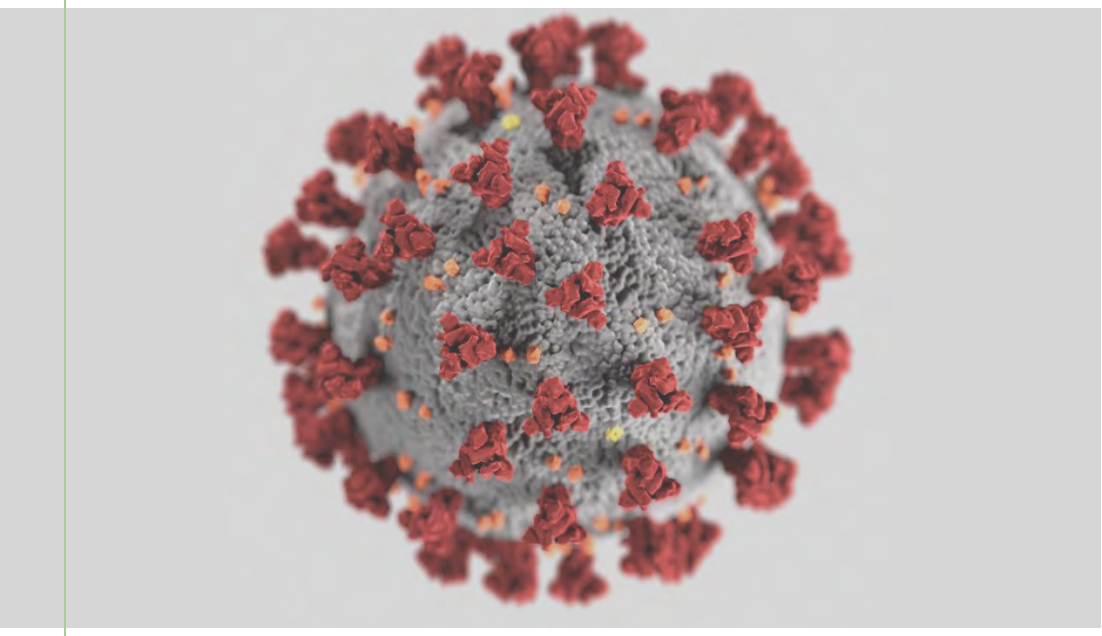

COVID-19 Vaccination Plan

ILLINOIS

Illinois Department of Public Health
FEBRUARY 11, 2021 | V6.0

Table of Contents

Table of Figures 2
Record of Changes 3
Introduction 6
Section 1: COVID-19 Vaccination Preparedness Planning 8
Section 2: COVID-19 Organizational Structure and Partner Involvement 10
Section 3: Phased Approach to COVID-19 Vaccination 11
Section 4: Critical Populations 13
Section 5: COVID-19 Provider Recruitment and Enrollment 20
Section 6: COVID-19 Vaccine Administration Capacity 22
Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management 25
Section 8: COVID-19 Vaccine Storage and Handling 34
Section 9: COVID-19 Vaccine Administration Documentation and Reporting 37
Section 10: COVID-19 Vaccination Second-dose Reminders 40
Section 11: COVID-19 Requirements for IISs or Other External Systems 42
Section 12: COVID-19 Vaccination Program Communication 44
Section 13: Regulatory Considerations for COVID-19 Vaccination 45
Section 14: COVID-19 Vaccine Safety Monitoring 46
Section 15: COVID-19 Vaccination Program Monitoring 47
Appendix A: Acronyms 49
Appendix B: I-CARE Re-Distribution Log Link 50

Table of Figures

Figure 1: Illinois Department of Public Health Organizational Chart 10
Figure 2: Example of Phased Approach Provided by the ACIP 12
Figure 3: Critical Populations for Vaccine Allocations 19
Figure 4: Illinois Department of Public Health COVID Vaccination Allocation Steps 25
Figure 5: COVID-19 Vaccinations Transportation 29
Figure 6: Vaccine Distribution 32
Figure 7: Illinois Department of Public Health Surplus Vaccine Redistribution Steps 30
Figure 8: Providers' Process at the Point of Dispensing 39
Figure 9: Individual's Process in Registering to Receive Vaccine and Reminder for 2nd Dose 40

Record of Changes

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
10/02/2020	1.1	10/02/2020	Section 1 – Additional language added for training, the COVID-19 Vaccination Planning Work Group relevant lessons – learned from H1N1. Section 2 - title changed to COVID-19 Vaccination Planning Assumptions. Performed final copy edit & review.	Vaccination Section
10/12/2020	2	10/12/2020	Adjusted plan to address feedback from the CDC & Performed final copy edit & review.	Vaccination Section
11/22/2020	3	11/22/2020	Adjusted to CDC Template, added more clarity & detail based on additional CDC feedback. Added Pharmacy Partnerships, enrollment and recruitment of providers, delineation of IDPH responsibilities in the ICS structure and added information about vaccine candidates, storage and handling of vaccine, etc. Performed final copy edit & review.	Vaccination Section
11/25–11/30/2020	3.1	11/25-30, 2021	Integration of NASEM framework. Added additional detail throughout the plan. Performed final copy edit & review.	Vaccination Section
12/2–12/3/2020	3.2	12/2-3, 2021	Implemented new ACIP recommendations and added more detail for Ultra-Cold vaccine distribution. Performed final copy edit & review.	Vaccination Section
12/29/2020	4	12/29-31, 2021	Section 3 & 4: Updated priority groups in phase 1a, 1b and 1c. Section 5: Added SIREN notification registration for providers. Section 7: Flow chart for notification of distribution and allocation steps. Added Redistribution graphic.	Vaccination Section

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
			Updated supplies within ancillary kits. Section 8: Unplanned Vaccine Repositioning. Section 10: Second dose distribution & waste prevention. Performed final copy edit & review.	
01/10/2021	4.1	01/10/2021	Section 3 and 4: Updates to 1a, 1b. Section 7: Direct Shipments containing dry ice, OSHA guidance. Extra doses. Section 9: Added EMTrack section' as well as, graphics for POD flow. Performed final copy edit & review.	Vaccination Section
01/25/2021	5.0	01/25-27, 2021	Section 1: Added CDC link to vaccination toolkits & mRNA. Section 4: Clarification to phase 1a language & Planning for the digital divide. Section 6: Added Illinois National Guard, CDC COVID-19 Vaccination Training Module & statement on expanded scopes of practice. Section 8: Added checklist of CDC best practices for vaccination POD's. Section 10: Added language & links on VaxText. Section 14: Added language & links on V-safe. Added CDC hyperlink to vaccine effectiveness information. Entire plan: Conducted final Copy Edit. Performed final copy edit & review.	Vaccination Section
02/03/2021	6.0	02/03-12, 2021	Throughout the plan: Added hyperlinks for relevant CDC guidance.	Vaccination Section

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
			Section 3: Added additional statement about LHDs creating stand-by lists to avoid vaccine waste & added 1b part 2. Section 4: Added 1b Part 2, IDHS disability memo language & language on severe weather planning. Section 6: Added language for EMS expanded scopes & allocations for the federal pharmacy partnership. Section 7: Added language on mixing diluent and vaccine for Pfizer & updated ancillary kits to account for 6th dose. Section 8: Added language on redistribution form being updated to a link. Section 10: Added language on 2nd dose clinical considerations (CDC). Performed final copy edit & review.	

Introduction

This draft document is designed to assist Local Health Departments in planning for vaccine distribution in response to the COVID-19 pandemic. Information contained in this document is based on limited and preliminary guidance from the Centers for Disease Control and Prevention (CDC) and the 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 Vaccination Section in developing this State of Illinois COVID-19 Vaccination Plan, as an attachment to the Vaccination Annex 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 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 Program is a federal cache of emergency medical supplies and equipment that can be deployed to states during a disaster. The CHEMPACK Program is the forward placement of nerve agent antidotes. IPS is a state-owned cache of emergency medical supplies and equipment. CRI is a program designed to ensure cross-border collaboration of municipalities, counties, and states during incidents where 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 accomplish the following:

- Provide technical assistance to Local Health Departments (LHDs) to inform local planning and ensure local plans align with state plans and/or guidance and maintain accountability.
- 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 ordering, administration, and tracking of the SARS-CoV-2/COVID-19 vaccine in the state.

- Ensure expanded scopes of practice for healthcare licenses as necessary to allow certain medical professionals the opportunity to assist in the vaccination campaign when working under the authority of the local public health jurisdiction or a healthcare 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, i.e., Illinois Helps.
- Provide a statewide system for disseminating information to vaccine providers and others with direct involvement in the COVID-19 vaccination administration mission, i.e., Health Alert Network—HAN/SIREN.
- 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 the following:
    - Available CDC resources and vaccine recommendations.
    - 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 & VaccineFinder.
    - Documenting and reporting vaccine wastage and 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.
    - Reporting on occupational and demographic data pursuant to state and federal requirements, guidelines, or policies.
    - Policies on encouraging vaccination and alleviating anxieties, hesitations, or fears of COVID-19 vaccination in order to achieve the best outcomes.
- 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 vaccination administration campaign and to provide guidance on reporting vaccine-adverse events to the CDC.

Section 1: COVID-19 Vaccination Preparedness Planning

COVID-19 Vaccination Planning Assumptions

- Vaccine distribution
  - Limited COVID-19 vaccine doses may be available in January 2021.
  - 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) as a COVID-19 Vaccine Provider.
  - 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, i.e., 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 SNS plan.
  - Vaccine providers will be required to enroll in Vaccine Finder and report inventory daily.
- Priority groups (see Section 3 "Phased Approach" for more information)
  - All people are assumed susceptible to the virus. Initial populations prioritized for COVID-19 vaccination will be as follows based on federal guidance and pending ACIP recommendations and subject to change based on ACIP guidance:
    - Health care Personnel and Long-Term Care Facility (LTCF) residents and staff
    - Persons aged 65 years and older and frontline essential workers
    - Persons aged 16-64 years with medical conditions that increase the risk for severe COVID-19 and other essential workers
  - Recommendations for groups on which to focus 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.
- 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 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 to 8°C) to frozen (-15°C to -25°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 approximately 21 or 28 days will be needed for immunity for some vaccine candidates. Both doses of the vaccine will 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, the 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 or messenger ribonucleic acid: Encodes the protein of the virus, which is inserted into cells to trigger an immune response and create antibodies to the virus.
  - Nonreplicating Vector: Only certain proteins of the virus are administered 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: The virus is modified to be inactive but is still alive. The 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.
- Providers will follow state & CDC guidance by vaccinating within the given phase.
- Steps will be taken to minimize vaccine wastage.

Requirements for COVID-19 vaccine administration will continue to evolve over time. Additional guidance is forthcoming pending ACIP recommendations.

Section 2: COVID-19 Organizational Structure and Partner Involvement

IDPH's COVID-19 response is organized under the Incident Command System (ICS) (see organizational chart in Figure 1). The Director of IDPH and the Director of the Illinois Emergency Management Agency (IEMA) operate under a Unified Command Response. The IDPH response is led by the Incident and Deputy Incident Commanders. In Figure 1, functions that interface with IEMA are marked in red boxes. For Vaccination, this is led under the Vaccination Section, which is led by a Section Chief and Deputy. There are functions that interface with local jurisdictions at both the command staff and in individual section levels.

Within the 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 all stakeholders from across the state. The Vaccination Section frequently holds ad hoc meetings and/or webinars to engage partners such as LHDs, state/local Emergency Management Agencies (EMAs), private industry, associations, pharmacies, correctional facilities, and institutes of higher learning.

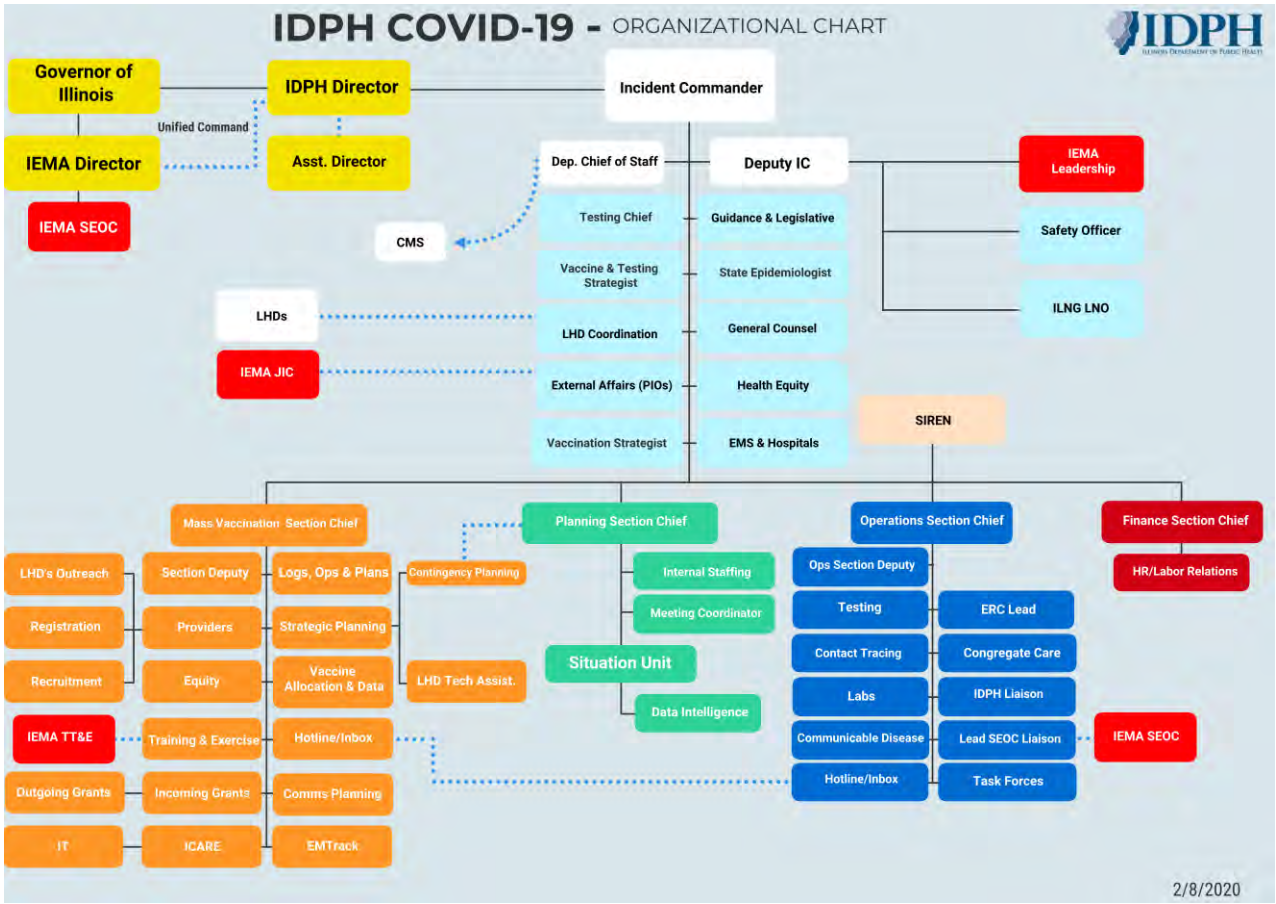

Figure 1: Illinois Department of Public Health Organizational Chart

Pandemic vaccination planning is a combined state and local responsibility that requires close collaboration and coordination among public health entities, external agencies, and community partners. An internal COVID-19 Vaccination Program planning and coordination team is critical to ensure that 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 per CDC and ACIP guidance, which are recommended based on "science, implementation, and ethics." Further ACIP recommendations are expected after the issuance of an EUA for vaccine candidates, which may alter the phased approach by adding phases or shifting populations from phase to phase. See Section 4 "Critical Populations" for more details about specific populations covered in each phase.

- **Phase 1:** Limited and/or scarce supply of COVID-19 vaccine doses are available. Initial efforts focus 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 are divided into three sub-phases: **(Note: Phases may be adjusted based on continued guidance from CDC/ACIP)**
    - **Phase 1A**
        - Health care Personnel
            - Hospital Settings
            - Non-hospital health care
            - Other Congregate Care
        - Long-Term Care Facility residents and staff
    - **Phase 1B**
        - Persons aged 65 years and older (Part I)
        - Frontline essential workers (Part I)
        - Inmates (Part I)
        - Persons aged 16 to 64 years with high-risk medical conditions (Part II)
    - **Phase 1C (Is still in draft form based on ACIP recommendations. Further updates to be released for Phase 1C for the context of Illinois) Possible groups cold include;**
        - Other essential workers

- **Phase 2:** Larger number of vaccines are available. The focus is on ensuring access to vaccine for members of Phase 1 critical populations not yet vaccinated and extend efforts to reach Phase 2 critical populations. **Possible groups could include, pending additional ACIP recommendations:**
    - The rest of the population.

As the state progresses through each phase, the IDPH Vaccination Section will conduct planning to address the next priority population. IDPH aims to achieve the overarching goal of herd immunity for the state. Jurisdictions and providers should also employ strategies for ensuring equitable administration of vaccines within the identified priority groups to communities hardest hit by COVID-19, such as low-income populations and communities and essential workers of color. IDPH will 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 use vaccine wastage reports provided to minimize waste. In situations where there is low COVID-19 vaccine demand, jurisdictions should monitor their supply and adjust strategies to avoid vaccine waste. An example of this is LHDs creating a stand-by list of people to contact in order to avoid vaccine waste or increasing outreach with community organizations to identify underserved populations that are eligible for vaccines but have not yet had access to vaccine. Finally, IDPH will provide COVID-19 vaccine administration reports to CDC as requested.

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

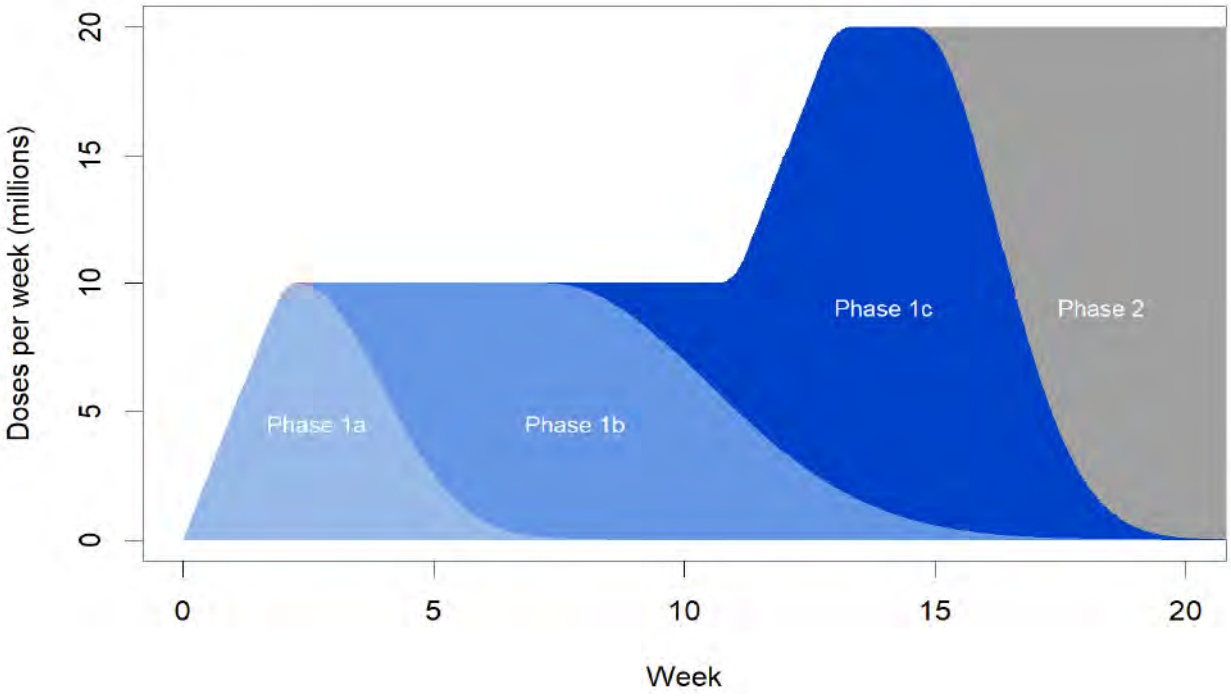

Figure 2: Example of Phased Approach Provided by the ACIP

Section 4: Critical Populations

The CDC has established an ACIP work group to review evidence on COVID-19 epidemiology and burden, vaccine safety, vaccine efficacy, evidence quality, and implementation issues to inform recommendations for a COVID-19 vaccination policy. 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 using 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 the effectiveness of vaccines in different populations and as further federal guidance may be issued.

Ariadne Labs and the Surgo Foundation have developed a free Vaccine Allocation Planner for COVID-19, which pulls data for each of the critical populations from various federal, state, and other datasets. The methodology for these allocation calculations can be found in that planning document. The State of Illinois will use 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., healthcare personnel and essential industries), populations at higher risk (e.g., racial and ethnic groups, incarcerated individuals, homebound individuals, and residents of nursing homes), and geographic distribution of active virus spread. IDPH's recommendations for vaccine prioritization will reflect 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 within the priority groups. 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 healthcare coalition, hospitals, long-term care and/or assisted living facilities, and other potential vaccine providers that serve frontline essential workers in their jurisdiction to ensure full coverage of vaccine first to the designated priority groups and then to the general public. LHDs should reach out to these groups now to determine number, type, and location of each priority group in the public health jurisdiction. LHDs should coordinate with their healthcare coalition, emergency management, and other response partners to develop a list of entities serving priority groups, determine their capabilities to serve as sites for vaccine administration (i.e., closed Points of Dispensing [PODs]), or develop plans for the LHD to service these groups at a general POD designed for these groups.

During the previously mentioned planning, LHDs should also address the following:

- Refrigerated, frozen, and ultra-cold storage for vaccine within the phase.
    - Local plans for the different types of vaccine, such as transporting vaccine stored at 2°C to 8°C from the Regional Hospital Coordinating Center (RHCC) to the LHD and/or to the vaccination site, and/or building partnerships to use ultra-cold storage capability in the county.
- Numbers of populations to be served in each priority group within the phase.
- Security of vaccine and proper disposal of vaccine vials and packaging.
- Projected vaccination throughput to determine time needed to use the total vaccine allocation.
- Local communication and public outreach.
- Partners that will be necessary to accomplish all aspects of the local plan (e.g., local law enforcement, local emergency management, local hospitals).
- Planning for the "digital divide" for those individuals who cannot access the internet or who have difficulty doing so, to schedule a vaccination appointment.
- Developing contingency measures for severe weather (e.g., planning for an alternate POD location, deciding on a date to reschedule, communicating with municipalities, reaching out to EMTrack [if using], working with emergency management and organizations such as the Red Cross, etc.). Recommendations may be adjusted based on continued guidance from CDC and the Federal Emergency Management Agency (FEMA).
- Pop-up POD's/clinics and vaccination sites in underserved communities and high risk populations within the priority groups to increase vaccine accessibility.
- Establishing vaccination sites with expanded schedules for essential workers with non-traditional work hours.

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

- **Phase 1A:**
    - Long-term care residents, defined by the CDC as adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently, and staff at Skilled Nursing Facilities, Assisted Living Facilities, Residential Treatment Centers for Substance Abuse, etc.
        - **LTCF Staff:** Nurses (RN, LPN), Nursing Assistants, Nursing Practitioners, Nurse's Aide, Physicians (DO, MD), Physicians Assistants, Medical Assistants, Respiratory Technicians, Dentists and Hygienists, LTCF Facility Staff, Pharmacists, Mental Health Clinicians, Environmental Services Staff, Reception Staff, Medical Facility Surveyor, Dietary Staff, Interpreters, and Laundry and Security Staff.
        - **Other Congregate Care:** All residents of "Other Congregate Care" settings as identified in Table 1 below.
    - Health care personnel are defined by the CDC as paid and unpaid workers in health care settings who have the potential for direct or indirect exposure to patients or infectious materials. Inclusion in Phase 1A is not dependent upon payment for a person's work or

job title. Situations associated with higher risk of transmission include caring for COVID-19 patients. This includes:

- **Hospital Settings:** Nurses (RN, LPN), Nursing Assistants, Nursing Practitioners, Nurse's Aide, Physicians (DO, MD), Physicians Assistants, Medical Assistants, Respiratory Technicians, Pharmacists, Emergency Medical Technicians (EMTs) (including Fire Departments EMTs and Air Medical Transport [rotor and fixed wing]), COVID-19 Sample Lab Workers, Organ Harvesters, and Students on Clinical Rotations. Other workers in hospital settings at elevated risk, such as Environmental Services Staff, Reception Staff, X-Ray Technicians, Phlebotomists, Infectious Waste Workers, Dietary Staff, Laundry Staff, Security Staff, Crisis Intervention Staff, Interpreters, and Clergy/Pastoral/Chaplains.
- **Non-hospital health care:** Nurses (RN, LPN), Nursing Assistants, Nursing Practitioners, Nurse's Aide, Physicians (DO, MD), Physicians Assistants, Medical Assistants, Respiratory Technicians, Dentists and Hygienists, Pharmacists, Plasma and Blood Donation Staff, Morticians, Public Health Nurses, Home Health, School Nurses, Optometrist, COVID-19 Testing Staff, Dermatologist, Dialysis Staff, Urgent Care Workers, Corrections Nurses/Aides, Physical/Occupational/Speech Therapists, Vaccine Clinic Workers, EMTs (including Fire Departments EMTs and Air Medical Transport [rotor and fixed wing]).
- **Other Congregate Care:** Nurses (RN, LPN), Nursing Assistants, Nursing Practitioners, Nurse's Aide, Physicians (DO, MD), Physicians Assistants, Medical Assistants, Respiratory Technicians, Group Home/Residential Staff, Pharmacists, Environmental Services Staff, Reception Staff, Home Aide/Caregiver, Corrections Nurses/Assistants, Congregate Care Surveyor, Hospice and Palliative Care Staff, Community Health Workers when acting as health aids or health translators.
- **Other Congregate Care:** All residents of "Other Congregate Care" settings as identified in Table 1 below.

- When vaccine is limited, priority should first be given to high-risk healthcare workers involved in direct patient care and those working in transport, environmental services, or other healthcare facility services where the risk of exposure to bodily fluids or aerosols exists. As more vaccine becomes available, all healthcare personnel in Phase 1A should have the opportunity to be vaccinated.
- According to an Illinois Department of Human Services (IDHS) memo dated January 21, 2021, those providing "Home Health" or serving as a "Home Aide/Caregiver" for a relative with a disability include those who care for people with any of the following conditions. This list is not necessarily exhaustive:
  - Cerebral Palsy
  - Down Syndrome
  - Epilepsy
  - Specialized health care needs, including dependence upon ventilators, oxygen, and other technology

Table 1: Phase 1A Eligible Locations, Personnel, and Residents in LTC and Congregate Care

Hospital Settings:	• Hospitals
Non-hospital Settings:	• Medical outpatients • Public Health Clinics • Local Health Department Points of Dispensing (PODs) • Federally Qualified Health Centers (FQHCs)
Long Term Care Facilities:	• Skilled Nursing Facilities (SNFs) • Assisted Living Facilities • Intermediate Care Facilities for Persons with Developmental Disabilities • Intermediate Care Facilities for Persons with Severe Mental Illness • State-run Veterans' Homes • State-operated Centers for Persons with Developmental Disabilities • State-operated Mental Health Centers • Residential Treatment Centers for Substance Abuse
Other Congregate Care:	• Continuing Care Residential Facilities • Residential Care Adult Homes • Support Housing for Seniors • Supportive Residential Facilities for Persons with Developmental Disabilities • Supportive Residential Facilities for Persons with Severe Mental Illness • Community Integrated Living Arrangements • Supervised Residential Facilities for Persons with Developmental Disabilities • Supervised Residential Facilities for Persons with Severe Mental Illness Note: All residents of the above facilities "Other Congregate Care" are eligible for vaccination in 1A.

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

Adjusted for ACIP and CDC recommendations, Phase 1B has been split into two parts, Part 1 & Part 2. (Note: As of the date of this plan, only Pfizer has been authorized for those ages 16 and up, whereas Moderna was authorized for those ages 18 and up.)

- **Phase 1B Part I:** Those 65 years of age and older and frontline workers with higher risk of exposure because of their inability to perform work duties remotely and work in proximity to other coworkers or members of the public:

- Persons aged 65 years and older.
- **Frontline essential workers,** who do not work remotely, are defined as those workers who are essential for the functioning of society and include the following:
  - **First Responders:** Firefighters (including volunteers), Law Enforcement Officers (LEOs), 911 Dispatch (Public Safety Answering Point – PSAP), Security Personnel, School Officers. EMS personnel are previously included under Phase 1A.
  - **Corrections Officers/Inmates:** Jail Officers, Juvenile Facility Staff, Workers Providing In-Person Support and Inmates.
  - **Food and Agriculture Workers:** Processing, Plants, Veterinary Health, Livestock Services and Animal Care.
  - **United States Postal Service Workers**
  - **Manufacturing Workers:** Industrial production of goods for distribution to retail, wholesale, or other manufacturers.
  - **Grocery Store Workers:** Baggers, Cashiers, Stockers, Pick-Up and Customer Service.
  - **Public Transit Workers:** Flight Crew, Bus Drivers, Train Conductors, Taxi Drivers, Para-Transit Drivers, In-Person Support and Ride Sharing Services.
  - **Education Workers (Congregate Child Care, Pre-K through 12th grade):** Teachers, Principals, Student Support, Student Aids, Day Care Workers and Frontline Support Staff.
  - **Shelters/Adult Day Care:** Homeless Shelter, Women's Shelter, Adult Day/Drop-In Program, Sheltered Workshop and Psycho-Social Rehab.

- **Phase 1B Part II:** Persons aged 16 to 64 years with high-risk medical conditions:
  - Persons aged 16 to 64 years with medical conditions that increase the risk for severe COVID-19. Conditions include Obesity, Diabetes, Pulmonary Diseases, Smoking, Heart Conditions, Chronic Kidney Disease, Cancer, Immunocompromised State from a Solid Organ Transplant, Sickle Cell Disease, Pregnancy, and Persons with Disability (Not otherwise covered in previous categories.)

- **Phase 1C: (Is still in draft form based on ACIP recommendations. Further updates to be released for Phase 1C for the context of Illinois)**
  - **Other essential workers, who do not work remotely, may include:**
    - **Transportation and Logistics**
    - **Food Service**
    - **Housing (e.g., Construction)**
    - **Finance (e.g., Bank Tellers)**
    - **Information Technology and Communication**
    - **Energy**
    - **Media**

- **Legal**
- **Public Safety (e.g., Safety Engineers)**
- **Water and Wastewater**
- **Public Health Workers**

(Note: As of the date of this plan, only Pfizer has been authorized for those ages 16 and up, whereas Moderna was authorized for those ages 18 and up.)

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

- **Phase 2 (more guidance to come pending ACIP recommendations):**
  - It is possible that Phase 2 will include the rest of the population aged 16 and up.
  - ACIP will make specific age recommendations as data becomes available.

  (Note: As of the date of this plan, only Pfizer has been authorized for those under from the ages 16 and up, whereas Moderna was authorized for ages 18 and up.)

Table 2 lists the estimated population sizes for the groups listed above by phase.

Table 2: Estimated Population Size by Group

Phase	Population Group	Statewide, Including Chicago
1A	Healthcare personnel	Est. 540,000
1A	Long-term care facility residents & staff	Est. 340,000
1B Part I	Frontline essential workers including first responders	Est. 1,400,000
1B Part I	Persons aged 65 and older	Est. 1,900,000
1B Part II	People with high risk comorbid conditions aged 16 to 64	Est. 3,400,000
1C	Other essential workers	Est. 1,500,000
2	Rest of population (aged 16+)	Est. 900,000

Population estimates are adapted from federal census data, DECO data, Tiberius and ACIP & IDPH data estimates. Population-group categories are not exclusive and may not add to the total population (e.g., within Phase 1A, an individual may fall under "Long-Term Facility Staff" and under "Healthcare Personnel"). Please note, the populations calculations do not include children under the age of 16.

Figure 3, below, shows critical population by vaccine supply. Phase allocations may change based on further guidance from the CDC.

2.10.2021

Critical Populations for Vaccine Allocation

Limited supply of vaccine			Increased Supply of vaccine	
Healthcare Workers & Long Term Care Facility Residents & Staff.	**Persons aged 65+, Frontline Essential Workers & Persons 16 to 64 with high-risk medical conditions.**		**1c is in draft, updates to be released for Phase 1c for the context of Illinois; Other essential workers.**	**Pending ACIP recommendations, possible groups could include; The rest of the population.**
Phase 1a	**Phase 1b Part 1**		**Phase 1c**	**Phase 2**
Healthcare Personnel: Defined by the CDC as paid and unpaid workers in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials. E.g. Nurses, Nursing Assistants & Aids, Nursing Practitioners, Physicians (DO, MD), Physicians Assistants, Respiratory Technicians, Pharmacists, Emergency Medical Services (EMS), etc. Other workers such as Reception Staff, Environmental Services Staff, X-Ray Technician's, Phlebotomists, Infectious Waste Workers, Dietary staff, Laundry staff, security staff, etc. **Long Term Care Facility Residents:** Defined by the CDC as adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently. **Other Identified Congregate Care Residents & staff:** See table 1 State of Illinois COVID-19 Vaccination Plan for list	**Persons aged 65 & over.** **Frontline Essential workers, who do not work remotely:** Includes those workers who are essential for the functioning of society and are at highest risk of exposure, such as firefighters (including volunteer), Law Enforcement Officers, 911 Dispatch, Security Personnel, Corrections Officers & Inmates, Food and Agriculture Workers, Postal Service Workers, Manufacturing Workers, Grocery Store Workers, Public Transit Workers, Education sector, including teachers and Support Staff and Shelters/Adult Day Care. **Phase 1b Part 2** **Persons aged 16 to 64 years with high-risk medical conditions, which include;** Obesity, Diabetes, Pulmonary Disease, Heart Condition, Chronic Kidney Disease, Cancer, Immunocompromised State from a Solid Organ Transplant, Sickle Cell Disease, Pregnancy and Persons with Disability.		**Further updates to be released for Phase 1c for the context of Illinois;** **Other Essential Workers, who do not work remotely:** Workers in transportation & logistics, food service, housing (e.g. construction), finance (e.g., bank tellers), Information technology and communication, energy, media, legal, public safety (e.g., safety engineers), water and wastewater and public health workers.	**Phase 2 is pending ACIP recommendations, possible groups could include;** **The rest of the population aged 16 & up.**
	1b Part 1	1b Part 2		
Est. Pop.	**880,000**	**3,300,000**	**3,400,000**	**1,500,000**	**900,000**

Figure 3: Critical Populations for Vaccine Allocations

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's 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 (FQHCs) 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 priority patients. In coordination with LHDs, the State of Illinois will also support the deployment vaccination mobile vaccination teams 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 used to identify gaps in coverage, and targeted recruitment efforts will be implemented to fill those gaps. IDPH will use an electronic database to enter newly enrolled providers and update it daily and submit it to the CDC.

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

- All vaccine providers must enroll in I-CARE and complete and submit (1) the CDC and (2) the IDPH COVID-19 Vaccination Program Provider Agreement electronically through 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 LHDs or approved COVID-19 Vaccine Providers to which the LHD allocates vaccine. Enrolled providers who did not initially execute the IDPH COVID-19 Vaccination Program Provider Agreement at registration must access the IDPH COVID-19 Vaccination Provider Agreement through a Smartsheets link provided in the January 15th SIREN guidance document, "COVID-19 Mass Vaccination Guidance for Providers." Providers must complete the COVID-19 Provider Agreement as a requirement to administer the COVID-19 vaccination.
- Local public health jurisdictions should collaborate with their RHCCs, hospitals, and long-term care and assisted living facilities within the county and with other potential vaccine providers that cater to critical infrastructure and/or frontline essential workers in their jurisdiction to ensure full coverage of vaccine first to designated priority groups and then 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, COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration, and use their best efforts to report administration data to the relevant system for the jurisdiction (i.e., IIS) as soon as practicable and no later than 72 hours after 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 he or she meets the requirements listed in the agreement. For vaccine administration tracking and reminders of a second dose, if needed, all vaccine providers must plan to use I-CARE or EMTrack. At this time the race and ethnicity data field requirement does

not apply to records that are uploaded through the HL7 interface option. However, HL7 standards specify if the EMR or sending system collects race and ethnicity. Those fields should be sent to I-CARE. This data is mandatory for those entering data manually into I-CARE.

- 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. The CDC is using 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 vaccine inventory information into VaccineFinder, all COVID-19 vaccine providers will receive an email from CDC/VaccineFinder on how to enroll into this program. The option for a site to be visible on the VaccineFinder public-facing website will be available when and/or 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' plans must include 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 vaccination administration mission.

State of Illinois Rapid Electronic Notification System (SIREN)

SIREN is a secure web-based persistent messaging and alerting system that leverages email, phone, text, pagers, and other messaging formats to provide 24/7/365 notification, alerting, and flow of critical information. This system provides rapid communication, alerting and confirmation between state and local agencies, public and private partners, and target disciplines and authorized individuals in support of state and local emergency preparedness and response.

To register for SIREN, visit https://www.siren.illinois.gov/agreement.php

SIREN, originally implemented as the core alerting service for the Illinois Department of Public Health's Health Alert Network, has been broadened in scope and utility to make it a robust tool for all state agencies and partners with alerting, notification and collaboration needs and is available to all agencies and partners.

SIREN is used for targeted alerting based on members' professional roles or functions. It is not intended for use as a public warning system at this time. During registration, participating entities will need to enter contact information and select a specific organization and function. IDPH, all public health partners, and other members may contact SIREN at *dph.siren@illinois.gov*; IEMA and emergency management partners may contact SIREN at *ema.siren@illinois.gov*. Emails should include a detailed message, including information about where you work and your role or title.

Section 6: COVID-19 Vaccine Administration Capacity

With the assistance of numerous state agencies and professional organizations IDPH is recruiting and enrolling COVID-19 vaccination providers. 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 expressing initial interest in becoming pandemic vaccine providers. Additionally, IDPH will use maps to indicate populations with a 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 numbers to vaccinate at-risk populations. This will allow the planning team to visualize gaps in access and recruit providers in specific regions.

Initial onboarding will focus on LHDs and all hospitals, with priority given to those with emergency departments and/or intensive care units.

Local pharmacies will be used to provide expanded access to a variety of communities. Pharmacists are not only highly accessible, but they are also commonly available for longer hours and for more days than non-pharmacy providers. 99 percent of the long-term care providers in the State of Illinois are using the partnership program established by CDC with Walgreens and CVS pharmacies to ensure their residents and staff are vaccinated. As of the date of this plan, this program has been activated and vaccination operations are in progress in LTCFs across the state.

IDPH plans to support the use of mobile vaccination teams to support and provide vaccination clinics to defined targeted groups and populations and to deploy to areas affected by health inequity, often referred to as areas with "at-risk" or "vulnerable" populations. This can occur in each of the phases, when necessary.

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

- Illinois Helps (*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.
- Thirty-eight 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 (e.g., LHD, hospital, Medical Reserve Corps [MRC], long-term care facility) manages individual volunteers that wish to work with that specific organization.
- A volunteer registers in the system, gives his or her information (including licensure and skills), and chooses from up to 15 organizations with which to work.
- The organization using the volunteer follows its 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, including LHDs, MRC, hospitals, and long-term care facilities are registered in Illinois Helps to request volunteers.

- Any healthcare organization wishing to access and manage volunteers may request to do so at illinois.helps@illinois.gov.
- Mass Vaccination Sites

CDC COVID-19 Training

The CDC has released immunization education & training for COVID-19 vaccine administration. The training includes three modules:

1. COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers
2. Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know
3. Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know

Illinois National Guard

The Illinois National Guard (ILNG) Mass Vaccination Augmentation Package is capable of augmenting county public mass vaccination operations or deployable as a standalone package for remote vaccination (established under the supervision of Local Health Department). Based on operational requirements, these teams can either operate individually with assistance from a health department, augment existing vaccination efforts, or multiple teams can deploy to a single location to provide vaccination surge capability. During the initial phases of this operation, the ILNG has the capability to deploy military personnel and medics providing up to 47,250 vaccinations per week. The ILNG will work under the supervision of the Illinois Department of Public Health, Local Health Department and take direct orders from the Governor of Illinois. Its mission will be evolving over the course of the vaccination program and tailored to best serve the citizens of Illinois.

Large Vaccination Sites

As vaccine supply increases, large vaccination sites will be established in northern, central, and southern Illinois. These sites will be fixed and strategically located to equitably serve all populations as efficiently as possible. Initially, the sites will be led by the ILNG, but different solutions will be leveraged as vaccination operations continue.

Expanded Scopes of Practice

The Illinois Department of Financial and Professional Regulation (IDFPR) has taken steps to expand scopes of practice for professions such as dentists and pharmacists. The Illinois Department of Public Health Division of Emergency Medical Services (EMS) and Highway Safety, has also provided for expanded scopes of practice for those EMS personnel licensed at the level of Advanced Emergency Medical Technicians (AEMT) and Emergency Medical Technicians – Intermediate (EMT-I), to vaccinate as approved by their EMS System Medical Director. According to an IDPH Proclamation, during the declared state of emergency due to the COVID-19 pandemic, EMT-Is and AEMTs (through the current disaster proclamation) may

administer vaccinations in an EMS Medical Director approved vaccination program. Any Illinois EMS System interested in beginning to use Illinois-licensed paramedics, EMT-Is, or AEMTs for vaccine administration must do so under the approval of the EMS Medical Director and the IDPH Division of EMS & Highway Safety. This plan can include agency personnel vaccine administration and community vaccination programs. A system plan for vaccine administration must be developed and include, at a minimum:

1) A written policy outlining the types of vaccines being administered.
2) A training program for paramedics, EMT-Is, or AEMTs that includes administration, documentation, and education about vaccine side effects or adverse reactions.
3) Communication plans for when paramedics, EMT-Is, or AEMTs will be used for vaccine administration and where they will be administering the vaccines.
4) A quality assurance plan for tracking and documenting the use of paramedics, EMT-Is, or AEMTs for vaccine administration.
5) Annual continuing education for paramedics, EMT-Is, or AEMTs as it relates to vaccine administration and medication education.
6) At this time, no person under 6 years of age may receive a vaccination from an Illinois licensed Paramedic, EMT-I, or AEMT.

   (Note: As of the date of this plan, only Pfizer has been authorized for those under from the ages 16 and up, whereas Moderna was authorized for ages 18 and up.)

Additionally, EMS Systems should consider the need for just-in-time training that may specifically address the type of medication being administered and the manufacturer recommended patient education. This education may vary based on manufacturer. This information and the requirements for EMS personnel to administer vaccines in an EMS Medical Director approved vaccination program is subject to change based on any future guidance from IDPH and other state and federal partners. All jurisdictions and providers should ensure that the appropriate medical personnel have issued a standing order, under which COVID-19 vaccinations can be administered.

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

The IDPH Immunization Section will use established I-CARE protocols to coordinate ordering and tracking use of the pandemic vaccines from the CDC, or from the designated vendors. LHDs will be the first to order while vaccine is scarce. IDPH will work with LHDs 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.

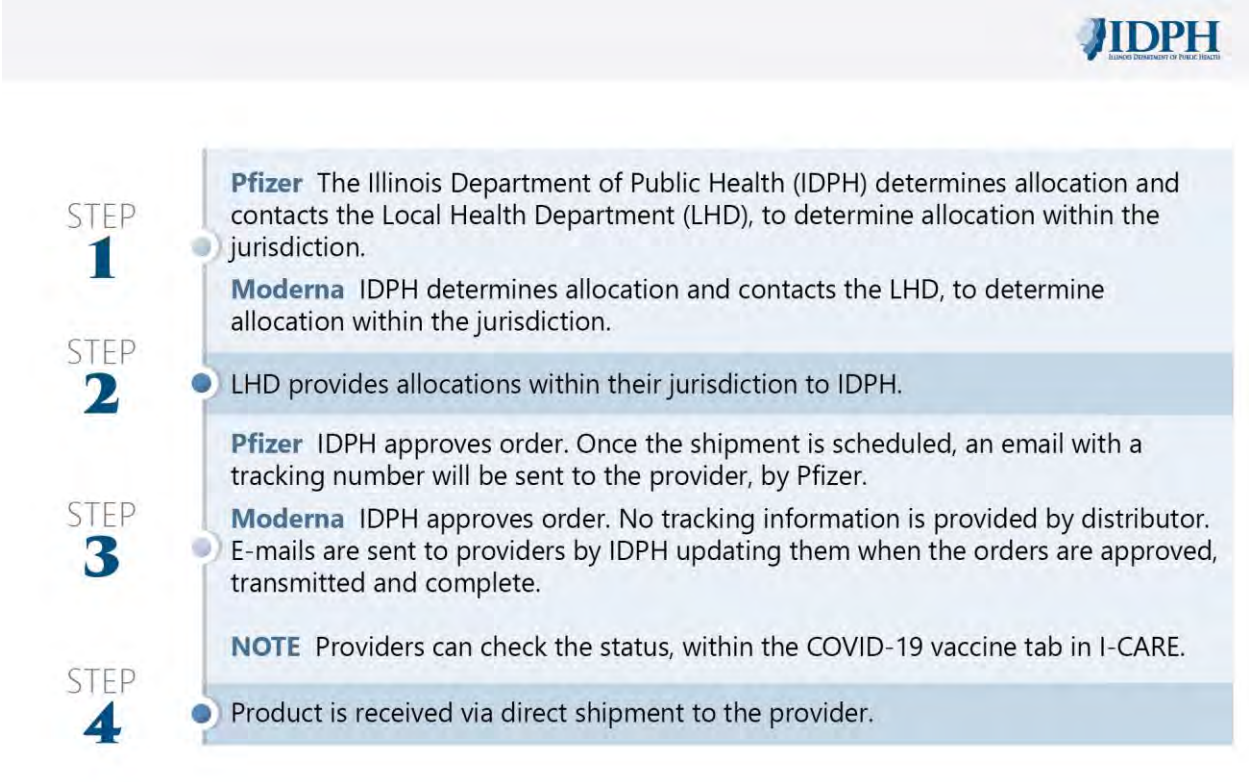

Figure 4: Illinois Department of Public Health COVID Vaccination Allocation Steps

For refrigerated and/or frozen vaccine, approved vaccine orders—including the adjuvant, if necessary, and all ancillary supplies—will be shipped directly to providers' designated locations. This shipment is executed by McKesson or the vaccine manufacturer and is 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 distribution of the vaccine. To ensure success of the mission, ICS may be expanded as needed, to possibly include but not be limited to, 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 healthcare coalition regions and public health jurisdictions, by provider type. This group will be led by regional staff who have experience working with LHDs, hospitals, long-term care facilities, and the healthcare coalitions.
- 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 shipped directly from the manufacturer to providers. IDPH staff familiar with distribution operations will lead.

Adult ancillary supply kits shipped by McKesson will include the following:

Moderna Vaccine ancillary supply kit for 100 doses:

- 85 needles (22-25G x 1")
- 20 needles (22-25G x 1.5")
- 105 syringes (1mL or 3mL)
- 210 alcohol pads
- 100 vaccination record cards, for each vaccine recipient
- 1 needle gauge and length chart
- Limited supply of personal protective equipment (PPE), such as surgical masks and face shields for vaccinators. Each ancillary kit contains 4 surgical masks and 2 face shields.

Pfizer Vaccine ancillary supply kit for 975 doses: (Note: The Federal Government is increasing the ancillary supply kits to account for the 6th dose and the increase from 975 doses to 1,170)

- 1,000 needles (22-25G X 1")
- 240 needles (22-25G X 1.5")
- 205 mixing needles (21-25G X 1.5")
- 1,240 syringes (1mL)
- 205 syringes (3mL or 5mL)
- 2,900 alcohol pads
- 1,200 vaccination record cards, for each vaccine recipient
- 200 Diluent vials
- 10 needle gauge and length charts
- Limited supply of personal protective equipment (PPE), such as surgical masks and face shields for vaccinators. Each ancillary kit contains 50 surgical masks and 25 face shields.

Supplies not included in shipments from McKesson or the vaccine manufacturer and to be procured by the provider include sharps containers, gloves, and bandages. Providers may need to plan for additional 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°C to 8°C) or frozen (-15°C to -25°C) temperatures, note Pfizer requires ultra-cold 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 initial orders at a central location and re-distribute to LHDs, depending on their allocation, at refrigerated (2°C to 8°C) temperatures. Providers should use the entire dose allocation and not hold first doses of vaccine back for a second doses, as the second dose will be provided closer to the time of its expected administration, per CDC guidance (Note: For the Pfizer vaccine, the CDC has issued guidance allowing the use of 6th and even 7th doses that are being drawn from the 5-dose vial, as long as they are complete doses. Vaccine from multiple vials should not be pooled, per the CDC, to make complete doses). As of the date of this plan, extra diluent should not be added to draw additional doses, per CDC guidance. See recommendations for how to mix diluent and vaccine, for Pfizer vaccine only. **Do not** mix Moderna vaccine with a diluent. Follow the hyperlinks for more information from the CDC regarding vaccine preparation and administration for Pfizer and Moderna.

Vaccine Allocation

The federal government will determine the amount of COVID-19 vaccine designated for each state. Using this allocation, IDPH will manage and approve orders from enrolled providers. During initial rollout when vaccine is scarce, LHDs determine the allocations within for their jurisdiction based on their local vaccination plan. The amount allocated 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 healthcare 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 vaccination operations for their population.

- IDPH will estimate overall allocations of COVID-19 vaccine based on the size of critical population groups within each local public health department's jurisdiction.
- 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, and planning tool used at the state level developed by Operation Warp Speed (OWS), is designed to calculate each jurisdiction's allocation, and will be used for this event. The tool will list public health jurisdictions, all eligible providers in the jurisdiction, and their vaccine administration capacity to efficiently allocate the vaccine in real-time as 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 the CDC: The Federal Bureau of Prisons, U.S. Department of Defense, the U.S. Department of State, the U.S. Department of Veterans Affairs, and the 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 not listed above should work with the state immunization program to ensure their staff is included in the plans for vaccination.

- In addition to the federal entities receiving vaccine directly from the federal government, pharmacies participating in the Federal Retail Pharmacy Partnership Program will receive vaccine directly from the federal government in addition to the State's allocation. Walgreens will be the first pharmacy to receive this additional federally-allocated vaccine, and more pharmacies will be added as vaccine becomes available at the federal level. In advance of the full activation of the Federal Retail Pharmacy Program, Illinois will transfer a portion of the state's allocation to partnering pharmacies and direct allocations to areas identified as more vulnerable through the COVID-19 Community Vulnerability Index (CCVI).

Vaccine Arrival and Distribution

All providers must have plans in place to receive vaccine and ancillary supplies shipped directly to the designated sites and a centralized distribution of vaccine where applicable. Each LHD's plan will be submitted to IDPH for review to ensure it is in line with the state strategy and to identify additional opportunities for technical assistance to provide to the LHDs. 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 allocations. 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; see Tier 2 Distribution below. Depending on the availability of vaccine, this hub and spoke model may be used in future distributions as well.

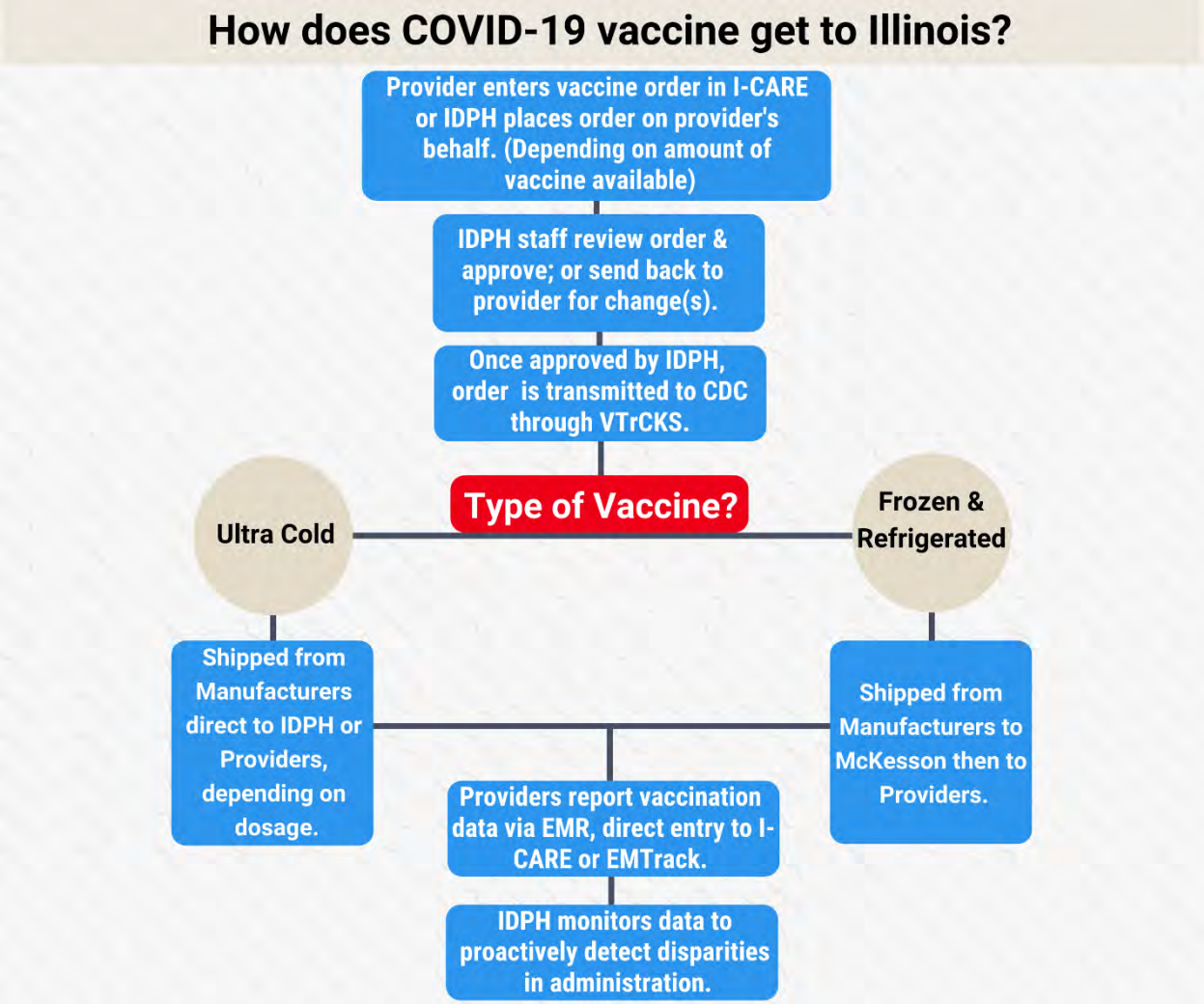

Figure 5: COVID-19 Vaccinations Transportation

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

- Tier 1 for refrigerated and frozen vaccines
    - Private carriers currently perform distribution and delivery to each provider. Vaccine will be sent directly to vaccination providers for administration or to designated depots for secondary distribution to administration sites. Once a load of vaccine is shipped to a provider site, the federal government will not redistribute the product.
    - Under the current vaccine-delivery processes, the CDC contracted McKesson, a third-party distribution company, to conduct the service.
    - Providers must ensure 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).

- To reduce waste, if a provider has vaccine that cannot be utilized in the given priority population, the provider shall contact their LHD to allocate extra doses with sufficient shelf life for transportation and administration for redistribution.
- LHDs may redistribute vaccines while maintaining the cold chain. With the challenge of meeting cold chain, LHDs should limit any redistribution to refrigerated vaccines only.
- Any necessary further distribution to sub-sites within the local jurisdictions is determined by the LHD and its community partners as part of that agency's pandemic response plan.
- If redistribution is not possible for a provider, or if the vaccine's shelf life does not facilitate a safe transfer, providers should administer the vaccine to the next priority group in the following phase to prevent vaccination waste; i.e., if in Phase 1A with a lack of 1A populations to utilize the surplus vaccine, the provider should then move to Phase 1B, in order not to waste the vaccine. If this occurs, the provider shall notify the LHD for the given jurisdiction.

- Tier 2 for ultra-cold vaccines
  - A centralized distribution model ("hub and spoke") will be executed for initial distribution of ultra-cold vaccine using a modified version of the State Strategic National Stockpile Plan. With the initial scarcity of vaccine supply to the State of Illinois and the minimum order size of 975 doses (1,170 doses accounting for the 6th dose in Pfizer Vials), this was the model to ensure widescale vaccine distribution without vaccine waste. This model also ensures the following:
    - Vaccines are maintained at the appropriate temperature of -60°C to -80°C, upon arrival, to ensure vaccine integrity.
    - Logistical and resource complexity on local jurisdictions are reduced.
    - The integrity of the vaccine during shipping due to ultra-cold requirements is ensured.
    - Vaccines needing to be held and/or stored will be kept in ultra-cold vaccine freezers to decrease the amount of dry-ice consumption needed for local operations and to ensure vaccine integrity.
    - Jurisdictions not meeting the 975 minimum dose allocation can still receive vaccine.
  - For providers that will be allocated at least 975 doses and/or in increments of 975, and can maintain the ultra-cold vaccine supply chain, IDPH may approve shipments directly to those providers' facilities.
    - COVID-19 vaccine (Pfizer) requires ultra-cold temperatures during shipment and will arrive in a thermal shipping container with dry ice. To unpack the vaccine, staff will need proper personal protective equipment (PPE) and should know how to handle dry ice safely.
    - For those receiving direct shipment of Pfizer, approximately 1 day after vaccine arrival, an additional shipment will arrive and will consist of:
      - Dry Ice Refill
      - Dry Ice Plastic Scoop
      - Dry Ice Gloves

        - Face Shield
        - OSHA Safety Documentation

    - Operations will be coordinated through the SEOC, as needed, and supported by the Illinois Emergency Management Agency (IEMA). The Illinois State Police will provide security for delivery vehicles, where indicated.

Distribution will take place as follows (excluding Chicago):

- Initial shipments and subsequent second doses of Pfizer ultra-cold vaccine, will be direct shipped to the Strategic National Stockpile (SNS) receipt Stage & Store (RSS) warehouse for Illinois. This model will be utilized until the supply of vaccine to the State of Illinois allows for direct shipments to all providers. This model will continue to be utilized if widescale shipments of Pfizer are indicated across the state under the 975-dose level. Otherwise, it will be direct shipped to the provider from the manufacturer.
- Vaccine will be transferred into ultra-cold freezers to maintain vaccine integrity at the SNS.
    - Upon arrival at the SNS-RSS facility, the logistics staff will conduct an in-depth inventorying of the vaccine against provided packing slips and upload information into the state's inventory management system to begin tracking movement and delivery of the vaccine. The vaccine will be kept in ultra-cold storage freezers until it is time to repackage for shipment. IDPH will provide the logistics staff and SNS-RSS incident command the allocations of vaccines to begin repackaging for delivery.
- Vaccine will be prepared for shipment to 10 RHCCs in the state (excluding Chicago) at 2°C to 8°C.
    - IEMA Logistics will coordinate transport with the Illinois State Police to secure the SNS-RSS and the transport of each shipment of each vaccine to each of 10 state RHCCs.
    - Vaccine may be shipped in an ultra-cold state to jurisdictions receiving vaccine that have ultra-cold capability to provide more time for local plan execution. Vaccine allocation will be based on allocation size, capability, and availability of ultra-cold shippers.
        - Once vaccine arrives at the RHCCs, each LHD that is receiving a vaccine allocation will pick up its allocation from its respective RHCC. The shipment will also include ancillary supplies. LHDs will transport the shipment back to their jurisdiction for vaccination operations. This will "start the clock" and be the first day of the 5-day window to use the Pfizer vaccine at the refrigerated temperature of 2°C to 8°C. Vaccine cannot be re-frozen.
        - Once LHDs arrive in their jurisdiction, the vaccine will be placed into a vaccine refrigerator in the jurisdiction to maintain the vaccine temperature. (Note: Shipping boxes and other shipping equipment, such as ice packs and the data logger, will be returned to IDPH via a return shipping label that will be included with the shipment.)

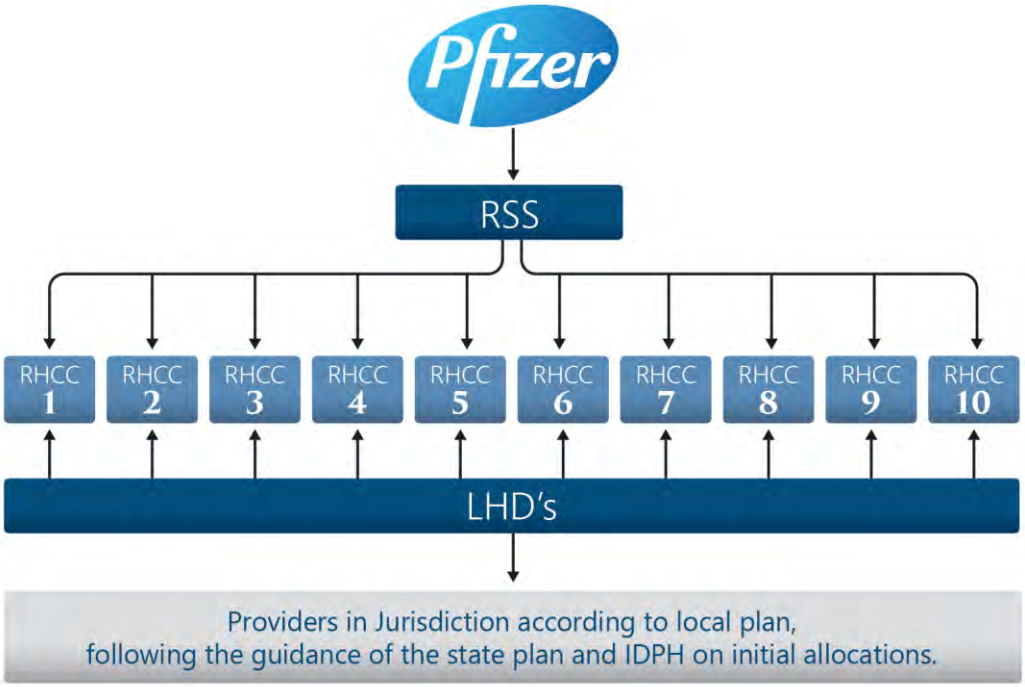

Figure 6: Vaccine Distribution

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, LHDs, universities, and colleges. These locations have been identified to act as contingency ultra-cold storage locations should additional capacity be needed. Additionally, state ultra-cold freezers have been staged in various regions across the state to increase statewide capability.

Inventory Management

COVID-19 vaccination providers will be required to report inventory of COVID-19 vaccines in VaccineFinder. Additional doses gained from vaccine vials should also be reported in I-CARE, this is to ensure your inventory it increased to account for additional doses drawn from vaccine vials. From this data, 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, manufacturer name, 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.

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).

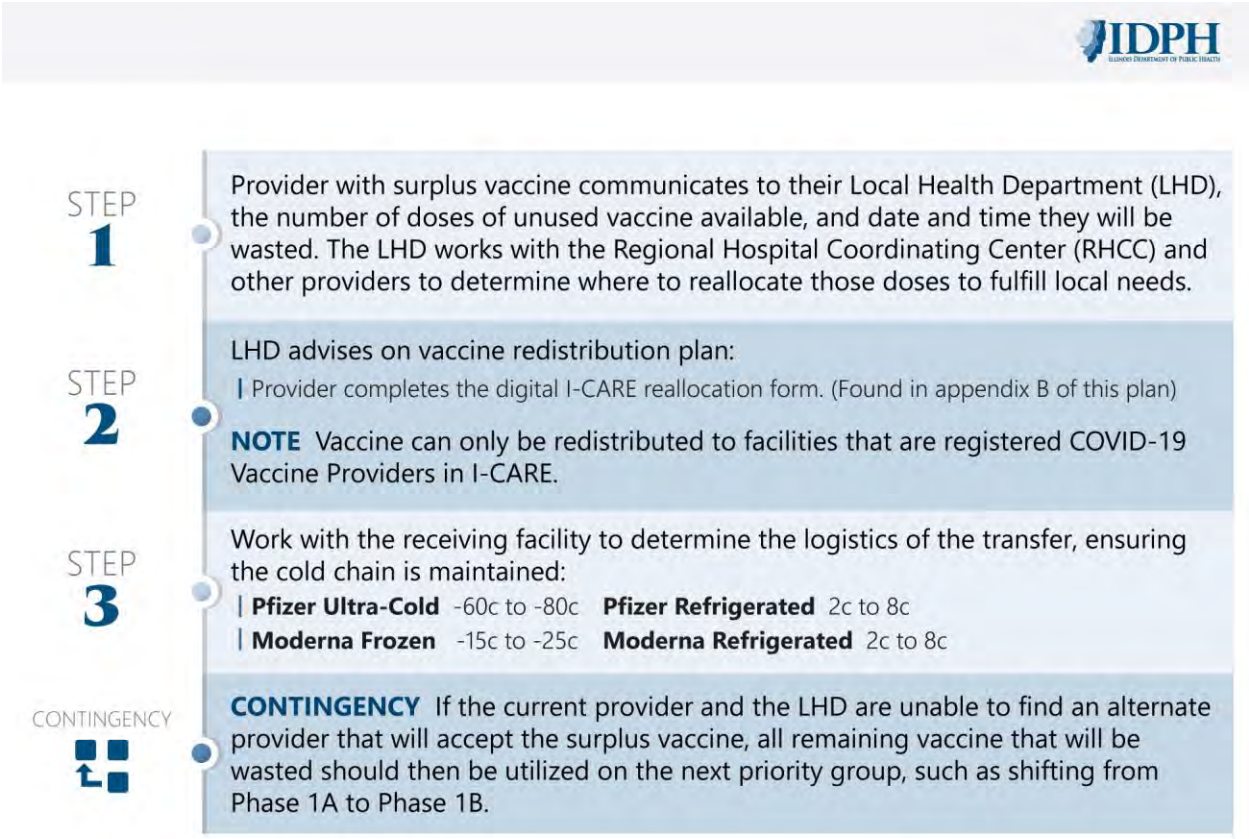

Figure 7: Illinois Department of Public Health Surplus Vaccine Redistribution Steps

Refrigerated and frozen vaccine will only be redistributed with the approval and involvement of IDPH and the guidance from the LHD. Depending on the circumstances, vaccine may be transported by regional immunization staff or the local or regional health department. IDPH will follow existing VFC Program protocols to coordinate safe transfer of vaccine in situations of unplanned repositioning. Providers are expected to contact their LHD and program staff in the event unplanned repositioning is necessary to prevent waste of vaccine. All providers will receive an educational packet that includes the expectation and program contact information once enrolled 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 safe transfer of vaccines. Digital Data Loggers (DDLs) will always remain with the vaccine before, during, and after 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 vaccine transfer is complete, the reconciled inventory will be transferred to the receiving facility's inventory and accepted by the new COVID-19 vaccine 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 and LHDs. Depending on the circumstances, vaccine may be transported by regional staff, the LHD, or other designated and approved providers.

Additional Doses from Pfizer Vials

According to the FDA, the Pfizer vaccine comes in multidose 5 dose vials. After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine may contain 5, 6 or 7 doses dependent on the type of syringe being utilized. Additionally, Moderna may also have 10 or 11 doses dependent on the type of syringe being utilized.

Per the FDA and the CDC:

- If the amount remaining in the vial, after the 5 doses (Pfizer) or 10 doses (Moderna), is enough for additional full doses, it may be utilized.
- If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial in a sharps container and waste any excess volume.
- Do **NOT** pool excess vaccine from multiple vials to create an additional full dose.

Vaccine Packaging Disposal

To maintain security and safety of the vaccines, proper disposal of all vaccine packaging is crucial. If vaccine packaging is not disposed of properly, bad actors can reuse this packaging for nefarious reasons.

- All used/depleted vials should be disposed of in medical sharp's container following disposal protocol.
- Pfizer trays "pizza boxes" should be shredded/destroyed before being disposed.
- All Pfizer shipper boxes should be shipped back to Pfizer utilizing the return mail label included with the shipment.

Visit the CDC COVID-19 Vaccination Toolkits page for useful CDC guidelines.

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 refrigerator and/or 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 and the maximum temperature in the morning and the temperature once in the morning and once in the afternoon. Providers must upload temperature logs into the IIS, and IDPH will only allow

sites to order vaccines if they can guarantee appropriate temperatures are 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°C to -25°C) to ultra-cold (-60°C to -80°C) in the freezer or within a dry-ice shipping container. Ongoing stability testing may affect 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 and spoke" model. IDPH has a means to store vaccine if an "unplanned repositioning" of vaccine is required. IDPH has procured resources to assist in adherence to all cold-chain requirements, including ultra-cold storage capacity.

Providers **should use the entire dose allocation** and **not** hold vaccine for a second dose, as the second dose will be provided closer to the time of its expected administration by the Federal Government, 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 LHDs. Vaccination clinics held in these settings have unique challenges, and providers must follow specific guidelines provided by the CDC for managing publicly supplied vaccine in these nontraditional settings. IDPH has procured ultra-cold storage freezers, which will be used for a centralized distribution of ultra-cold vaccine and can also act as contingency should ultra-cold vaccines need to be stored.

Visit the CDC Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations for a step-by-step guide on overseeing vaccination clinics.

Visit the CDC COVID-19 Vaccination Toolkits page for useful CDC Toolkits.

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, and monitoring and documenting temperatures.

- Upon arrival at a 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 movement of any vaccine for redistribution, providers must submit a request to the immunization program by filling out the I-CARE Redistribution Form, this digital form is also available in Appendix B as a link, and contact their LHD. 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 the waste 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, and after transport to the receiving facility is completed (See Figure #7 above "Surplus Vaccine Redistribution Process").

Temperature Excursion Reporting

Cold-chain maintenance at individual provider locations will require appropriate vaccine storage and temperature-monitoring equipment, 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 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 its 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 the CDC via the IZ Gateway. Ensuring that each COVID-19 vaccination provider is ready and able to report required COVID-19 vaccine administration data elements to IIS is part of the COVID-19 provider-onboarding process. The COVID-19 Vaccine Provider Reference Guide is posited on the I-CARE announcements page upon login to the system, which acts as an onboarding/reference document and serves as a frequently asked questions/troubleshooting guide for providers.

Vaccine Administration Reporting

- Prior versions of the State of Illinois COVID-19 Vaccination Plan referenced daily vaccine accountability reports to IDPH. However, the federal system, Tiberius, gives continuous live views of vaccine status across the state, thus removing this requirement. Data in Tiberius is generated based on allocations to the state form the CDC and daily inventory reported by COVID-19 Vaccine Providers in the VaccineFinder system. These numbers assessed when making vaccine allocations, which happens weekly.
- IDPH is required to submit daily inventory reports to CDC. Daily reports must be submitted to CDC by 4:00 p.m. CST. Reporting frequency and required data metrics will be updated as more guidance is received from CDC.
- IDPH will evaluate timeliness and completeness of reporting in VaccineFinder and I-CARE of COVID-19 vaccine administration at the organization and facility level. These teams will reach out to 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 use data provided in I-CARE and VaccineFinder to identify how many vaccines have been administered, how much vaccine is on hand, and vaccination administration versus documentation entry timestamps. This will provide insight into accurate and complete status of vaccine operations in the state.

Vaccine Administration Tracking

- At the provider level, two systems will be available in Illinois for patient vaccine administration tracking:
  - I-CARE: For overall patient tracking in Illinois, I-CARE is used to track individual patient information and conduct and/or recall notification for additional doses.
  - EMTrack: EMTrack is currently utilized in Illinois by EMS systems for patient tracking. The EMTrack Mass Testing and Vaccination Module was utilized for vaccination clinics/PODs during the H1N1 pandemic and is utilized at seasonal flu clinics. The module enables clients to schedule appointments and be pre-screened for vaccination prior to going to a vaccination site. EMTrack was upgraded for the COVID-19 pandemic is an optional system for all COVID-19 vaccine providers in the State of Illinois, at no cost.

- All providers must plan to use I-CARE or EMTrack for vaccine administration tracking and reminders to recipients of a second dose if needed. Providers may use 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 providers for the second dose with identifying the correct vaccine for the patient. Additionally, to ensure reporting of adverse events to the vaccine, administration data needs to be tracked. Finally, this provides assurance that all priority groups have adequate access to the vaccine and that enough of the population can be vaccinated in a timely fashion.
- One of the needed outputs from the IIS is to determine gaps in vaccine administration across geographic or demographic populations to inform focused outreach efforts.

EMTrack

The EMTrack - Vaccination Module is a solution designed by Juvare for use by COVID-19 providers at the state, region, county, or city level. The solution includes a website/portal, which enables providers to schedule COVID-19 Points of Dispensing (PODs) or Clinics.

This solution is free for all COVID-19 providers in the State of Illinois and includes:

1. A portal for individuals/patients who qualify, to register, self-attest to the priority group they belong to and pick an appointment time, within each phase. This includes a ticket that is generated with a unique identifier.
2. The system sends reminders to individuals/patients for their first dose appointments and when to schedule their second dose appointment.
3. Provides a digital application for POD operations to utilize on smart devices for providers to scan individuals/patients through each section of the POD.
4. The system automatically uploads/reports all required data into I-CARE.

If you are a COVID-19 vaccine provider in the State of Illinois and would like to start registering your **PODs** now in the EMTrack system, for more information please visit the IDPH Point of Dispensing Online Training Center. The password for initial POD registration was distributed via a SIREN on January 6th. You can request the password from DPH.Covid.Vaccination@Illinois.gov via your agency email account, if needed.

POD Setup and Operations

- LHDs should plan to collaborate with their local partners, such as hospitals, long-term care and/or assisted living facilities, emergency management and other potential vaccine providers that serve priority groups in their jurisdiction, to ensure access to vaccine to the designated priority groups and eventually to the general public. LHDs should work with these local partners to ensure they are reaching the hardest hit communities within the identified priority groups.
- LHDs should reach out to these groups to determine the number, type, and location of each priority group in the public health jurisdiction.

Utilizing systems like EMTrack, persons in the priority groups of the given phase can register online for an appointment for vaccinations at their desired POD location. Once a person is registered, they are provided a ticket with a QR code on their electronic device or provided a receipt that can be printed, that can be used to check in on arrival to the POD. Once checked in, the person will then be screened. After screening, the person will be vaccinated and per CDC guidance, will be observed for 15 minutes or for 30 minutes, if the individual has a history of anaphylaxis. The observation period is intended to monitor for any health complications from the vaccine. Once cleared after the observation period, they will be checked out/discharged from the POD. The individual/patient is then contacted with a second dose reminder.

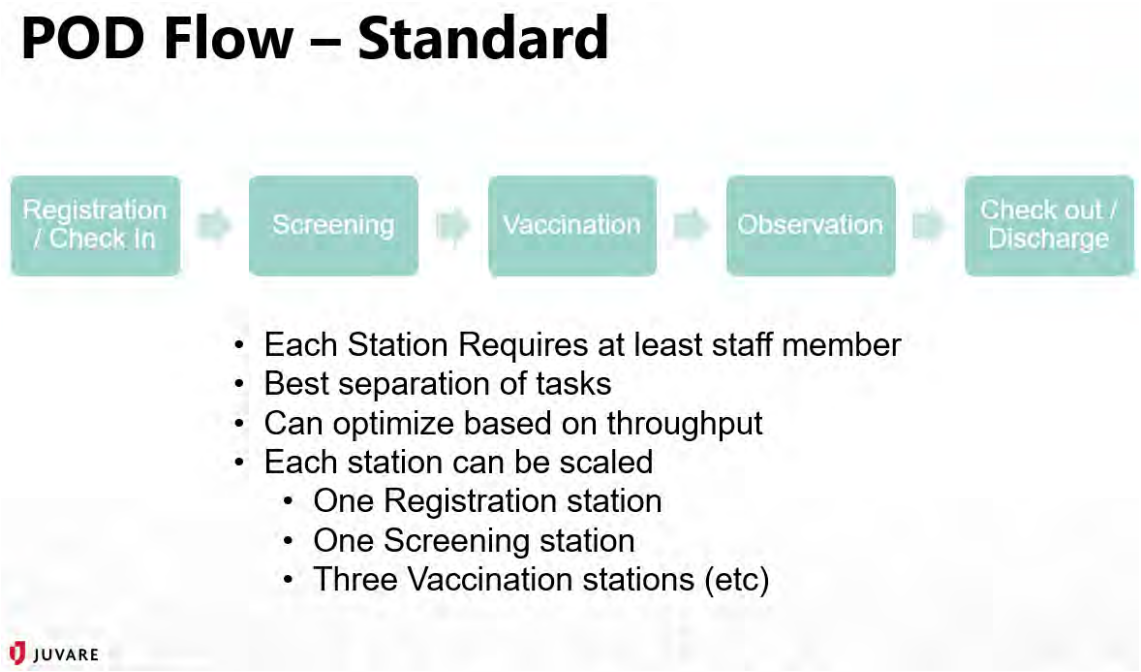

Figure 8: Providers' Process at the Point of Dispensing

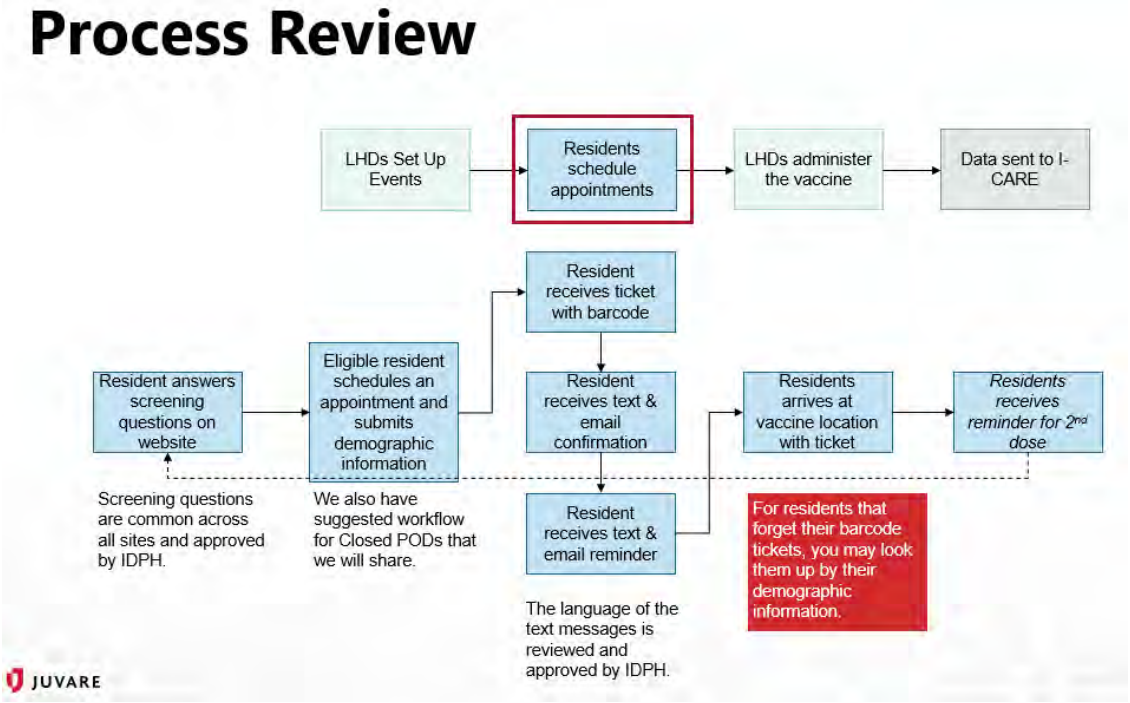

Figure 9: Individual's Process in Registering to Receive Vaccine and Reminder for 2nd Dose

Visit the CDC Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations for a step-by-step guide on overseeing vaccination clinics.

Visit the CDC COVID-19 Vaccination Toolkits page for useful CDC Toolkits.

Section 10: COVID-19 Vaccination Second-dose Reminders

All providers should utilize their entire allocation from the state vaccine distribution program completely without the concern of preserving the second dose. The goal for IDPH is to limit waste and give access to vaccine to as many people as possible with the first round of vaccine. If a provider is done with the current phase of the Vaccination Program within their jurisdiction to the appropriate priority group, they should use the remaining allocation for the next priority group in the next phase, in order not to waste vaccine.

For an adequate immune response, dependent on the specifications from the CDC and the manufacturer, individuals may be required to take two doses of the COVID-19 vaccine administered approximately 21 to 28 days apart. Per the clinical considerations from CDC, "persons should not be scheduled to receive the second dose earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period should not be repeated." The clinical considerations from CDC further states, "the second dose should be administered as close to the recommended interval as possible. However, if it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of the Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled up to 6 weeks (42 days) after the first dose. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered beyond these intervals, there is no need to restart the series."

If two doses are required, it will be necessary to ensure that the vaccinated person return for the second dose. LHDs will arrange for information about the need for a second dose to be provided to recipients at the time of initial vaccination, IDPH will provide technical assistance as needed to the LHD's. Per CDC guidance, the second dose will be provided and distributed by the federal government as part of the state's weekly allocations in the Tiberius system.

Providers will make sure that each person receives documentation of vaccination at the time of administration that includes the vaccine 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 are encouraged to schedule the patient's second-dose appointment at the time of delivering the first dose. The CDC has stated that vaccination verifications and reminder cards will be included with the vaccine shipments. Providers will be required to provide vaccination cards to those receiving their COVID-19 vaccination.

EMTrack automatically reminds individuals/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.

VaxText

The VaxText text messaging resource is a free/voluntary service offered to vaccine recipients by the CDC. The VaxText text messaging service will ask vaccine recipients who participate for basic vaccination information (i.e., vaccination date, COVID-19 vaccine name) so it can provide reminders based on the correct vaccination schedule (e.g., 21 or 28 days between the first and second doses). The VaxText service will not collect any personally identifiable information or personal health information from users and users can opt out or stop receiving messages at any time, even after they enroll.

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

Immunization registries, also known as Immunization Information Systems (IISs), 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 is a web-based immunization record-sharing application developed by IDPH that allows public and private healthcare providers to share 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, date of birth, race, ethnicity, address, and sex. 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. Effective Monday, February 8th, 2021, the race and ethnicity data fields in I-CARE became mandatory data fields. If these data fields have already been entered, please continue to do so. If not, IDPH encourages organizations to ensure those data fields are added to current intake forms and that there are processes in place to communicate the importance of completing this information with patients during the COVID-19 vaccine registration process. At this time, the race and ethnicity data field requirement does not apply to records that are uploaded through the HL7 interface option, but for those records that are entered manually. However, HL7 standards specify if the EMR or sending system collects race and ethnicity. Those fields should be sent to I-CARE. All providers should plan to strictly adhere to the use of I-CARE for tracking vaccine administration and to report additional doses over your inventory. Additionally, your daily on-hand inventory must be reported through VaccineFidner. I-CARE is the state's IIS and will be the primary system used 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, such as 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 and/or recall outreach to improve vaccination rates, and management of vaccine inventory.
- For access, all I-CARE providers must be authorized via the IDPH Immunization Program.
- Enrolling in I-CARE to receive COVID-19 vaccine is a two-step process:
    - Step 1: Complete the required enrollment forms to become an established provider (site) in I-CARE and enroll an individual user to have access to this site.
    - Step 2: Complete the fillable CDC and IDPH COVID-19 Vaccine Provider Agreement form within I-CARE. Once it is approved and a COVID PIN is assigned, the site is eligible to

receive vaccine when available. Providers are not currently able to order vaccine on their own. This includes agreeing to follow proper storage and handling procedures for each vaccine received.

- Three documents are required to register an organization for I-CARE access:
  - The I-CARE 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 a username and password.
  - The I-CARE Individual User Agreement form stating and agreeing to IDPH security and confidentiality policies.
- The 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 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. Planned contingencies for network outages or other access issues ensures that blank vaccine administration sheets are available in hard copy (i.e., as paper copies) and in soft copy on the vaccination user desktops and laptops (i.e., in Excel spreadsheets). All data gathered about vaccine administration is confidential and subject to state and federal privacy laws (e.g., the Health Information and Portability and Accountability Act [HIPAA], the 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 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 vaccination mission. Furthermore, COVID-19 vaccine provider organizations can use SIREN to communicate on organization-specific information with staff members and partners.

IDPH will also monitor its website to ensure that the following are available online:

- General information and education for the public regarding vaccination locations
- Providers', vaccinators', and public health department education and training information, including EUA fact sheets for providers and vaccine recipients and a place for Vaccine Information Statements (VISs)
- Federal vaccine call center information and a frequently asked question section
- A data repository allowing Illinois residents 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, website postings, interviews, newspaper editorials, flyers, billboards, television, and radio broadcasts. Messages may include understanding the key differences between U.S. Food and Drug Administration (FDA) emergency-use authorization and FDA approval, a timeline of vaccine availability, authorization, distribution, targeted populations, 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 and authorization processes, safety, and efficacy of COVID-19 vaccines. The program will also use traditional education materials for countering myths about the vaccine and information regarding 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 that will likely result in a multifaceted communication strategy to ensure effective messaging across all populations. 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 used to collect information from the public that could be used to maximize COVID-19 vaccination uptake, including information specific to subpopulations. Information and data obtained via the survey would be used to develop appropriate messaging for the public and healthcare providers.

LHDs should also plan for populations that have difficulty with internet access and internet communication, or the "digital divide," the goal of which is for all populations to have access to the most up to date vaccination information, including registering for appointments, regardless of digital literacy.

Section 13: Regulatory Considerations for COVID-19 Vaccination

Providers will receive an educational packet upon enrollment in the COVID-19 Vaccination Program. Guidance documents will include product-specific EUA fact sheets for COVID-19 vaccination providers and 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. 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 the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or 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 the 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 period (i.e., for the duration of the COVID-19 pandemic) to meet response needs. Additional information on EUAs, including guidance and frequently asked questions, is located on the FDA website.

Product-specific EUA fact sheets for COVID-19 vaccination providers will be made available by the FDA that include information on the specific vaccine product and instructions for its use. The FDA will develop EUA fact sheets for vaccine recipients. EUA fact sheets will likely be made available on the FDA website and through the CDC website. IDPH will use multiple communication medias 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 or patient prior to administering vaccine.

Vaccine Information Statements (VISs)

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 the way EUA fact sheets will be disseminated.

Section 14: COVID-19 Vaccine Safety Monitoring

VAERS

In response to vaccine safety, IDPH will use 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, including vaccine recipients, healthcare providers, and vaccine manufacturers. Patient identity is kept confidential. VAERS complies with all U.S. 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.

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

Providers should:

- Work with sites administering COVID-19 vaccines to encourage adherence to CDC guidance for anaphylaxis, including having the necessary supplies available to manage anaphylaxis
- Communicate with patients on vaccine safety
- Communicate with patients on vaccine effectiveness

V-safe

V-safe is a free/voluntary smartphone-based tool from the CDC that utilizes text messaging and web surveys to provide personalized health check-ins after a COVID-19 vaccination. Through v-safe, the CDC will be notified of any side effects that individuals experience after receiving the COVID-19 vaccine. Depending upon information received from a vaccinated individual, the CDC may call to verify reports of adverse effects and obtain more information. After registering with V-safe, reminders will be sent to the individual that it is time for their second COVID-19 vaccine dose, if necessary.

Section 15: COVID-19 Vaccination Program Monitoring

Provider Enrollment

Provider enrollment is monitored through a database that tracks progress through the three stages of onboarding: enrollment, storage and handling capabilities, and submission of the completed CDC Provider Agreement, IDPH Provider Agreement, and Profile. 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 percent of vaccine providers enrolled in the VFC program. It is anticipated that a similar protocol will be used 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

Tiberius integrates COVID-19 vaccine distribution planning, tracking, modeling, analysis, and other data from federal agencies, state and local partners, private-sector partners, and open data providers to create a comprehensive common operating picture of COVID-19 vaccine planning, distribution, and administration efforts. 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 timeliness and completeness of reporting of COVID-19 vaccine administration at the organization and facility levels. Staff will review this frequently to ensure completeness, accuracy, and timeliness of reporting 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 daily reports using IIS data to generate a list of providers who have not accepted an order into their inventory within 7 business days. This information will be sent to ordering staff for follow-up with the provider. The staff wil generate a monthly report using IIS data to identify providers who are not reconciling their inventory every 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 monitoring via an electronic ledger. Invoices are processed electronically, and requests for purchases 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 and monitors and modifies grants and contracts with adequate justification. The program manager also 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 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 vaccination operations receive training. Training and exercise modules are continually being developed by the COVID--19 Vaccination Section. The 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 and/or webinars will be scheduled as necessary. Additionally, IDPH plans to conduct workshops, webinars and/or tabletop/functional exercises for state partners as necessary. It is anticipated that most training and exercise offerings will be done virtually or on-demand.

Training topics may include but are not limited to the following:

- 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
- Ordering and receiving 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 reporting vaccine inventory via I-CARE
- Documenting and reporting vaccine waste and spoilage
- Procedures for reporting to VAERS
- Providing EUA fact sheets and/or VISs to vaccine recipients
- Public messaging
- Outreach to priority groups, vulnerable populations, and hard-to-reach populations

Appendix A: Acronyms

ACIP	-	Advisory Committee on Immunization Practices
AEMT	-	Advanced Emergency Medical Technician
CCVI	-	COVID-19 Community Vulnerability Index
CDC	-	Centers for Disease Control and Prevention
COP	-	Common Operating Picture
CRI	-	Cities Readiness Initiative
CVX	-	Vaccine Administered
DDL	-	Digital Data Logger
DHS	-	U.S. Department of Homeland Security
EHR	-	Electronic Health Record
EMA	-	Emergency Management Agency
EMR	-	Electronic Medical Record
EMS	-	Emergency Medical Services
EMT-I	-	Emergency Medical Technician - Intermediate
EMT	-	Emergency Medical Technician
ESAR-VHP	-	Emergency System for Advance Registration of Volunteer Health Professionals
EUA	-	Emergency Use Authorization
FDA	-	U.S. Food and Drug Administration
FEMA	-	Federal Emergency Management Agency
FQHC	-	Federally Qualified Health Centers
GIS	-	Geographic Information System
I-CARE	-	Illinois Comprehensive Automated Immunization Registry System
ICS	-	Incident Command System
IDFPR	-	The Illinois Department of Financial and Professional Regulation
IDPH	-	Illinois Department of Public Health
IEMA	-	Illinois Emergency Management Agency
IIS	-	Immunization Information System
IPS	-	Illinois Pharmaceutical Stockpile
LEO	-	Law Enforcement Officer
LHD	-	Local Health Department
LTC	-	Long-term Care
MRC	-	Medical Reserve Corps
NASEM	-	National Academic of Science, Engineering, and Medicine
OHPt	-	Office of Health Protection
OWS	-	Operation Warp Speed
PIO	-	Public Information Officer
POD	-	Point of Dispensing
PPE	-	Personal Protective Equipment
RHCC	-	Regional Hospital Coordinating Center
RSS	-	Receipt, stage and store
SEOC	-	State Emergency Operations Center
SIREN	-	State of Illinois Rapid Electronic System
SNS	-	Strategic National Stockpile
SNF	-	Skilled Nursing Facility
VAERS	-	Vaccine Adverse Event Reporting System
VFC	-	Vaccine for Children
VIS	-	Vaccine Information Statement
VtrckS	-	Vaccine Tracking System

Appendix B: I-CARE Re-Distribution Log Link

https://app.smartsheet.com/b/form/a944f58b0dcf45b49b977646e2a6f3fe