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# SARS-CoV-2/COVID-19 Mass Vaccination Planning Guide



## Mass Vaccination Planning Guide

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## Frequently Asked Questions

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## Planning Guide

### Introduction

This is a draft document designed to assist Local Health Departments in planning for vaccine distribution. Information contained in this document is based on limited and preliminary guidance from the Center for Disease Control and Prevention (CDC) & Advisory Committee on Immunization Practices (ACIP) and will be continuously updated as that guidance evolves. All information in this document is subject to change.

The Illinois Department of Public Health (IDPH) Office of Health Protection (OHPT) Immunization Section and IDPH Office of Preparedness and Response (OPR) Medical Countermeasures Program have led the collaborative efforts of the COVID-19 Mass Vaccination Planning Work Group in developing this SARS-CoV-2/COVID-19 Mass Vaccination Plan, as an attachment to the Mass Vaccination Annex 3.0 of the State of Illinois Pandemic Plan. This plan should be used by state and local partners to inform planning efforts for the administration of SARS-CoV-2/COVID-19 vaccines. IDPH will ensure quality improvement by soliciting feedback from partners and stakeholders throughout the implementation of this plan and as new information becomes available.

The IDPH/OPR Medical Countermeasures Program develops and maintains plans for request, receipt, distribution, mass dispensing and the administration of life-saving emergency medical supplies and equipment during a disaster, where the public's health is at risk. This includes plans in response to human-caused and natural events. The Medical Countermeasures Program includes the Strategic National Stockpile (SNS) Program, the CHEMPACK Program, the Illinois Pharmaceutical Stockpile (IPS) and the Cities Readiness Initiative (CRI). The SNS is a federal cache of emergency medical supplies and equipment that can be deployed to states during a disaster. The CHEMPACK is the forward placement of nerve agent antidotes. IPS is a state-owned cache of emergency medical supplies and equipment. The CRI is a program designed to ensure cross-border collaboration of municipalities, counties, and states during incidents where the emergency medical supplies and equipment are deployed.

The IDPH/OHPT Immunization Section maintains the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE), a system for vaccine management and operations, which includes ordering, shipping, handling, and storing procedures for all vaccine purchases in the State.

This is a state level plan; however, the City of Chicago will receive direct allocation of vaccine from the Federal government. IDPH has worked with CDPH to ensure both the state and city level plans are in sync and complementary.

To accomplish the goal of providing SARS-CoV-2/COVID-19 vaccines to enough of the population to elicit herd immunity, as supply of vaccines permits, the State of Illinois will:

- Provide technical assistance to Local Health Departments to inform local planning to ensure local plans are in alignment with state plans/guidance and accountability can be maintained.
- Closely monitor activities at the local level to ensure the COVID-19 vaccine administration plan is implemented throughout each local jurisdiction, in adherence with federal and state guidance and requirements, and that there is equitable access to COVID-19 vaccination across the state.
- Activate the State Emergency Operations Center (SEOC) to coordinate the ordering, administration, and tracking of the SARS-CoV-2/COVID-19 vaccine in the state.
- Ensure expanded scopes of practice for health care licenses, as necessary to allow certain medical professionals the opportunity to assist in the mass vaccination campaign, when working under the authority of the local public health jurisdiction or a health care entity.
- Provide a statewide system for tracking vaccine administration and for notifying clients of the need for a second dose of the vaccine, if a second dose is needed.
- Provide a statewide system for volunteer management and tracking – Illinois Helps.
- Provide a statewide system for disseminating information to vaccine providers and others with direct involvement in the COVID-19 mass vaccination administration mission – Health Alert Network –

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- Provide oversight of provider enrollment, tracking, and vaccine location.
- Identify and map priority populations and determine sub-allocations of vaccine for distribution within the state.
- Track relevant data to inform the statewide vaccination strategy and ensure Federal requirements are met.
- Provide guidance and training to vaccine providers on:
  - Available Center for CDC resources, and vaccine recommendations, when available.
  - Ordering and receiving the COVID-19 vaccine.
  - Vaccine storage and handling, including transportation requirements, specific to COVID-19 vaccines.
  - Vaccine administration, including reconstitution, use of adjuvants, diluents, etc.
  - Documenting and reporting vaccine administration via I-CARE and/or EMTrack.
  - Managing and reporting vaccine inventory via I-CARE.
  - Documenting and reporting vaccine wastage/spoilage.
  - Procedures for reporting to the Vaccine Adverse Event Reporting System (VAERS).
  - Providing Emergency Use Authorization (EUA) fact sheets and/or vaccine information statements (VISs) to vaccine recipients.
- Collaborate with local Public Information Officers (PIOs) to conduct a statewide media campaign to share facts about the vaccine and to encourage residents to be vaccinated.
- Activate a statewide hotline to address questions regarding the mass vaccination administration campaign and to provide guidance on reporting vaccine adverse events to the CDC.

# Section 1: COVID-9 Vaccination Preparedness Planning

## COVID-19 Mass Vaccination Planning Assumptions:

### Vaccine distribution

- Limited COVID-19 vaccine doses may be available in December 2020.
- COVID-19 vaccine supply will increase substantially in 2021, allowing regular shipments to states.
- Vaccine providers will be required to enroll in the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE).
- Vaccine providers will be required to agree to follow CDC guidance on vaccine administration, storage, and handling by signing the CDC COVID-19 Vaccination Program Provider Agreement.
- Vaccine providers will be allocated vaccine, as it becomes available, based on the overall jurisdiction's population size and disease burden, while ensuring equity.
- Vaccine will be delivered via the Vaccines for Children (VFC) model, shipped directly to providers, when possible.
- In the early phases of vaccine distribution for vaccines requiring ultra-cold (-80 C) temperature controls and the inability to distribute less than 975 doses, IDPH and IEMA will coordinate a centralized distribution model, by modifying the State's Strategic National Stockpile (SNS) plan.
- Vaccine providers will be required to enroll in Vaccine Finder and report inventory daily.

## Priority Groups

- It should be noted that all people are assumed susceptible to the virus.
- Initial populations prioritized for COVID-19 vaccination will be the following based on federal guidance and pending ACIP recommendations, all phases subject to change based on ACIP guidance:
  - Health Care Personnel & Residents from Long Term Care Facilities.
  - Essential frontline workers including first responders.
  - Those with high risk medical conditions and adults over 65 years of age.
- Recommendations for groups to focus on will likely change after vaccine is available, depending on characteristics of each vaccine, vaccine supply, and disease epidemiology.
- Because of the uncertainty of COVID-19 vaccine production, plans must be flexible and should include high-demand and low-demand scenarios.

Note: See Section 3 “Phased Approach” for more information.

## Vaccination

- Vaccination will be voluntary.
- Adequate federal funding will be available to implement a large-scale vaccination response.
- Initial doses of COVID-19 vaccine may be authorized for use under an Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA), based on available safety and efficacy data.
- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2°C – 8°C) to frozen (-20°C) to ultra-cold (-60°C to -80°C).
- Frozen and refrigerated vaccines will be shipped in 100 dose increments kitted with ancillary supplies. Ultra-cold vaccine will be shipped in 975 dose increments.
- Two doses of COVID-19 vaccine, separated by  $\geq 21$  or  $\geq 28$  days, will be needed for immunity for some vaccine candidates; It is expected that both doses of the vaccine will need to be with the same vaccine type, produced by the same manufacturer, but not the same lot of the vaccine. This will require stringent tracking of vaccine administered and patient reminders.
- Per CDC Guidance, vaccine should be provided to enough of the population to elicit herd immunity, as supply of vaccines permits.
- Vaccination will take place over many months and provided in phases, as more vaccine becomes available.
- Vaccine administration planning must reflect the four types of vaccines being manufactured:
  - mRNA - Messenger ribonucleic acid. Encodes protein of the virus, which is inserted into cells to trigger an immune response and create antibodies to the virus.
  - Nonreplicating Vector - Injecting only certain proteins of the virus to stimulate the immune system. Uses a harmless viral vector to deliver the protein into the cells.
  - Protein Adjuvant - Virus protein is packaged into a nanoparticle and delivered into cells with an adjuvant to enhance the immune response.
  - Live Attenuated - Modify the virus to be inactive but still alive. Virus can infect the cells but not replicate to cause disease.
- CDC will provide standard communication materials on the EUA for the general public, similar to the Vaccine Information Statement (VIS), and specific communication to vaccine providers on the EUA.
- Monitoring for adverse events will be necessary and important.
- Vaccine distribution for common vaccine preventable diseases will not alter from routine procedures.
- Seasonal influenza vaccine production and campaign will continue.

- Demand for the pandemic vaccine may be high throughout the response.

Note: Requirements for COVID-19 vaccine administration will continue to evolve over time. More guidance to come pending ACIP recommendations.

## Section 2: COVID-19 Organizational Structure and Partner Involvement

The COVID-19 Response with IDPH is organized under an Incident Command System (ICS) via an organizational chart. The Director of IDPH and the Director of the Illinois Emergency Management Agency (IEMA) are operating under a Unified Command Response. The IDPH response is led by the Incident and Deputy Incident Commanders. In the proceeding organization chart, functions that interface with IEMA are marked in red boxes. For Mass Vaccination, this is led under the Mass Vaccination Section, which is led by a Section Chief and Deputy. There are functions that interface with local jurisdictions at both the command staff levels and in individual sections.

Within the Mass Vaccination Section, each box represents a function that has a lead and support staff, as required, thus creating redundancy. This core team works in tandem with the Mass Vaccination Planning Group, which includes relevant stakeholders from across the state. The section frequently holds ad hoc meetings/webinars to engage other partners such as Local Health Departments (LHD's) & local Emergency Management Agencies (EMA's), private industry, associations, pharmacies, correctional facilities and institutes of higher learning.

Pandemic vaccination planning is a combined state and local responsibility that requires close collaboration and coordination between public health, external agencies, and community partners. An internal COVID-19 Vaccination Program planning and coordination team is critical to ensure the vaccination response to COVID-19 is thoughtfully planned and successfully executed.

## Section 3: Phased Approach to COVID-19 Vaccination

Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning will be flexible but as specific as possible to accommodate a variety of scenarios. It is anticipated that vaccine supply will be limited initially, so the allocation of doses must consider vaccination providers and settings for vaccination of limited critical populations. The vaccine supply is projected to increase quickly, allowing vaccination efforts to be expanded to include additional critical populations and the general public. Additionally, recommendations on the various population groups for initial doses of vaccine could change after vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors.

IDPH is adopting the National Academies of Science, Engineering, and Medicine's (NASEM) "A Framework for Equitable Allocation of COVID-19 Vaccine." This framework focuses on reducing severe morbidity and mortality and negative societal impact due to the transmission of SARS-CoV-2. Emphasized in the framework is that the

goal of the COVID-19 vaccination program is to vaccinate all those who choose to be vaccinated and who do not have medical contraindications to the vaccine.

The following explains the phased approach as per CDC and ACIP guidance, which were recommended based on “science, implementation and ethics.” It should be noted, further ACIP recommendations are expected after the issuance an Emergency Use Authorization (EUA), which may alter the phased approach by adding phases or shifting of populations from phase to phase. Please see Section 4, “Critical Populations,” for more details about specific populations covered in each Phase.

**Phase 1: Limited/scarce supply of COVID-19 vaccine doses available. Focus initial efforts on reaching critical populations. Ensure vaccination locations selected can reach populations, manage cold chain requirements, and meet reporting requirements for vaccine supply and uptake. Vaccine administration strategies in phase 1, is broken into three (3) sub-phases:**

#### Phase 1a:

- Health Care Personnel.
- Long Term Care Facility Residents.

#### Phase 1b:

- Possible groups could include: More guidance to come pending ACIP recommendations.
- Possible groups could include: Essential Frontline Workers.

#### Phase 1c:

- Possible groups could include: More guidance to come pending ACIP recommendations.
- Possible groups could include: Adults with high risk medical conditions and those over 65 years of age.

**Phase 2: Larger number of vaccine doses available. Focus on ensuring access to vaccine for members of Phase 1 critical populations not yet vaccinated, extend efforts to reach Phase 2 critical populations. Possible groups could include;**

- possible groups could include: More guidance to come pending ACIP recommendations.
- possible groups could include: Workers in industries and occupations important to the functioning of society.
- Possible groups could include: People with moderate comorbid conditions.

**Phase 3: Vaccine supply even more widely available.**

- More guidance to come pending ACIP recommendations.
- Possible groups could include: Immunization of children (if a pediatric vaccine is approved/available).
- Possible groups could include: Young adults (18-30).

Phase 4: Sufficient supply of vaccine doses are available for the entire population (surplus of doses). Possible groups could include; All groups are included in this phase. The focus in this phase is ensuring everyone who qualifies and needs or wants a COVID-19 vaccine receives the requested vaccine at no cost. Federally Qualified Health Centers, Rural Health Clinics, private providers, and pharmacies will assume the majority of the vaccination efforts in their areas in this Phase. Local Health Departments will focus vaccination efforts toward the most vulnerable populations, such as homeless populations with limited access to care. IDPH will also use mobile health units, as needed or requested. More guidance to come pending ACIP recommendations

In each phase, once the priority groups have been satisfactorily reached, vaccine administration planning can then focus on reaching the next population of focus and/or the general population where the overarching goal is to elicit herd immunity. Throughout each phase of COVID-19 vaccine administration, it is important that jurisdictions and providers ensure equitable allocation and administration of the vaccine to all identified priority groups. IDPH will also continue to monitor COVID-19 vaccine orders by assessing ordering reports supplied by the immunization program. IDPH will also monitor vaccine uptake and coverage and reassess strategies to increase uptake in populations and/or communities with low vaccine coverage. IDPH will also utilize vaccine wastage reports provided to assure minimal waste. Another situation that could arise is low COVID-19 vaccine demand, so jurisdictions should monitor their supply and adjust strategies to minimize vaccine wastage. Finally, IDPH will provide COVID-19 vaccine administration reports to CDC as requested.

Note: See Section 4 “Critical Populations” for more information including estimate population numbers.

Example of phased approach provided by ACIP:

## Section 4: Critical Populations

The 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. The National Academies of Sciences, Engineering, and Medicine (NASEM) has developed a framework to determine populations of focus for COVID-19 vaccination and ensure equity in access to COVID-19 vaccination across the United States. IDPH is utilizing the NASEM framework for initial allocation and prioritization, but ACIP may issue additional guidance that could shift priority populations. The priority populations listed below are for planning purposes and are subject to change as more is learned about the effects of COVID-19 and effectiveness of vaccines in different populations, and as further federal guidance may be issued.

Ariadne Labs, along with the Surgo Foundation, has developed a free Vaccine Allocation Planner for COVID-19, which pulls data for each of the critical populations from various federal, state, and other data sets. The methodology for these allocation calculations can be found here. Illinois will utilize this tool to inform critical population sizes.

IDPH will continually review additional guidance provided by the federal government and updates to ACIP recommendations, regarding allocation priorities, and the populations that will be served successively as vaccine supplies increase. Among the factors that IDPH is expecting to consider are: health disparities and other health access issues; individuals at higher risk (e.g., elderly and those with underlying health conditions); occupations at higher risk (e.g., frontline health care personnel and essential industries); populations at higher risk (e.g., racial and ethnic groups, incarcerated individuals, and residents of nursing homes); and geographic distribution of active virus spread. IDPH's recommendations for vaccine prioritization will reflect the recommendations set forth by ACIP with minimal changes. IDPH recognizes the potential for alterations of these recommendations based on the evolving epidemiology of COVID-19 and will monitor national recommendations for changes that may occur.

After the target priority groups have been vaccinated and additional vaccine stocks become available, IDPH will ensure that communities suffering disproportionately from COVID-19, including communities of color, older adults, people with disabilities, and people with comorbidities, are prioritized appropriately for vaccination. IDPH will work with local community partners and providers to strategically target underserved populations for vaccinations. IDPH will phase-in vaccination for the remainder of the population, based on age or other criteria to ensure fair, equitable, and orderly distribution.

## Prioritization of Vaccine Allocation and Administration:

Local public health jurisdictions should plan to collaborate with their regional health care coalition, hospitals, long-term care/assisted living facilities, and other potential vaccine providers in their jurisdictions that serve frontline workers in their jurisdiction to ensure full coverage of vaccine first to the designated priority groups and then to the general public.

Local Health Departments should reach out to these groups now to determine the number, type, and location of each priority group in the public health jurisdiction. Local Health Departments should coordinate with their health care coalition, emergency management, and other response partners to develop a list of entities serving the priority groups, determine their capabilities to serve as sites for vaccine administration, i.e. closed Points of Distribution (PODs), or develop plans for the Local Health Department to service these groups at a general POD designed for these groups.

During the previously mentioned planning, LHD's should also address the following;

1. Refrigerated, frozen & ultra-cold storage for vaccine within the phase.
  - a. Local plans for the different types of vaccine, such as transporting 2c to 8c vaccine from the Regional Hospital Coordinating Center (RHCC) to the LHD and/or to the vaccination site, and/or building partnerships to utilize ultra-cold storage capability in the county.
2. Numbers of populations to be served in each priority group, within the phase.
3. Security of vaccine.
4. Projected vaccination throughput to determine time needed to utilize the total vaccine allocation.
5. Local communication & public outreach.
6. Partners that will be necessary to accomplish all aspects of the local plan. (E.g. Local law enforcement, local emergency management, local hospitals, etc.)



Recommendations for Phase 1 subset groups include (adjusted for ACIP recommendations and adapted from NASEM Framework).

### Phase 1a:

- Health Care Personnel are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients' infections materials.  
Examples include:
  - Clinicians: Such as nurses, physicians, respiratory technicians, dentists, and hygienists.
  - Other workers in health care settings: Such as Nursing assistants, environmental services staff, assisted living facility staff, long-term care facility staff, group home staff, and home caregivers. This also includes Emergency Medical Services (EMS).
- Inclusion in Phase 1a is not dependent upon payment for their work or job title. Situations associated with higher risk of transmission include caring for COVID-19 patients, cleaning areas where COVID-19 patients are admitted, treated, and housed, and performing procedures with higher risk of aerosolization such as endotracheal intubation, bronchoscopy, suctioning, turning the patient to the prone position, disconnecting the patient from the ventilator, invasive dental procedures and exams, invasive specimen collection, and cardiopulmonary resuscitation. Also included in this group are those individuals distributing the vaccine, such as pharmacists, plasma and blood donation workers, public health nurses, and other public health and emergency preparedness workers. Morticians, funeral home workers, and other death care professionals involved in handling bodies are included in this high-risk group. When vaccine is scarce, priority should be given to high risk health workers who are involved in direct patient care, as well as those working in transport, environmental services, or other health care facility services – who risk exposure to bodily fluids or aerosols. Access to vaccine when scarce should not be defined by professional title, but rather by an individual's actual risk of exposure to COVID-19.
- Long Term Care Facility Residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.

The proceeding phases are widely seen as the next potential groups to be eligible to be vaccinated. These phases have been prepared in order to assist LHD's to be prepared with a plan, which can be updated as further ACIP guidance is released.

### Phase 1b: More guidance to come pending ACIP recommendations;

- Possible groups could include: Essential Frontline Workers, which are defined as those workers who are essential for the functioning of society.
- Examples include:
  - First Responders such as police, firefighters (including volunteer), national guard acting in the capacity of a first responder. (Note: EMS is included in Health Care Personnel)
  - Food & agriculture, such as meat processing plants.
  - Utilities.
  - Transportation, such as transit and trucking.
  - Corrections officers.
  - Education.
- ACIP will make specific age recommendations as data become available.

As recommendations are released from ACIP, it is expected that essential frontline workers will include those designated by the U.S. Department of Homeland Security (DHS) as belonging to categories of Essential Critical Infrastructure Workers who are at a higher risk of exposure and not able to reduce risk through telework or isolation.

#### Phase 1c: More guidance to come pending ACIP recommendations;

- Possible groups could include: Adults with High Risk Medical Conditions, such as obesity, diabetes, COPD, Heart Conditions, chronic Kidney conditions, Cancer, Solid Organ Transplant, Sickle Cell Disease, etc.
- Possible groups could include: Adults over 65 years of age.
- ACIP will make specific age recommendations as data become available.

#### Phase 2: More guidance to come pending ACIP recommendations;

- Possible groups could include: Workers in industries and occupations important to the functioning of society, such as personnel in dentist offices, medical and diagnostic labs, food/beverage manufacturing facilities and stores, cosmetic and beauty supply stores, optical goods stores, other health/personal care stores, transportation industries, postal service and couriers/messengers, general warehousing and storage, pharmaceutical and medicine manufacturing.
- Possible groups could include: People of all ages with comorbid and underlying conditions that put them at moderately higher risk include the same list as Phase 1c.
- ACIP will make specific age recommendations as data become available.

#### Phase 3: More guidance to come pending ACIP recommendations;

- Possible groups could include: Young adults, defined as adults aged 18-30.
- Possible groups could include: Children under the age of 18. This is dependent upon a pediatric vaccine approval/availability.

#### Phase 4: More guidance to come pending ACIP recommendations;

- Possible groups could include: Includes all persons residing in Illinois who did not have access to the vaccine in previous phases (and for whom the vaccine is not medically contraindicated, if contraindications are known for the vaccine).

\*Population estimates adapted from Ariadne Labs' Vaccine Allocation Planning Tool (methodology) and adjusting to exclude the City of Chicago, which will receive its own vaccine allocation from CDC. Population group categories are not exclusive and may not add to the total population (e.g. within phase 2, an individual may fall under "teachers/school staff" and also under "all older adults").

Note: More guidance to come pending ACIP recommendations.

# Section 5: COVID-19 Provider Recruitment and Enrollment

An adequate network of trained, technically competent COVID-19 vaccination providers in accessible settings is critical to the COVID-19 Vaccination Program success. IDPH's first priority was to enroll LHDs. Enrollment then expanded to include hospitals in the state, so that they may provide vaccine to qualifying staff. After hospitals, IDPH will focus on Federally-Qualified Health Centers (FQHC's) and pharmacies, especially those in rural areas that do not have hospitals or other opportunities to access vaccines outside of the health departments. By enrolling these pharmacies, IDPH is able to provide vaccine to many of the priority patients. In coordination with LHDs, the State will also be deploying vaccination mobile vaccination teams that will be able to conduct on-site vaccination events for targeted populations that may not have ready access to another vaccine provider. Once hospitals and pharmacies are on boarded, IDPH will begin focusing on pharmacies, urgent care clinics, and community providers that will be able to reach additional individuals within these priority populations, as well as other private medical providers. Geographic Information System (GIS) mapping will be utilized to identify gaps in coverage and targeted recruitment efforts will be implemented to fill those gaps. IDPH will use an electronic database to enter the newly enrolled providers that will be updated daily; that data will be submitted to the CDC.

Provider requirements, including local public health jurisdictions, hospitals, and others wanting to administer the COVID-19 vaccine:

- All vaccine providers must register in I-CARE and sign and return the CDC COVID-19 Vaccination Program Provider Agreement and Profile form, electronically through I-CARE. Local Health Departments, hospitals, and other vaccine administrators will order and receive the SARS-CoV-2/COVID-19 vaccine via I-CARE. Vaccine will be shipped directly from the manufacturer or distributor to the provider or, in the case of early distribution of the ultra-cold Pfizer vaccine, from IDPH to the Local Health Departments.
- Local public health jurisdictions should collaborate with their Regional Hospital Coordinating Center (RHCC), hospitals and long-term care/assisted living facilities within the county, and with other potential vaccine providers that cater to critical infrastructure/essential frontline workers in their jurisdiction, to ensure full coverage of vaccine first, to the designated priority groups and finally, to the general public.
- All entities must provide training to staff assigned as vaccinators and to other staff members assigned to assist with vaccine administration operations.
- As part of the CDC COVID-19 vaccine provider agreement, the enrollee must attest/agree to being able to receive the vaccine and report to the Immunization Information System (IIS) (I-CARE) within 24 hours of vaccine administration. Site visits are not required for COVID-19 vaccine providers, but the Chief Medical Officer associated with each site that signs the vaccine provider agreement is attesting that they meet the requirements listed in the agreement. For vaccine administration tracking and reminders of a second dose, if needed, all vaccine providers must plan to utilize I-CARE or EMTrack.
- All vaccine providers must daily report vaccine administration and on-hand inventory to IDPH for tracking and reporting data elements as defined by the CDC. CDC is utilizing VaccineFinder to help facilitate reporting of COVID-19 vaccine supply, and as appropriate to help direct people to locations offering vaccine. All providers must report supply information into VaccineFinder (instructions from CDC will be forthcoming). The option for their site to be visible on the VaccineFinder public facing website will be available when/if providers want to increase access to vaccine to the public.

- All vaccine providers must share with vaccine recipients the required EUA fact sheets and/or VIS on the vaccine administered.
- All providers must include in their plans, procedures for reporting clinically important adverse events. Adverse events also will be monitored through Electronic Health Records (EHR) and claims-based systems such as Vaccine Safety Datalink.
- All vaccine providers must be registered in the Illinois Health Alert Network – HAN/ SIREN to receive vaccine guidance and critical updates on the COVID-19 mass vaccination administration mission.

## Section 6: COVID-19 Vaccine Administration Capacity

IDPH is recruiting and enrolling COVID-19 vaccination providers with the assistance of numerous state agencies and professional organizations. These providers will vary in types and settings to address each of the previously described phases of vaccine availability.

IDPH will use GIS mapping to identify the locations of organizations that have expressed initial interest in becoming pandemic vaccine providers. Additionally, IDPH will use maps that indicate populations with higher prevalence of conditions or circumstances that increase the risk of significant morbidity and mortality from COVID-19. Particular attention will be paid to those identified areas to ensure vaccine providers are recruited in those geographic areas in sufficient number to vaccinate those at-risk populations. This will allow the planning team to visualize gaps in access and recruit providers in specific regions.

The initial onboarding focused on Local Health Departments, as well as all hospitals, with priority to those with emergency departments and/or intensive care units.

Local pharmacies will also be utilized and can provide expanded access to a variety of communities. Pharmacists are not only highly accessible, but they are also commonly available for longer hours and more days than non-pharmacy providers. To date, 99% of the Long-Term Care (LTC) providers within the state of Illinois are utilizing the partnership program established by CDC with Walgreens and CVS Pharmacies, to ensure their residents and staff are vaccinated.

IDPH plans to utilize “mobile vaccination teams” to support and provide mass vaccination clinics to defined targeted groups and populations. Another objective of the mobile vaccination teams will be to deploy to areas impacted by health inequity, often referred to as “at-risk” or “vulnerable populations.” This can occur in each of the phases as necessary.

To assist with mass vaccination operations at POD sites, COVID-19 vaccine providers can utilize Illinois Helps to search for qualified volunteers.

- Illinois Helps ([www.illinoishelps.net](http://www.illinoishelps.net) (<http://www.illinoishelps.net>)) is a state registry of volunteers for both medical and non-medical occupations, who can be requested in a disaster or public health emergency.
- 38 states use a platform similar to Illinois Helps, built on the federal standard Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP).
- Illinois Helps is a decentralized system whereby each organization (Local Health Department, hospital, Medical Reserve Corps, Long-Term Care facilities) manages individual volunteers that wish to work with

that specific organization.

- A volunteer registers in the system, gives their information including licensure and skills, and picks up to 15 organizations to work with.
- The organization using the volunteer, follows their own protocols, including background checks, if appropriate, to onboard the volunteer.
- This is not an event-based system but rather a holistic volunteerism program, whereby each organization works with volunteers in a variety of ways.
- Approximately 270 qualifying organizations, such as Local Health Departments, Medical Reserve Corps (MRC), hospitals, and long-term care facilities, are registered in Illinois Helps to request volunteers.
- Any healthcare organization wishing to access and manage volunteers can request to do so at [illinois.helps@illinois.gov](mailto:illinois.helps@illinois.gov) (mailto:illinois.helps@illinois.gov).

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

The IDPH Immunization Section will utilize established I-CARE protocols to coordinate ordering and tracking utilization of the pandemic vaccines from the CDC, or from the designated vendors. Providers will log into I-CARE to order the vaccine. IDPH staff will approve the orders in I-CARE and transmit the request into CDC's Vaccine Tracking System (VTrckS). LHD's will be the first to order while vaccine is scarce. IDPH will work with LHD's to determine which providers should be prioritized in their jurisdiction. Once the supply of vaccine increases and later phases are entered, orders can be processed directly with all providers.

For refrigerated/frozen vaccine, the approved vaccine orders, including the adjuvant, if necessary, and all ancillary supplies, will be direct shipped to the providers' designated locations. This shipment is executed by McKesson or the vaccine manufacturer and will be expected to ship within 24 hours of the order being received through VTrckS. However, this timeframe is dependent on vaccine availability and on McKesson and the vaccine manufacturers to meet this timeline.

On initial distribution, Illinois will activate the State Emergency Operations Center (SEOC), to support and monitor the distribution of the vaccine. To ensure success of the mission, the Incident Command System will be expanded to include the following positions:

- The IDPH Immunization Group is the lead for processing and approving vaccine orders in I-CARE. The Immunization Group will also be responsible for monitoring patient tracking and for monitoring adverse events reporting. This group is headed by the Vaccines for Children Administrator and staff.
- The Vaccine Administration Division is responsible for liaising with vaccine providers in each of the health care coalition regions and public health jurisdictions, by provider type. This group will be led by regional staff who have experience working with Local Health Departments, hospitals, long-term care facilities, and the health care coalitions.
- The I-CARE administration staff is responsible for COVID-19 vaccine provider enrollment and technical support. This group will be led by the I-CARE Administrator and staff.
- The RSS/Distribution Group is responsible for tracking COVID-19 vaccine orders from the manufacturer direct-shipped to the providers. This group will be led by IDPH staff familiar with distribution operations.

- Ancillary Supplies shipped by McKesson will include consist the following:
- Each kit will include supplies needed to administer 100 doses of vaccine.
- 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.
- COVID-19 vaccination record cards for each vaccine recipient, 100 per kit.
- Limited supply of Personal Protective Equipment (PPE) such as surgical masks and face shields for vaccinators. Each ancillary kit contains four surgical masks and two face shields.
- Needle information card, 1 per kit.

Note: Supplies not included in the shipments from McKesson or the vaccine manufacturer and to be procured by the provider: Sharps containers, gloves, bandages, etc. Providers may need to plan for additional Personal Protective Equipment (PPE), depending on vaccination site needs.

Minimum order size for CDC-distributed vaccine will be 100 doses per order for vaccines stored at refrigerated (2-8 C) or frozen (-20 C) temperatures. Minimum orders for ultra-cold vaccines that are shipped directly from the manufacturer will be 975 doses per package and will be shipped in special shipping containers containing dry ice. Due to the limited allocations of the initial doses of ultra-cold vaccine, IDPH will receive most orders at a central location and re-distribute to Local Health Departments, depending on their allocation, at refrigerated (2-8 C) temperatures. Providers should utilize the entire dose allocation and not hold vaccine back for a second dose, as the second dose will be provided closer to the time of its expected administration, per CDC guidance.

### Vaccine Allocation:

The federal government will determine the amount of COVID-19 vaccine designated for each state. Using this allotment, IDPH will then manage and approve orders from enrolled providers. During initial allocations when vaccine is scarce, LHD's determine the allocation for their jurisdiction based on their local mass vaccination plan. The amount allotted will change over time and may be based on critical populations recommended for vaccination, COVID-19 vaccine production and availability, and overall population of the jurisdiction.

Federal agencies and additional commercial partners will also receive allocations directly from the CDC once larger volumes of vaccine are available. The CDC is currently developing procedures to ensure that jurisdictions have full visibility into COVID-19 vaccine supply and vaccination activities among these entities located within their boundaries. Local public health jurisdictions should plan outreach to their regional health care coalition, hospitals, long-term care/assisted living facilities, and with other potential vaccine providers in their jurisdictions to determine each entity's capacity to order and receive vaccine to assist with mass vaccination operations for their population.

- IDPH will estimate the overall allocations of COVID-19 vaccine based on the size of critical population groups, within each local public health department's jurisdiction and weighted using the COVID-19 Community Vulnerability Index (CCVI).
- The City of Chicago will receive a separate, pro rata allocation of SARS-CoV-2/COVID-19 vaccine directly from the CDC.
- Tiberius, a vaccine allocation tool to be utilized at the state level, is designed to calculate each jurisdiction's allocation, has been developed by Operation Warp Speed (OWS) and will be utilized for this event. The tool will list the public health jurisdictions, all eligible providers in the jurisdiction and their vaccine

administration capacity so to efficiently allocate the vaccine in real-time as that information is received from the CDC.

- Jurisdictions should anticipate that allocation strategies may shift during the response based on supply, demand, and needs within the state.
- The following federal entities will receive direct allocation of COVID-19 vaccines from CDC: Federal Bureau of Prisons, Department of Defense, Department of State, Veterans Health Administration, and Indian Health Service. Federal agencies are planning to implement ACIP recommendations and will be included in early vaccine allocation and distribution. Vaccine allocation to these federal entities will not count against a jurisdiction's vaccine allocation.

Federal agencies that are involved in the response but are not listed above, should work with the state immunization program to ensure their staff is included in the plans for vaccination.

### Vaccine Arrival & Distribution:

All providers must have plans in place to receive vaccine and ancillary supplies shipped directly to the designated sites, as well as, centralized distribution of vaccine, where applicable. Each LHD's plan will be submitted to IDPH for review to ensure they are in line with the state strategy, to identify additional opportunities for technical assistance to provide to the Local Health Departments. Plans must reflect and adhere to the CDC's requirements for storage and handling of the different types of vaccines. Providers willing to administer the vaccine continue to be enrolled in the Immunization Information System (IIS) and agree to requirements for receiving, storing, administering, and tracking vaccine administration. Enrolled providers will place orders for the vaccine with the state immunizations program. (See Section 11 for more details.) The CDC is expected to provide each state an allocation of vaccine based on population, and states can prioritize and fill orders against those allotments. Orders are then sent to the CDC and vaccines will be shipped directly to the provider through a centralized vaccine distributor. Note: Ultra-cold vaccine will be initially distributed through a centralized "hub and spoke" model, please see Tier 2 Distribution below.

The state of Illinois has developed a two-tiered strategy to ensure vaccine delivery:

#### Tier 1 – For Refrigerated & Frozen Vaccines;

- Distribution/delivery to each provider is currently performed via private carriers. Vaccine will be sent directly to vaccination provider locations for administration or designated depots for secondary distribution to administration sites. Once vaccine is shipped to a provider site, the federal government will not redistribute the product.
- Under the current vaccine delivery processes, the CDC contracts with a 3rd party distribution company, McKesson, to conduct the service.
- Providers must ensure the proper equipment is in place and have developed plans to receive the vaccine directly from McKesson or the vaccine manufacturer, at their designated site(s).
- Local Health Departments may redistribute vaccines, while maintaining the cold chain. However, with the challenge of meeting cold chain LHD's should limit any redistribution to refrigerated vaccines only, if there is not a plan in place to maintain Ultra-cold temperatures.
- Further distribution to sub-sites within the local jurisdictions, if necessary, is determined by the Local Health Department and its community partners as part of that agency's pandemic response plan.

## Tier 2 – For Ultra-cold Vaccines;

- For the initial distribution of Ultra-cold Vaccine, a centralized distribution model, otherwise known as “Hub & Spoke,” will be executed utilizing a modified version of the State Strategic National Stockpile Plan. The is to ensure;
  - Vaccines are maintained at the appropriate temperature of -80 C, to ensure vaccine integrity.
  - Reduce complexity in logistics and resources on local jurisdictions.
  - Ensure the integrity of the vaccine during shipping, due to the ultra-cold requirements.
  - Should vaccines need to be held/stored, they will be kept in ultra-cold vaccine freezers to decrease the amount of dry ice consumption needed for operations and to ensure vaccine integrity.
- Ultra-cold vaccine will be shipped from the manufacturers in shipping containers that are packed with dry ice and can store vaccine for an extended period and can be repacked for longer use. Due to the challenges presented with maintaining the Ultra-cold vaccine supply chain, Ultra-cold vaccines will be delivered to an IDPH central location and redistributed in smaller amounts to Local Health Departments. For providers that will be allocated at least 975 doses of vaccine and can maintain the Ultra-cold vaccine supply chain, IDPH may approve shipments directly to their facilities.
- Operations will be coordinated through the SEOC supported by the Illinois Emergency Management Agency (IEMA). The Illinois State Police will provide security for delivery vehicles, where indicated.

### This distribution will take place as follows: (Excluding Chicago)

- Pfizer Ultra-Cold Vaccine will be direct shipped to the Strategic National Stockpile (SNS) for Illinois.
- Vaccine will be transferred into ultra-cold freezers to maintain vaccine integrity at the SNS.
  - Upon arrival at the SNS facility, the logistics section will conduct an in-depth inventorying of the vaccine against the provided packing slips and upload information into the state’s inventory management system to begin tracking the movement and delivery of the vaccine. The vaccine will be kept in ultra-cold storage freezers until it is time to repackage it for shipment. IDPH will provide the logistics section the allotments of vaccines for delivery to begin repackaging the vaccine for delivery.
- Vaccine will be prepared for shipment to the ten (10) Regional Hospital Coordinating Centers (RHCC) in the state, excluding Chicago, at 2c to 8c.
  - IEMA logistics will coordinate transport with the Illinois State Police who will secure the SNS and the transport of each shipment of each vaccine to each of the ten (10) RHCC’s.
  - For Jurisdictions receiving vaccine that have ultra-cold capability, vaccine may be shipped in an Ultra-Cold state to provide more time for local plan execution, this is based on allocation size, capability and availability of ultra-cold shippers.
- Once the vaccine arrives at the RHCC’s, each Local Health Department, who is receiving a vaccine allotment, will pick up their allotment from their respective RHCC. The shipment will also include ancillary supplies. LHD’s will transport the shipment back to their jurisdiction for mass vaccination operations. This will be day one (1) of the five (5) day window to utilize the Pfizer vaccine at the refrigerated temperature of 2c to 8c. Vaccine cannot be re-frozen.
- Once the LHD’s arrives in their jurisdiction, the vaccine will be placed into a vaccine refrigerator in the jurisdiction to maintain the vaccine temperature. (Note: The shipping box and other shipping equipment, such as Ice Packs, will be kept for return to the RHCC’s on the next allocation.)



The state conducted an initial baseline survey of ultra-cold storage capability across the State of Illinois, identifying capability and capacity in locations such as Hospitals, Local Health Departments, Universities and Colleges. These locations have been identified to act as a contingency, should additional capacity be needed. Additional, state ultra-cold freezers have been staged in various regions across the state to increase statewide capability.

#### Inventory Management:

IDPH will maintain, on a real-time basis, a database inventory of each dose of vaccine that is shipped from the manufacturer or distributor and received at each ship-to site. Ship-to sites will maintain, on a real-time basis, an inventory of vaccine in stock, the manufacturer, lot numbers, expiration dates for each lot, and a record of each dose of vaccine transferred to any clinics designated to conduct the vaccination clinics. COVID-19 vaccination providers will be required to report inventory of COVID-19 vaccines in I-CARE and in VaccineFinder.

#### Unplanned Repositioning:

IDPH plans to minimize redistribution of COVID-19 vaccine to every extent possible by ensuring appropriate allocation to vaccination partners; however, some redistribution will be unavoidable. Redistribution for initial shipments of ultra-cold vaccine will be distributed and coordinated centrally to ensure the integrity of the ultra-cold chain. (See “Tier 2 – For Ultra-cold Vaccines” above)

Reirrigated and frozen and vaccine will only be redistributed with the approval and involvement of IDPH. Depending on the circumstances, vaccine may be transported by regional immunization staff, and possibly the local or regional health department. IDPH will follow existing VFC Program protocols to coordinate the safe transfer of vaccine in situations of unplanned repositioning. Providers are expected to contact Program staff in the event unplanned repositioning is necessary to prevent wastage of vaccine. All providers will receive an educational packet including this expectation and Program contact information upon enrollment into the COVID-19 Vaccination Program. All COVID-19 vaccine transfers will be conducted with the assistance of the immunization program. Immunization field staff are located across the state and are trained in conducting VFC Program activities, including the safe transfer of vaccines. Digital Data Loggers (DDLs) will remain with the vaccine at all times before, during, and after the transfer. All transport requirements and recommendations outlined in section 6 of the CDC’s Storage and Handling Toolkit, will be followed. As vaccine is being initially retrieved, a final inventory reconciliation will be conducted and documented in the IIS. Once the vaccine transfer is complete, the reconciled inventory will be transferred to the receiving facility’s inventory and accepted by the provider.

IDPH plans to minimize redistribution of COVID-19 vaccine to every extent possible by ensuring appropriate allocation to vaccinating partners; however, some redistribution will be unavoidable. Redistribution will be coordinated centrally for initial shipments of Ultra Cold Vaccine to ensure the integrity of the cold chain and, at least initially, vaccine will only be redistributed with the approval and involvement of IDPH. Depending on the circumstances, vaccine may be transported by regional staff, the Local Health Department, or other designated and approved providers.

## 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 risk of administering COVID-19 vaccine with reduced effectiveness. Jurisdictions should work with staff at each COVID-19 vaccination provider site to ensure appropriate vaccine storage and handling procedures are established and followed. Providers need to provide refrigeration/freezer certificates to the IDPH Immunization program. Additionally, providers must review data-logging equipment logs regularly and upload them to I-CARE to validate compliance. Providers must also record the minimum/maximum in the morning and the temperature once in the morning and once in the afternoon. Providers must upload the temperature logs into the IIS and IDPH will only allow sites to order vaccines if they can guarantee the appropriate temperature is maintained. IDPH and CDC requirements will be shared with providers during the enrollment process.

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° to -25°C) to ultra-cold (-60°C to -80°C) in the freezer or within the dry ice shipping container. Ongoing stability testing may impact these requirements.

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. Jurisdictions and vaccination providers are responsible for maintaining vaccine quality from the time a shipment arrives at a vaccination provider site until the dose is administered. IDPH will 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, such as initial shipments of ultra-cold vaccine, will be distributed through a centralized "hub & spoke" model. IDPH does have a means to store vaccine if an "unplanned repositioning" of vaccine is required. IDPH has procured resources to assist in adhering to all cold chain requirements including ultra-cold storage capacity.

Providers should utilize the entire dose allocation and not hold vaccine back for a second dose, as the second dose will be provided closer to the time of its expected administration, per CDC guidance.

### Satellite, Temporary, and Off-Site Clinics:

Satellite, temporary, and off-site vaccination clinics play an important role in improving vaccination coverage rates and vaccinating hard-to-reach populations. Providers are encouraged to discuss and coordinate these clinics with their Local Health Departments. Vaccination clinics held in these settings have unique challenges and providers must follow specific guidelines provided by CDC for managing publicly supplied vaccine in these non-traditional settings. IDPH has procured ultra-cold storage freezers, which will be utilized for a centralized distribution of ultra-cold vaccine and can also act as contingency should ultra-cold vaccines need to be stored.

To better assist with this situation, the following will be required:

- 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 possibly transport the vaccine appropriately. This is essential to minimizing vaccine wastage and spoilage.
- COVID-19 vaccines may be transported — not shipped — to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. The procedures will include transporting vaccines to and

from the provider site at appropriate temperatures, using appropriate equipment, as well as monitoring and documenting temperatures.

- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate 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 excursions at any time, the temperature excursion should be documented, reported, and acted upon according to the immunization program's procedures.

#### Unplanned vaccine repositioning:

- Before the movement of any vaccine, providers must submit a request to the immunization program, at which time the program will provide the CDC redistribution form to the site. Before the approval of the movement of vaccines, cold-chain management must be secured. IDPH will follow existing VFC Program protocols to coordinate the safe transfer of vaccine in situations of unplanned repositioning. Providers are expected to contact Program staff in the event unplanned repositioning is necessary to prevent wastage of vaccine. All COVID-19 vaccine transfers will be conducted with the assistance of IDPH staff. DDLs will remain with the vaccine at all times before, during, and after the transfer. DDL reports will be evaluated for temperature excursions, prior to vaccine transport, as well as after transport to the receiving facility is completed.

#### Temperature excursion reporting:

- Cold chain maintenance at individual provider locations will require appropriate vaccine storage and temperature monitoring equipment, a trained provider staff, and consistent, accurate inventory management as already discussed. All enrolled providers will be required to report temperature excursions by the next business day to IDPH. Providers are also expected to label vaccine that has undergone a temperature excursion as "Do Not Use" and cease administration of the vaccine until stability has been determined by the Program. Staff will be assigned to handle incoming temperature excursions per program protocols, and support will be provided by the immunization field staff should the situation require assistance. Providers that fail to report temperature excursions within one (1) business day will be at high risk for wasting vaccine and the need to re-vaccinate patients. Facilities failing to report a temperature excursion and facilities with repeated temperature excursions will be closely monitored and required to submit weekly data logger reports to the program. Facilities identified as having these issues will be reviewed on a case-by-case basis and will risk having their vaccines reallocated to other facilities, if these issues are not corrected or if it is determined that the facility is negligent in their handling of vaccines.

## Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Illinois will use I-CARE, the State's Immunization Information System (IIS), to collect information about COVID-19 vaccine doses administered by providers. The immunization program manages the IIS and supports its users. COVID-19 vaccine information will be collected through the IIS and sent to CDC via the IZ Gateway. Ensuring that each COVID-19 vaccination provider is ready and able to report the required COVID-19 vaccine administration data elements to IIS, is a part of the COVID-19 provider onboarding process. As COVID-19 providers are going through the onboarding process, the onboarding team ensures that every provider meets three (3) overall requirements: the COVID-19 Provider Agreement and Profile has been completed and signed, the facility where the vaccine will be stored meets the Storage and Handling Requirements, and the facility and its staff are registered as IIS users.

### Vaccine Administration Reporting:

- Providers are required to submit daily accountability reports to IDPH in the format requested. Reports must be submitted by 8:00 PM CST daily. The reporting frequency and required data metrics will be updated as more guidance is received from CDC.
- IDPH is required to submit daily inventory reports to CDC. Daily reports must be submitted to CDC by 4:00 PM CST. The reporting frequency and required data metrics will be updated as more guidance is received from CDC.
- IDPH will create reports that evaluate timeliness and completeness of reporting of COVID-19 vaccine administration at the organization and facility level. These teams will reach out to the COVID-19 providers who are not reporting every 24 hours and help with troubleshooting barriers to successful reporting. All providers must abide by CDC program requirements to be authorized to receive vaccine.
- IDPH will regularly pull reports from I-CARE identifying how many vaccines have been administered and how much vaccine is on hand, as well as vaccination administration versus documentation entry timestamps. This will provide insight into accurate and complete documentation.

### Vaccine Administration Tracking:

- For overall patient tracking in Illinois, I-CARE will be utilized to track individual patient information and conduct reminder/recall for additional doses. At the provider level, two (2) systems will be available in Illinois for patient vaccine administration tracking: (1) I-CARE - For overall patient tracking in Illinois, I-CARE will be utilized to track individual patient information and conduct reminder/recall for additional doses. (2) EMTrack – EMTrack is currently being utilized in Illinois by Emergency Medical Services (EMS) systems for patient tracking. The EMTrack Mass Testing and Vaccination Module was utilized for mass vaccination clinics during H1N1 and is regularly used at seasonal flu clinics. The Module enables clients to schedule an appointment and to be pre-screened for vaccination, prior to coming to the vaccination site.
- All providers must plan to utilize I-CARE or EMTrack for vaccine administration tracking and reminders to recipients of a second dose, if needed. Providers may utilize their Electronic Medical Record (EMR) systems if they have their systems connected and reporting to I-CARE.
- Vaccine administration tracking is essential to the SARS-CoV-2/COVID-19 vaccine campaign for several reasons. Each person may need to receive two doses of the same vaccine separated by 21 or 28 days and the vaccine administration record will assist the provider for the second dose with identifying the correct vaccine for the patient. Additionally, to ensure reporting of adverse events to the vaccine, the administration data need to be tracked. Finally, this provides assurance that all priority groups have adequate access to the vaccine and that enough of the population, to elicit herd immunity, can be vaccinated in a timely fashion.

- Determine gaps in vaccine administration across geographic or demographic populations, to inform focused outreach efforts, will be one of the needed outputs from the IIS.

## Section 10: COVID-19 Vaccination Second-Dose Reminders

Some vaccines for COVID-19 will require two doses, administered approximately 21 to 28 days apart, to produce an adequate immune response. If two doses are required, it will be necessary to ensure that vaccinated persons return for the second dose. IDPH, along with Local Health Departments, will arrange for information about the need for a second dose to be provided to recipients at the time of initial vaccination.

Providers will make sure each person will receive documentation at the time of vaccination. This will include the manufacturer name, lot number, dose, site, and date of vaccination for the patient's records and the date when the second dose is due. This documentation may be a COVID-19 vaccination record card provided as part of vaccine ancillary kits by CDC, a vaccination record card provided by IDPH, or a printed copy of proof of vaccination from the provider's EHR and/or I-CARE.

COVID-19 vaccine providers will be encouraged to schedule the patient's second-dose appointment when delivering their first dose. The CDC has stated that vaccination "verifications and reminder cards" will be included in the vaccine shipments and that providers will be required to provide vaccination cards to those receiving their COVID-19 vaccination.

Providers utilizing EMTrack will have the ability to do remind patients about their second dose within that system. IDPH will also encourage all providers to use the reminder/recall functionality in I-CARE as well.

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

Immunization registries, also known as Immunization Information Systems (IIS), are defined by the CDC as confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area. Immunization registries offer a consolidation of patient immunization records. Compiling all immunizations in one database allows easy access for healthcare providers. Certificates for proof of immunization are also easier to obtain for the purposes of school and childcare centers. The registry also offers timely reminders for vaccines coming due for patients.

I-CARE, or the Illinois Comprehensive Automated Immunization Registry Exchange, is a web-based immunization record-sharing application developed by the Illinois Department of Public Health (IDPH). The application allows public and private healthcare providers to share the immunization records of Illinois residents with other physicians statewide. I-CARE is able to capture standard data elements submitted via an HL7 message, including patient demographic information such as name, DOB, race, ethnicity, address, sex, etc. I-CARE is also able to capture and store detailed vaccine administration information such as CVX, lot number,

vaccine expiration date, precautions and contraindications, and additional data requirements set by the CDC. IDPH plans to capture two additional fields – race and ethnicity – during the COVID-19 vaccination campaign. All providers should plan to strictly adhere to the use of I-CARE for tracking vaccine administration and to report on-hand inventory back to IDPH and to the CDC.

- The Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE) is the state's Immunization Information System (IIS) and will be the primary system utilized to order and track SARS-CoV-2/COVID-19 vaccine administration during an event.
- I-CARE works by taking in data from a variety of sources, consolidating data into high-quality patient immunization records, applying vaccine evaluation and forecasting algorithms, and transforming this data into actionable information for clinicians, public health practitioners, and other IIS users to support immunization practice and improvement in one secured system.
- Some functions support overall operations, like establishing interoperable connections with other systems and deduplication functionality for achieving high data quality. Other functionality supports clinical decision making for an individual patient, assessment of vaccine coverage rates for groups of patients or populations, reminder/recall outreach to improve vaccination rates, and management of vaccine inventory.
- For access, all I-CARE providers must be pre-authorized via the IDPH Immunization Program.
- Enrolling into I-CARE to receive COVID-19 vaccine is a two (2) step process: step 1 – complete the required enrollment forms to become an I-CARE provider; step 2 – complete the fillable CDC COVID-19 Vaccine Provider Agreement and Profile form, within I-CARE, to order and receive the vaccine. This includes agreeing to follow proper storage and handling procedures for each vaccine received.
- There are three (3) documents that are required to register an organization for I-CARE access: The Provider Site Enrollment form. The Web Portal Registration Authority Agreement (PRA registration); each intended user will need to follow the IDPH Web Portal Online Registration process to create their Username and Password. Individual User Agreement form stating and agreeing to IDPH security and confidentiality policies.
- The COVID-19 Vaccine Providers Program Process and Guidance document is in development. The purpose of this document is to outline the requirements for approval to access I-CARE, levels of access available, roles in I-CARE, suggestions on who should have I-CARE access, frequently asked questions, and an online I-CARE training video.
- Mass Immunization Module is an integral part of, and is built into, the IIS, eliminating the need to build an interface. The Mass Immunization Module allows for faster data entry during mass vaccination events as Lot Number Defaults are added prior to conducting these events. Setting the default lot number(s) results in the lot number being automatically populated in the patient's record. When the administered vaccine and lot number are added to the patient record, the vaccine dose is subtracted from the inventory, maintaining vaccine dose accountability and accurate inventory management.

In the event that I-CARE is unavailable, vaccine administration information will be recorded on paper logs or in Excel spreadsheets that will be transcribed into the IIS when access returns. The planned contingencies for network outages or other access issues is ensuring that blank vaccine administration sheets are available in hard copy (paper copies) and in soft copy on the mass vaccination user desktops/laptops (i.e., Excel spreadsheets). It should be noted, all data gathered about vaccine administration is confidential and subject to State/Federal privacy laws (e.g. HIPPA, Communicable Disease Code, etc.)

# Section 12: COVID-19 Vaccination Program

## Communication

All vaccine providers must be registered in the Illinois Health Alert Network – HAN/SIREN to receive vaccine guidance and critical updates on the COVID-19 mass vaccination administration mission. The Illinois Health Alert Network – HAN/ SIREN is a statewide, web-based solution for quickly and effectively disseminating health information, emergency notifications, and alerting staff. It serves as a central point in the State for finding, creating, and sharing information. All COVID-19 vaccine providers must ensure that key staff members are registered in SIREN to ensure that they are receiving information and updates on the COVID-19 mass vaccination mission. Also, COVID-19 vaccine provider organizations can utilize SIREN to communicate with their staff members and partners on organization specific information.

IDPH will also monitor its website to ensure that the following are available online: (1) General information/education for the public with vaccination locations; (2) Providers, vaccinators, and public health department education and training including Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients and a place for Vaccine Information Statements (VISs); (3) Federal vaccine call center information and a frequently asked question section; and (4) Data repository allowing Illinoisans to stay informed with up-to-date statistics. The CDC Vaccine Finder website link will also be placed on the vaccine information webpage and pandemic providers will be asked to participate.

Public information may be disseminated via social media, web site postings, interviews, newspaper editorials, flyers, billboards, television and radio broadcasts. Messages may include understanding the key differences in FDA emergency use authorization and FDA approval, a timeline of vaccine availability, authorization, distribution, who the targeted populations are, why the vaccine is essential, and that situations are continually evolving. One of the primary goals will be to ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines. The program will also use traditional education materials for countering myths about the vaccine the safe handling, storage, preparation, and administration of the actual vaccine to ensure education for providers.

IDPH is in the process of organizing a vaccine communication strategy. A number of pathways are being explored and will likely result in a multifaceted communication strategy to ensure effective messaging across all populations. In order to understand attitudes about potential COVID-19 vaccines, IDPH is also considering working with external partners to develop a statewide assessment of public and provider attitudes and beliefs surrounding the COVID-19 vaccine. This survey would be utilized to collect information from the public that could be utilized to maximize COVID-19 vaccination uptake, including but not limited to information specific to subpopulations. Information and data obtained via the survey would be utilized in the development of appropriate messaging for the public and healthcare providers.

# Section 13: Regulatory Considerations for COVID-19

## Vaccination

Providers will receive an educational packet upon enrollment into the COVID-19 Vaccination Program. Guidance documents will include the product-specific EUA fact sheets for COVID-19 vaccination providers and the EUA fact sheets for vaccine recipients or VISs, once they are made available by CDC. Providers will be instructed to read both types of EUA fact sheets and VISs and reach out to the IDPH Immunization Program with any questions prior to beginning administration of COVID-19 vaccine. Providers will also be informed of the federal requirement to provide the recipient fact sheet or VIS to each patient prior to vaccine administration. The fact sheets and VISs will also be linked on IDPH's COVID-19 website, located where other relevant information for providers is contained.

Updates to EUAs or VISs will be distributed via SIREN or a COVID-19 provider distribution email group and posted to the COVID-19 website.

### Emergency Use Authorization (EUA) Fact Sheets:

The EUA authority allows the 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 utilized and any conditions that must be met to use the vaccine. FDA will coordinate with CDC to confirm these "conditions of authorization." Vaccine conditions of authorization are expected to include distribution requirements, reporting requirements, and safety and monitoring requirements. The EUA will be authorized for a specific time period to meet response needs (i.e., for the duration of the COVID-19 pandemic). Additional information on EUAs, including guidance and frequently asked questions, is located on the FDA website.

Product-specific EUA fact sheet for COVID-19 vaccination providers will be made available by the FDA that will include information on the specific vaccine product and instructions for its use. The FDA will develop EUA fact sheets for vaccine recipients. The EUA fact sheets will likely be made available on the FDA website and through the CDC website. IDPH will use multiple communication mediums to reach COVID-19 vaccine providers, such as email distribution lists, webpages, and SIREN alerts to contact enrolled providers and make them aware of the appropriate EUA fact sheets. Furthermore, IDPH will provide training webinars on the EUA fact sheets and the VISs to ensure that providers understand the information, and are clear on the requirement to provide the recipient fact sheet to each client/patient prior to administering vaccine.

### Vaccine Information Statements (VIS):

VISs 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 (e.g., such as with zoster vaccines). Plans for developing a VIS for COVID-19 vaccine are not known at this time but will be communicated as additional information becomes available. IDPH will disseminate VISs similarly to how the EUA facts will be disseminated.

## Section 14: COVID-19 Vaccine Safety Monitoring

In response to vaccine safety, IDPH will utilize the Vaccine Adverse Event Reporting System (VAERS) to report and investigate adverse events following immunization with the COVID-19 vaccine. VAERS is a national passive surveillance reporting system that is co-sponsored by the CDC and the FDA. Reports are accepted



from anyone such as, vaccine recipients, health care providers, vaccine manufacturers, etc. Patient identity is kept confidential. VAERS complies with all US Government security standards and protections concerning health information.

VAERS reports should go directly to the VAERS site. Providers will receive an educational packet upon enrollment into the COVID-19 Vaccination Program. Guidance documents will include information on required reporting of vaccine adverse events to VAERS. IDPH will provide technical assistance and communicate with the CDC on all aspects of vaccine adverse event reporting. Vaccine safety and education will be provided by the CDC and the IDPH to providers statewide and the link to the VAERS site will be posted on the IDPH COVID-19 website, located where other relevant information for providers is contained.

CDC is working to expand safety surveillance through new systems and additional information sources, as well as by scaling up existing safety monitoring systems. More information can be shared when it becomes available from the CDC.

## Section 15: COVID-19 Vaccination Program Monitoring

### Provider enrollment:

Provider enrollment is monitored through a database that tracks progress through the three (3) stages of onboarding: enrollment, storage and handling capabilities, and submission of the completed CDC Provider Agreement and Profile. The location of providers will be mapped via GIS so that geographic coverage of providers may be monitored, and providers recruited in areas where gaps are identified.

### Quality Control:

IDPH performs quality control reviews of 25% of vaccine providers enrolled in the VFC program. It is anticipated that a similar protocol will be utilized to review COVID-19 vaccine providers during this mission. Monitoring communication:

IDPH will ensure that provider training documents are received and reviewed by requiring acknowledgement of receipt and attestation of review. Pandemic-related communications that are critical to the healthcare workforce will be shared via SIREN. Public communications may be monitored through social media site metrics.

### Tiberius:

An additional OWS information system is the Tiberius platform. Tiberius provides a COVID-19 vaccine distribution planning, tracking, modeling, and analysis ecosystem to support the OWS mission. Tiberius integrates data sources from Federal agencies, State and Local partners, private sector partners, and open

data providers to create a comprehensive Common Operating Picture (COP) for the COVID-19 vaccine planning, distribution, and administration effort. Tiberius provides flexible and real time data-backed applications that enable users of all types to make data-driven decisions.

## Provider-level data reporting:

Epidemiologists will monitor and report the timeliness and completeness of reporting of COVID-19 vaccine administration at the organization and facility levels. Staff will review this frequently to ensure completeness and accuracy of data, as well as the timeliness of reporting that data.

Staff will also monitor provider ordering and inventory management practices and evaluate adherence to COVID-19 vaccine reconciliation and inventory requirements. Staff will run a daily report using IIS data to generate a list of providers who have not accepted an order into their inventory within seven (7) business days. This information will be sent to ordering staff for follow-up with the provider. The staff will generate a monthly report utilizing IIS data to identify providers that are not reconciling their inventory every thirty (30) days. This information will be sent to ordering staff for follow-up with the provider, as well.

## Monitoring Fiscal Resources for Incoming Grants:

The Illinois Jurisdiction methods and procedure for monitoring budget resources include by grant number and categories the monitoring via an electronic ledger. Invoices are processed electronically and request for purchase must have several levels of approval and adequate justification. All approved invoices and salary payments must be documented in the ledger prior to payment. The program manager reviews contracts, monitors and modify grants and contracts with adequate justification. The program manager assesses, reconciles and modifies the budget accordingly. The program manager and/or other appropriate staff plan and implement relevant competency training for staff (Microsoft package, Smartsheet, etc.) as needed.

The Illinois Jurisdiction methods and procedures for monitoring staffing resources include monitoring staff performance, through regular meetings and performance reviews. The Immunization section meets every morning with management and priorities for the day are reviewed. As staff assignments change, adequate staff to support the mission are assigned to the tasks needing to be completed.

The Illinois Jurisdiction methods and procedures for monitoring supplies include electronically and manually monitoring inventory of supplies, annual comprehensive manual inventory assessment and real-time and regular electronic monitoring.

## Training:

All providers should also ensure that their vaccinators and other staff involved in mass vaccinations operations receive training. Training and exercise modules are continually being developed by the COVID-19 Mass Vaccination Work Group. The mass vaccination section will conduct technical assistance webinars, review vaccine allocation tools, review the CDC PanVax Tool for pandemic vaccination planning, and answer

questions of local provider staff. Follow up meetings/webinars will be scheduled, as necessary. Additionally, IDPH plans to conduct workshops/tabletop exercises for state partners, as necessary. It is anticipated that most training and exercise offerings will be done virtually or on-demand.

- I-CARE Training for Providers.
- Vaccine Administration and Tracking.
- Vaccine Call Down Drills and Exercises.
- Just in Time Training for Tier 2 Distribution is developed and checklists are found in the SNS Plan.
- Available CDC resources, and vaccine recommendations, when available.
- Ordering and receiving the COVID-19 vaccine.
- Vaccine storage and handling, including transportation requirements, specific to COVID-19 vaccine.
- Vaccine administration, including reconstitution, use of adjuvants, diluents, etc.
- Documenting and reporting vaccine administration via I-CARE or EMTrack.
- Managing and report vaccine inventory via I-CARE.
- Documenting and reporting vaccine wastage/spoilage.
- Procedures for reporting to the Vaccine Adverse Event Reporting System (VAERS).
- Providing Emergency Use Authorization (EUA) fact sheets and/or vaccine information statements (VISs) to vaccine recipients.
- Public messaging.
- Outreach to priority groups, vulnerable populations, and hard-to-reach populations.

*Protecting health, improving lives.*