey will both be used to capture long-term care facility staffing numbers at the facility-level (both for nursing homes and assisted living staff). To further refine facility-level hospital numbers, Nebraska DHHS will use existing data collected by the Nebraska Hospital Association regarding numbers of hospital staff and will collaborate with local health departments to better estimate numbers at the jurisdictional and county levels. By employing a combination of these various data sources, DHHS will arrive at facility-level estimates of staff in various healthcare settings. To locate this critical population, data will be broken down and mapped to the county-level local health department jurisdiction level, when available.

Other essential workers (not including healthcare workers above) will be identified using the additional information in the NAS Framework for Equitable Allocation. Prioritized essential worker groups include first responders/protective services, food and agriculture workers, teachers and educational workers, transportation workers, and other groups as determined by the DHHS vaccine planning workgroup. To estimate numbers of other essential workers, a combination of data sources will be used, including the U.S. Census Bureau American Community Survey, employment statistics from the U.S. Bureau of Labor Statistics, and employment data from the Nebraska Department of Labor. To further locate these populations, DHHS and local health departments will coordinate communication with regional healthcare coalitions, employers, key business stakeholders (e.g., city governments, chamber of

commerce) to provide vaccine information. Enumeration of these populations will be done by place of employment and not place of residence.

Long-term care facility residents (e.g., nursing home and assisted living facility residents)

Nebraska DHHS recently completed a survey to establish numbers of residents in nursing homes and will be expanding this survey to enumerate numbers of residents in assisted living facilities. Since these resident numbers by facility tend to vary over time compared with staffing numbers, this survey will be repeated as needed in the future nearer the time of making final vaccine allocation decisions based on known allotment volumes.

People with underlying medical conditions that are risk factors for severe COVID-19 illness

To estimate the number of persons with underlying medical conditions, data from the Nebraska Behavioral Risk Factor Surveillance System (BRFSS) were used. The BRFSS is a cross-sectional telephone health survey targeted at adults 18 and older in the state. It covers a variety of important health topics, including chronic health conditions, health behaviors, and use of preventive health services. To enhance the geographic representativeness of data across the entire state, the Nebraska BRFSS design includes an annual oversample of each of the 19 local health department (LHD) regions. While BRFSS data support representative estimates of each LHD region, they do not support representative estimates at the individual county level.

Of the eight underlying medical conditions prioritized for COVID-19 vaccine planning in the state, the BRFSS collects data annually for six of them, including self-reported heart disease, diabetes, cancer, kidney disease, COPD, and obesity (based on height and weight). The Nebraska BRFSS does not capture information for organ transplantation or sickle cell disease.

In addition to looking at each of the six conditions individually, it is also important to capture the number of adults with multiple health conditions. As a result, the following nine BRFSS indicators will be selected for analysis:

- Ever told they had a heart attack or coronary heart disease
- Ever told they have diabetes (excluding pregnancy)
- Ever told they have cancer (in any form)
- Ever told they have kidney disease
- Ever told they have COPD
- Obese (BMI=30+)
- Has at least two of the following conditions: heart disease, diabetes, cancer, kidney disease, COPD, or obesity
- Has at least three of the following conditions: heart disease, diabetes, cancer, kidney disease, COPD, or obesity
- Has at least four of the following conditions: heart disease, diabetes, cancer, kidney disease, COPD, or obesity

The following process will generate county-level estimates for the nine selected indicators:

- First, BRFSS analysis will generate percentage estimates:

- For each of the 19 LHD regions in Nebraska
- For years 2017-2019 combined. While BRFSS data are available annually through year 2019, combining three-years of data will generate more stable estimates.
- For all persons 18 and older as well as those 18-64 and 65 and older. It is important to differentiate between those 65 and older, who are already at increased risk due to their age, from those 18-64, and who are not considered at increased risk solely due to their age.

- Second, compile population estimates from the U.S. Census Bureau:
  - For 2019 for each Nebraska county
  - For all persons 18 and older as well as those 18-64 and 65 and older.
  - Combine individual counties together to generate estimates for each LHD region.
  - Within each of the 16 multi-county health department regions (three are single county), determine the proportion of the population residing within each county.
- Third, apply the BRFSS percentage estimates to the U.S. Census population estimates
  - Apply BRFSS estimates for each LHD region and age group to the corresponding Census population estimates to generate estimates for the actual number of persons with underlying medical conditions within each of the 19 LHD regions.
  - For the 16 multi-county health department region, apply the estimated number of actual persons at the LHD region level proportionately to each county to generate the estimated number of actual persons with each condition at the individual county level.
  - Compile estimates in each county, age group, and conditions into a single table

<u>Other Critical Populations</u>

(People 65 years of age and older; people from racial and ethnic minority groups and tribal communities; those incarcerated/detained in correctional facilities, experiencing homelessness/living in shelters, attending colleges/universities, living and working in other congregate settings, and living in rural communities; and people with disabilities and who are under- or uninsured.)

Nebraska DHHS will use the American Community Survey (ACS) to arrive at population estimates by county of vulnerable populations stratified by age group, gender, race, and ethnicity. The ACS will be further leveraged to arrive at estimates for individuals incarcerated/detained in correctional facilities, individuals experiencing homelessness/living in shelters, college/university enrollment, people living in other congregate settings such as treatment facilities and military barracks, and people with disabilities. To further define and augment ACS estimates which will be used as a starting point, Nebraska DHHS will identify partners and stakeholders that work with each of these vulnerable populations and can help to most accurately identify and define those populations. Stakeholders will include Local Health Departments (LHDs), Federally Qualified Health Centers (FQHCs), Northern Plains Tribal Epidemiology Center, universities, corrections, organizations that work with the African-American and Hispanic and Latino community, as well as other community-based organizations. Each Nebraska LHD has an Emergency Operations Coordinator who has local, community based data on vulnerable populations in their jurisdiction as well as relationships and networks to both define and help reach those populations. Finally, DHHS will be sending a survey to local health departments in order to establish data estimates for critical populations that the State does not already have, including volunteer fire, EMS, and other first responders, people experiencing homelessness/living in shelters, etc. Therefore, the survey will be supplementing datasets DHHS already maintained or to be developed as described herein.

The critical infrastructure workforce, not already described above as healthcare workers and other essential workers, will be identified using additional guidance from the Cybersecurity and Infrastructure

Security Agency (CISA - https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce). To estimate numbers of other essential workers, a combination of data sources will be used, including the U.S. Census Bureau American Community Survey, employment statistics from the U.S. Bureau of Labor Statistics, and employment data from the Nebraska Department of Labor. DHHS and local health departments will coordinate communication with employers, key business stakeholders (i.e. city governments, chamber of commerce) to provide vaccine information.

DHHS will utilize current COVID positivity or case rates by county to establish areas of most immediate need. We might also consider number of underlying medical conditions in individuals (e.g., 2, 3, 4, or more) to help with allocations and sub setting. Nebraska plans to have team members become proficient with Tiberius to use this platform as applicable along with other applicable COVID data factors in order to create highest risk, highest priority tiers within the Phase 1 groups which creates additional population subsets. Furthermore, DHHS will collaborate with local health departments in order to determine subset groups based on closed POD throughputs and other logistical implementation factors which would impact vaccine distribution effectiveness. This collaboration includes not only creating LHD specific reports containing county level data for review, but also separate workshops to discuss the data, allocation, overall planning.

By analyzing data in this way, NE will be able to describe how many people in each of the Phase 1 categories reside in each county or LHD region. This analysis will inform not only vaccine allocation but also messaging and outreach efforts both at the state level and locally.

Nebraska is currently assessing Tiberius, a web-based micro-planning tool offered by the federal government. Tiberius is founded on data from multiple national datasets, and has mapping capabilities as well as the ability to create scenarios based on differing quantities of vaccine supply. The assessment will compare data in Tiberius with data from the analysis described above to determine necessary modifications and/or the best method of micro-planning.

NDHHS Immunization Point of Contact (POC)-DHHS

Immunization Program Manager……..Jeri Weberg-Bryce
Vaccination Information……Karen Rutherford
NESIIS……Ernad Klipic
Vaccine Preventable Disease……Alison Keyser-Motobo
Ordering Specialist……Gary Miller
Preparedness……Brittany Herrington
VAERS……Ally Kreft

Section 5. COVID-19 Vaccination Provider Recruitment 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 the NDHHS Immunization Program, by signing and agreeing to conditions outlined in the *COVID-19 Vaccination Program Provider Agreement.* Phase 1 providers will have agreements sent via email**,** and subsequent phase providers can locate *COVID-19 Vaccination Program Provider Agreement* on the NDHHS Immunization Program webpage.

- NDHHS will continue provider recruitment and enrollment as the vaccine supply increases.
- NDHHS will maintain these agreements for a minimum of three years.
- NDHHS will collect and submit *COVID-19 Vaccination Program Provider Agreement* to CDC for each enrolled vaccination provider/site. This data will be submitted twice per week via CSV file and will include:
  - 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.
- Enrolled COVID-19 providers must
  - have active credentials and licensed to provide vaccinations
  - be willing to comply with federal instruction regarding use, maintenance, reporting and disposal of unused COVID-19 vaccine, and
  - report adverse events to VAERS.
- Training tools will be posted online and given to newly enrolled providers. Providers will have to verify in NESIIS that required training has been completed. Training material will include the following:
  - ACIP COVID-19 vaccine recommendations
  - Ordering and receiving process
  - Storage and handling, temperature excursions/wastage
  - Vaccine administration
  - Documentation and reporting
  - Managing Inventory
  - Vaccine communication - EUA or VIS (links located in the resource section of this document)

CDC is currently developing and updating a variety of clinical educational and training resources for healthcare professionals related to COVID-19 vaccine(s). Some of these materials will soon be available to assist with planning for vaccine implementation. Other materials will become available as regulatory authorization or approval from FDA for each vaccine candidate is acquired. Each manufacturer is also developing educational and training resources for its individual vaccine candidate. Once these materials are established, NDHHS will make available links for providers to utilize.

Role of Commercial and Federal Partners

Some multijurisdictional vaccination providers (e.g., select large drugstore chains, some IHS locations, Veterans Administration clinics and hospitals, and other federal providers) will enroll directly with CDC to order and receive COVID-19 vaccine. Nebraska will monitor which entities are receiving direct allocations via communication with CDC. Nebraska expects to receive vaccine administration data, since these direct partners will be required to report vaccine supply and uptake information. The option exists for Nebraska to partner with commercial entities that are enrolled directly with CDC to reach their populations. Large drugstore chains, for example, may be particularly helpful in conducting PODs as well as vaccinating LTCF residents and staff. Health insurance issuers and plans may also assist in informing their enrollees about vaccination efforts.

Below are federal entities expected to receive vaccine directly from the federal government, and thus to vaccinate their own populations.

Federal Entity	**Population Served**

Bureau of Prisons (BoP)	• All BoP-managed facilities: facility staff and inmates Private contracted facilities and contracted residential reentry centers (RRCs) not included
Department of Defense (DoD)	• Active duty personnel and their dependents • Retirees (does not include their dependents) • U.S. Coast Guard (does not include their dependents) • DoD civilian and contractor employees (those who regularly receive care through DoD as well as those who don't) • To be determined: Reserves and National Guard (including those not activated)
Department of State (DoS)	• All personnel under Chief of Mission eligible to receive care through DoS • Stateside civil service employees
Indian Health Service (IHS)	• Tribal nations selecting IHS for vaccine allocation • Potentially includes IHS/Tribal/Urban facility staff and individuals served
Veterans Health Administration (VHA)	• VA staff (including volunteers and trainees) and veterans regularly receiving care at VHA facilities

Section 6. Vaccine Administration Capacity

Vaccine administration capacity, as defined by CDC, is the maximum achievable vaccination throughput regardless of public demand for vaccination. To identify phase 1 providers, NDHHS considered the following:

- Local providers currently enrolled in the VFC program and NESIIS
- Clinic location, populations served
- Weekly vaccination throughput- PanVax Tool for Pandemic Vaccination Planning
- Staffing capacity
- Connectivity to critical workforce, ability to offer satellite and closed pod clinics
- Readiness to comply with Federal and State requirements
- Preparedness
    - Review local data to identify and connect with various populations
    - Work with other local partners to achieve vaccination goal
    - Establish work flow

Section 7. Ordering, Distribution, Allocation, and Inventory Management

Distribution of vaccine will utilize the same model used for the distribution of vaccines under the Vaccines for Children (VFC) program. If there is a vaccine shortage/limit, NDHHS Immunization staff will ensure vaccine ordering is based on equitable distribution of vaccine across Nebraska designed to vaccinate identified priority groups.

The process for vaccine ordering and distribution as follows:

- Provider indicates the number of doses requested by submitting an order in NESIIS.
- NDHHS Immunization Ordering Specialist will review and approve COVID-19 vaccine orders.
- Vaccine orders will be uploaded daily (or multiple times per day) to the CDC VTrcKS system
- VTrckS sends the order to McKesson warehouse in Aurora, CO for fulfillment and direct shipment to providers.
- Providers will be required to connect with NESIIS and report vaccine administration data in order to receive vaccine. Failure to report vaccine administrations will prevent any future COVID-19 vaccine shipments.

Vaccine requiring storage at ultra-low cold temperatures may have a different distribution process in Phase 1a. Nebraska has identified facilities with the storage capability and the ability to administer this particular vaccine in a high throughput to assist CDC with pre-positioning. It is possible that orders and shipment to these specific facilities may be handled differently to ensure that vaccine is available for administration immediately upon receipt of FDA approval (i.e. EUA) and ACIP recommendations.

Any redistribution of COVID-19 vaccine will take place at the local level, however approval of vaccine redistribution must come from NDHHS.

- Providers must complete, sign, and submit CDC COVID-19 Vaccine Redistribution Agreement to NDHHS Immunization Program for approval.
- Cold chain and vaccine requirements must be respected.
- NDHHS will monitor redistribution to ensure appropriate handling of vaccine and that inventory in NESIIS is accurately modified.

Nebraska will report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours) using the CDC provided data dictionary. This data is captured in NESIIS and thus is available for monitoring and tracking as needed.

Vaccines that are shipped directly from the manufacturer will include a combined kit. This combined kit will include administration supplies, mixing supplies, and vials of diluent to prepare the vaccine for use. Because it contains diluent, providers will not have the option to opt out of requesting this combined ancillary kit. The kit will contain ancillary supplies to administer 100 doses including:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
    - 25-gauge, 1” (if vaccination indicated for pediatric population)
    - 22–25-gauge, 1-1.5” (adult)
- Syringes, 105 per kit (ranging from 1–3 mL)
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators per kit

- COVID-19 vaccination record cards for vaccine recipients, 100 per kit
- Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)

NDHHS can assist Phase 1 providers in obtaining needed supplies that are not provided kits via existing subaward agreements and the PPE ordering mechanism. Such supplies could include:

- Gloves
- Alcohol wipes or
- Bandages

Allocation

The federal government will determine the amount of COVID-19 vaccine designated for each jurisdiction; however, Nebraska is responsible for managing and approving orders from enrolled providers.

- As the amounts allotted changes overtime, NDHHS will be ready for this shift based on the following:
  - ACIP recommendations
  - Estimated number of does allocated and timing of availability
  - Distribution considerations will include all of Nebraska
  - Providers ability to secure appropriate vaccine storage and handling/minimizing waste of all vaccine supplies
- Allocation consideration include
  - Priority populations
  - provider capabilities
  - vaccine product type, temperament, and availability
  - provider partnership and
  - state and local data

If there is insufficient vaccine, NDHHS will prioritize subsets of critical populations by analyzing a number of factors, including but not limited to (1) COVID county positivity rates, (2) hospitalization rates, and (3) throughput of local health department Points Of Dispensing (POD). Allocation decisions will include factors such as:

  - Provider vaccine administration capacity, location, reporting and vaccination abilities, and staffing
  - Proximity to priority populations and community contacts/connectivity
  - Ability to maintain the cold chain, temperature excursions, adverse events

Inventory Management

COVID-19 vaccination providers will be required to report doses wasted daily using VaccineFinder as well as in NESIIS. Preregistration for VaccineFinder should occur once a provider is enrolled in VTrckS. Inventory should be managed in accordance with storage and handling requirements of the specific

vaccine, and should be kept up to date in NESIIS. Please note that vial and carton labels for vaccines authorized under a EUA will have slight variations.

Section 8. COVID-19 Vaccine Storage and Handling

COVID-19 vaccine products will be temperature-sensitive and storage and handling practices are critical to minimize vaccine loss and limit risk of reduced effectiveness. Providers are expected to be familiar with CDC's *Vaccine Storage and Handling Toolkit*.

- Expected cold chain storage and handling requirements
  - refrigerated (2°C to 8°C)
  - frozen (-15 to -25°C)
  - ultra-cold (-60°C to -80°C)
    - NDHHS has identified local venders offering dry ice, and a map of dry ice venders is being provided to local partners.
- For proper storage and handling practices to be successful, three elements must be in place:
  - Well-trained staff-current VFC providers have attested that staff are trained and have VFC manual on hand for reference.
  - Reliable storage and temperature monitoring equipment-current VFC providers have had site visits every two years of enrollment.
  - Accurate vaccine inventory management-current VFC providers submit monthly transaction reports and keep NESIIS inventory current.
- To assess redistribution requests to off-site or satellite storage, NDHHS will consider
  - Quantity to be transported
    - anticipated number of vaccine recipients
    - ability to maintain cold chain
      - monitor excursions
      - using proper equipment- current VFC providers have NDHHS approved transport refrigeration/freezer units and digital data logging thermometers.
- To ensure appropriate training and reference materials, NDHHS will make the *Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations* as well as *Vaccination Guidance during a Pandemic* available to enrolled providers.

Section 9. COVID-19 Vaccine Administration Documentation, Reporting and Systems

CDC requires that enrolled providers report certain data elements within 24 hours of administration. Objectives are:

- **Response:** Provide guidance on the overall vaccination response, the role jurisdictions will play in this effort, and steps jurisdictions can take to prepare for a COVID-19 vaccine as soon as fall 2020
- **Data Consistency:** Ensure the same data are available from all IISs and are comparable to data from other platforms (e.g., NESIIS, VAMS).
- Ensure all jurisdictions have data that are useful for their analytical and reporting needs.
- **Vaccine Monitoring:** Monitor vaccine doses administered and generate vaccination coverage estimates from different population groups.

IIS Data Elements:

Required Data Element	Standard or Mass Vaccination
Administrated at location: facility name/ID	Standard
Administered at location: type	Standard
Administration address (including county)	Standard
Administration date	Standard
CVX (product)	Standard
Dose number	Standard
IIS recipient ID	Standard
IIS vaccination event ID	Standard
Lot number: unit of use and/or unit of sale	Standard
MVX (manufacturer)	Standard
Recipient address*	Standard
Recipient date of birth*	Standard
Recipient name*	Standard
Recipient sex	Standard
Recipient ethnicity	Standard
Recipient race	Standard
Sending organization	Standard
Vaccine administering provider suffix	Standard
Vaccine administering site (on the body)	Standard
Vaccine expiration date	Standard
Vaccine route of administration	Standard
Vaccination series complete	Mass Vaccination

IIS Data Elements: Optional

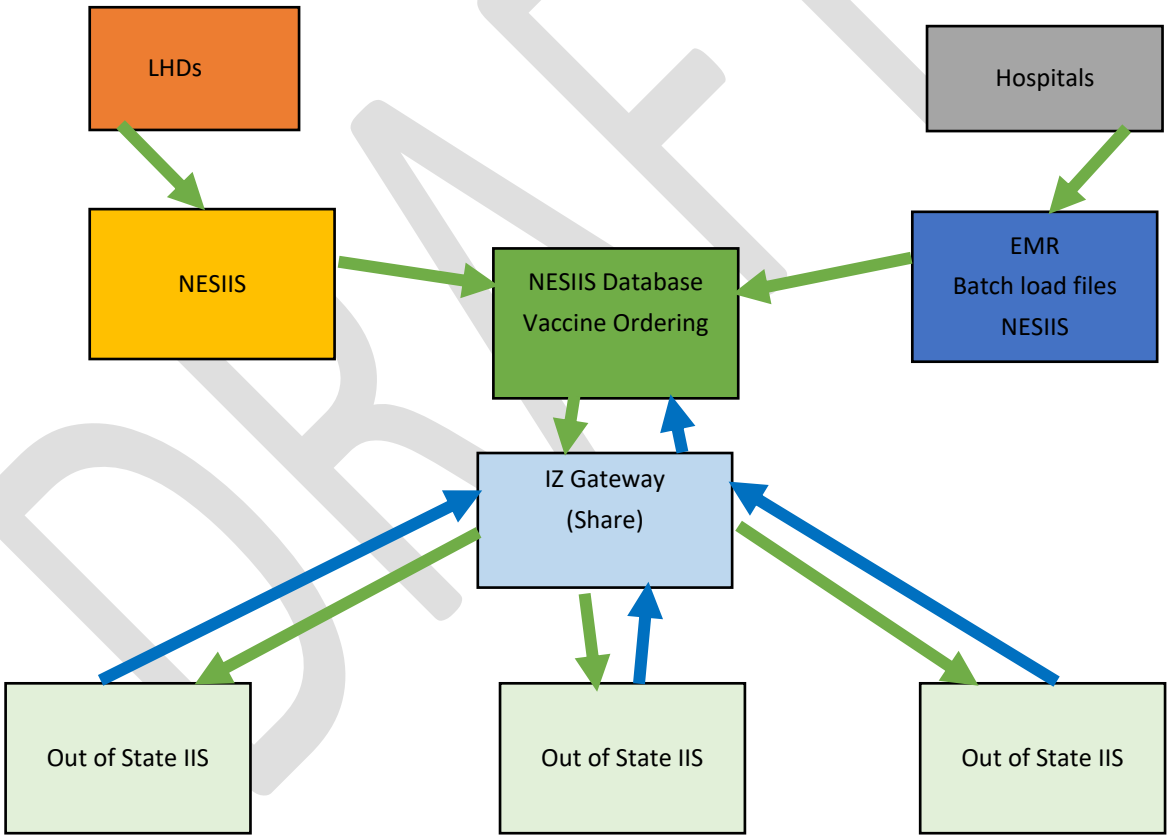
Required Data Element	Standard or Mass Vaccination
Comorbidity status (Y/N)	Mass Vaccination
Recipient missed vaccination appointment (Y/N)	Mass Vaccination
Serology results (presence of positive result, Y/N)	Mass Vaccination
Vaccination refusal (Y/N)	Standard

Additionally, we are adding the ability to capture occupation and critical priority/occupation groups.

Plan A-System NESIIS

Nebraska State Immunization Information System (NESIIS)

- Systems of use-
  - NESIIS- Nebraska State Immunization Information System (NDHHS system)
  - VTrckS – Vaccine Tracking System (CDC system)
  - IZ Gateway (CDC system)-facilitates electronic messaging, secure, allowing IIS systems to share vaccine administration data between jurisdictions
  - EMR-Electronic Medical Record
  - Batch load files-used for loading electronic data files, generally from low-grade EMRs, into NESIIS. Batch load file is a collection of one or more messages uploaded via the NESIIS user interface (as opposed to being sent via SOAP web services or PHINMS). Manual upload of data in NESIIS requires the provider to sign into the NESIIS application and upload the file directly within the registry.



Plan B-System VAMS

Vaccine Administration Management System (VAMS)

- Systems of use-
  - VAMS - Vaccine Administration Management System (CDC system)
  - IZ Gateway (CDC system)-facilitates electronic messaging, secure, allowing IIS systems to share vaccine administration data between jurisdictions
  - NESIIS - NE State Immunization Information System (NDHHS system)
  - VTrckS – Vaccine Tracking System (CDC system)
- Web-based Vaccine Administration Management System (VAMS) to support vaccination operation and data collection/tracking to meet COVID-19 vaccination requirements.
- Patient interface will allow patient registration and appointment management, clinic flow, supply management, patient record keeping, and reporting.
- Training- plans for various VAMS end user groups are currently taking place. In addition, a centralized help desk will be available to help with issues that may arise.
- VAMS ⟹ IZ Gateway ⟹ NESIIS ⟹ VTrckS ⟹ McKesson/ Pharmaceutical company ⟹ Provider
- Providers should plan to utilize second-dose reminders or what is referred to as Reminder/Recall found in both NESIIS and VAMS. Any subsequent systems would have reminder/recall as well.

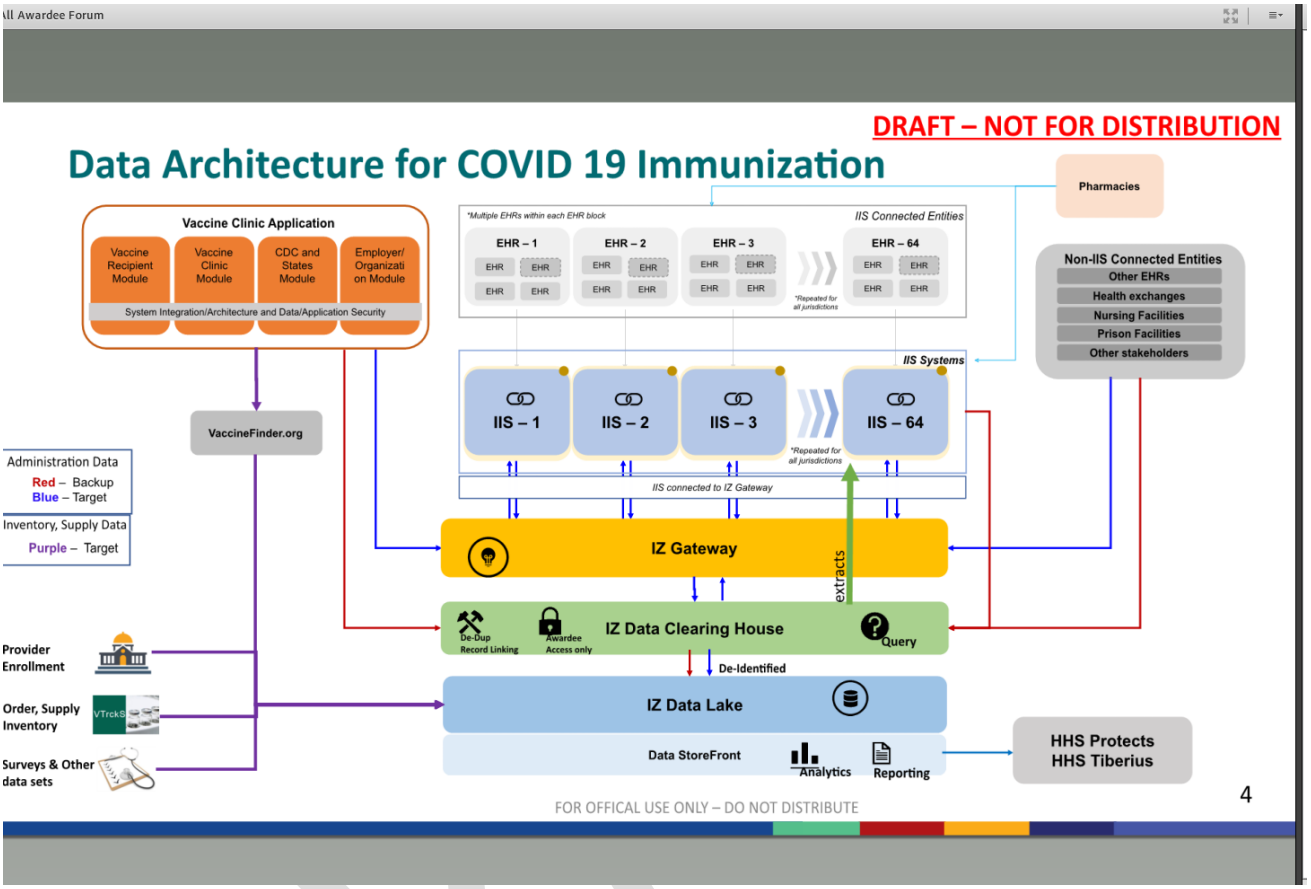
Plan C

NDHHS could employ the use of both NESIIS and VAMS depending on the following:

- System capabilities
- System availabilities
- Vaccine availability, type, and temperament
- Phase, priority population, and provider growth

Flexibility could be paramount to COVID-19 vaccination success. NDHHS will be flexible if the systems allow for it.

Data flow includes processes.



As of now, 90 percent of immunizations in Nebraska are received via electronic data exchange through EHR partners. NESIIS also supports 2D barcode scanning to expedite entry, with staff currently evaluating a solution to also allow roster based entry of immunizations via the user interface. Current system infrastructure was fully refreshed (servers, storage, and software) in 2019 to enhance capacity. NESIIS is able to support receipt of HL7 2.5.1 and 2.3.1 messages, and supports both SOAP based web services with the CDC WSDL, along with PHINMS. NESIIS can support both individual client and aggregate reporting, and are implementing a Logi analytics platform this year. The Logi analytics platform will allow for visualization of vaccine coverage data to allow for program monitoring, reporting to leadership, and reporting to the general public. In addition, the NESIIS team is exploring IZ Gateway Connect for IZ Share and validating the feasibility of participating if it can be constrained to only sending and receiving COVID-19 vaccines.

To ensure data quality NESIIS runs weekly and monthly data quality reports to identify issues with formatting (MSH-4, etc.), data (invalid CVX/NDC codes, etc.), non-senders, and senders of invalid eligibility. Recent implemented provider report cards to enable providers to take action on data quality issues.

To rapidly enroll and onboard into NESIIS, program staff are doing the following:

- Creating and offering online NESIIS trainings
- Data exchange
- Batch load file uploads

NESIIS staff will be made available for provider vaccination preparation with on-boarding into NESIIS for vaccine ordering/system training.

- NESIIS staff will:
  - Continue to ensure that the IIS is operating effectively, efficiently and at full capacity
  - Consider options for data storage
  - Prioritize and fix bugs when identified
- NESIIS has:
  - Secured Interjurisdictional agreements (DUA)
  - Connected to the IZ Gateway
  - Ensured system infrastructure including
    - reminder/recall COVID-19 vaccination record cards will be provided as part of the ancillary kits, however the NESIIS system can complete this task as well.
    - dose-level accountability
    - data management
- COVID-19 vaccination providers need to have a plan in place in the stance there is a temporary power/internet outage during vaccinations. NDHHS suggests the following options:
  - Utilize a Vaccine Administration Record for COVID-19to capture patient and vaccine information
  - Charged laptop with an uploaded Excel data sheet to NESIIS. This allows a file to be created while vaccines are taking place which can be used offline and then uploaded at a later time when power returns.

Section 10. COVID-19 Vaccination Program Communication

Nebraska Department of Health and Human Services will continue to clearly and effectively communicate COVID-19 vaccine messaging as it becomes available. Messaging should be proactive, transparent, informative, culturally diverse and available in multiple languages. Information shared must be evidence-based, truthful/credible, respectful, and shared with a sense of urgency.

Communications objectives are to:

- Educate the public
  - Vaccine distribution (phases), development, authorization
  - Vaccine confidence that includes data, safety, efficacy
  - Work with internal and external partners to understand needs and concerns
  - Provide toolkits, resources, and guidance to local providers
  - Monitor public perception, address hesitancy, and vaccine population uptake
- Target Key Audiences
  - Healthcare personnel/associations
  - Urban/rural employers
  - Nebraskans from diverse populations in general

        - Priority populations
        - Groups at risk of severe outcomes or increased chance of acquisition or transmission
        - Public/consumers
        - Those with limited access
- Provide messaging that addresses myths, cultural/historic mistrust, and/or product hesitancy.
    - Prevaccine
        - General vaccine education
        - Product safety
        - Populations identified as priority populations
    - Vaccine availability
        - limited supply
        - increasing in availability as vaccine production progresses
        - how to find a COVID-19 provider

The NDHHS Communications team meets with the COVID-19 planning group, participates in program webinars, and updates the program of any newly identify strategies for effectively communicating with Nebraskans. Communications has proposed the following:

- Conduct a state-wide survey asking consumers vaccine survey
- Create messaging that addresses consumer concerns and questions as described above
- Utilize various avenue of communication
    - Social media
    - Churches
    - Cultural community centers
    - Print ad
    - Robo Calls
    - Box trucks
    - Public Service Announcements
    - Facebook live
    - Electronic billboards/gas station video messages
    - Modify CDC materials
    - Share CDC material with local levels to create local messaging
- NDHHS Communication staff will continue to establish points of contacts with organizations, employers, and leaders within critical population groups by having a coordinated public information campaign. Information will be shared publicly, as well as through multiple local partnerships including VFC providers, local health departments, healthcare coalitions, etc. in order to leverage pre-existing relationships and communication pathways.

In Nebraska, local health departments function as the local public health authority and voice within their communities. NDHHS will support these efforts by providing and coordinating messaging across the state and will provide support to local health departments when needed.

Section 11. Regulatory Considerations

Emergency Use Authorization (EUA) Fact Sheets

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

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. A **EUA fact sheet for vaccine recipients** will also be developed, and both will likely be made available on the NDHHS website, as will links to both FDA and CDC websites.

Section 12. Adverse Reaction Reporting

https://vaers.hhs.gov/

VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA. VAERS is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. This way, VAERS can provide CDC and FDA with valuable information that additional work and evaluation is necessary to further assess a possible safety concern.

Providers will need to be vigilant as identifying and reporting any "signals" that might indicate possible safety problems. Provider reporting will help CDC detect new or unusual adverse events, will help monitor the increase of known side effects, and identify patient risks related to particular health problems.

NDHHS will ensure that providers are aware of and agree to use the VAERS, by posting links on the website and including in training materials. Continual adverse reaction support and education will be provided to providers, throughout COVID-19 vaccination phases, as well as frequent program website updates when made available.

Adverse events will also be monitored through electronic health record (EHR)-and claims-based systems or https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html .

NDHHS VAERS coordinator is:

Alexandra Kreft	Alexandra.kreft@nebraska.gov	402-471-0375

Vaccine Safety Datalink

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

https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

Vaccine Information Statements (VIS)

VISs are required only if a vaccine is added to the Vaccine Injury Table. Plans for the development of a VIS for COVID-19 vaccine is currently underway. Additional information will be share when it becomes available.

https://www.cdc.gov/vaccines/hcp/vis/current-vis.html

v-safe

CDC will implement **v-safe**, a new smartphone-based tool that uses text messaging and web surveys to check in with vaccinated individuals for adverse events after a COVID-19 vaccination. **v-safe** will also provide second-dose reminders (if needed) and live telephone follow up by CDC if vaccinated individuals report a medically significant event during a **v-safe** check-in. **v-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. The **v-safe** information sheet and counseling script are in development and will be made available electronically when competed. It is critically important for vaccine safety monitoring and assessment that healthcare professionals give each patient a **v-safe** information sheet at the time of vaccination and encourage patients to enroll.

Clinical Immunization Safety Assessment Project

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

https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

Section 13. Vaccination Program Monitoring

Nebraska will monitor progress in COVID-19 Vaccination Program implementation by tracking provider enrollment, the population's access to vaccination services, NESIIS performance, reporting, vaccine ordering and distribution, and vaccination coverage. Nebraska is tracking provider enrollment by transferring data captured on the Provider Agreement forms to a spreadsheet, which can then be utilized to create maps showing where enrolled providers are located and thus access to vaccination services, as well as translated to a CSV file for submission to CDC twice weekly. Nebraska will utilize reports within both NESIIS and VTrckS as well as ad hoc data analysis to track vaccine ordering and distribution by provider, by locality within the state, and/or by product type. Additionally, Nebraska is creating a dashboard which will query data captured within NESIIS and produce regularly updated visualization tools. This dashboard will be used to monitor and report out vaccine coverage rates at

various levels across NE to both internal and external partners. At this date, the specific metrics and location of the dashboard is to be decided, and will be included in this plan once finalized.

Methods and procedures to monitor resources and communication will utilize the standard processes in place within the NDHHS Immunization Program. The state level budget is monitored by using reports from the enterprise-wide accounting system, allowing staff to track expenses and available funds. Supplemental funds were distributed to local level partners along with traditional funds to allow the primary Phase 1 partners to expand their operation as needed to address both influenza and COVID-19 vaccination activities. Those agreements require regular reporting and submission of invoices to allow state staff to monitor both activities and expenses within the local organizations. The NDHHS Immunization Program has a variety of ways to communicate with enrolled providers, including email, fax, phone, and the ability to post messages on the front-facing page within NESIIS – ensuring that providers see communication when looking to order product or enter administration data. Additionally, resources will be posted online – a provider specific page that will include COVID-19 specific resources as well as a page for the public containing more general information (http://dhhs.ne.gov/Pages/Coronavirus.aspx). Nebraska will continue to utilize the existing COVID-19 Information Line (phone: (402) 552-6645, Toll Free (833) 998-2275) at least initially to ensure that Nebraskans have a way to get accurate, reliable information regarding COVID-19 vaccination services across the state.

To enhance situational awareness the CDC will offer two dashboards:

- Weekly Flu Vaccination Dashboard-to provide weekly estimates of influenza vaccinations
- Operation Warp Speed Tiberius-this real-time platform is intended to track, model, and analyze data for decision making.

APPENDIX

Appendix

https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

https://www.naccho.org/uploads/downloadable-resources/COVID-19-Vaccination-Scenarios-for-Jurisdictional-Planning-Phase-1.pdf

https://www.cdc.gov/cpr/readiness/resources.htm

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

https://www.cdc.gov/flu/pandemic-resources/planning-preparedness/vaccine-medical-countermeasures.html

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-increased-risk.html

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

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#A1

https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process

https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html

https://www.cdc.gov/vaccines/acip/meetings/slides-2020-08.html

http://dhhs.ne.gov/Pages/Immunization.aspx

Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations
The guidance is broken down into four categories:

- Planning activities
- Pre-clinic activities
- During the clinic activities
- Post-clinic activities

https://www.cdc.gov/vaccines/pandemic-guidance/index.html

https://www.cdc.gov/flu/pandemic-resources/tools/panvax-tool.htm

https://www.cdc.gov/vaccines/acip/meetings/slides-2020-08.html

https://www.hrsa.gov/coviduninsuredclaim

https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures

https://www.fema.gov/emergency-managers/national-preparedness/exercises/tools

https://jamanetwork.com/journals/jama/fullarticle/2766370

Vaccine storage and handling: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

https://www.centerforhealthsecurity.org/our-work/publications/interim-framework-for-covid-19-vaccine-allocation-and-distribution-in-the-us

https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities

https://www.vaccinefinder.org/

https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

https://www.cdc.gov/vaccines/programs/iis/index.html

http://dhhs.ne.gov/Pages/Nebraska-Immunization-Information-System.aspx

Vaccine administration:

- www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
- www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
- www.cdc.gov/vaccines/hcp/admin/resource-library.html

https://www.cdc.gov/coronavirus/2019-ncov/communication/

https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/index.html

https://www.cdc.gov/coronavirus/2019-ncov/community/communication-plan.html

https://emergency.cdc.gov/cerc/manual/index.asp

https://enroll-ne.org/

https://www.atsdr.cdc.gov/placeandhealth/svi/index.html

https://www.euro.who.int/__data/assets/pdf_file/0007/187171/Vaccine-Safety-Events-managing-the-communications-response-final.pdf

Injection safety: www.cdc.gov/injectionsafety/providers.html

Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/

Dry Ice in Nebraska:
http://nedhhs.maps.arcgis.com/apps/webappviewer/index.html?id=1624ead6625a49c8830052cef9e41dec

Videos on preparation and administering LAIV: www.cdc.gov/vaccines/hcp/admin/resource-library.html (includes videos on intramuscular injections and administration of live, attenuated influenza vaccine)

The Immunization Action Coalition has a skills checklist for staff administering vaccines: www.immunize.org/catg.d/p7010.pdf.

The Immunization Action Coalition and the Alliance for Immunization in Michigan have patient education materials available:

- Screening tools: http://www.immunize.org/handouts/screening-vaccines.asp
- Vaccination after-care:
  - Children: www.immunize.org/catg.d/p4015.pdf
  - Adults: www.aimtoolkit.org/docs/vax.pdf

The Immunization Action Coalition has information on the medical management of vaccine reactions:

- Children and adolescents: www.immunize.org/catg.d/p3082a.pdf
- Adults: www.immunize.org/catg.d/p3082.pdf

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

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

https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html#:~:text=Other%20OCR%20Resources&text=To%20learn%20more%20about%20privacy,HIPAA%20and%20COVID%2D19%20page.&text=For%20assistance%2C%20contact%20the%20HHS,emailing%20OCRMail%40hhs.gov.

Manufacturers' product information and package inserts with specific, detailed storage and handling protocols for individual vaccines: www.immunize.org/packageinserts/pi_influenza.asp.

Data Management share documents

- **APHL – Jurisdiction DUA IZ Gateway (3August2020revision)** 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 Aug 3, 2020 for this expanded use.

- **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 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.

Countermeasures Injury Compensation Program

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

The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are:

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

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

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

V. Covered Persons

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

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

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