

COVID-19 Vaccination Plan

ILLINOIS

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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.	Vaccination Section
			Section 2 - title changed to COVID- 19 Vaccination Planning Assumptions.	
			Performed final copy edit & review.	
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.	Vaccination Section
			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.	
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.	
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.	
12/29/2020	4	12/29-31, 2021	Section 3 & 4: Updated priority groups in phase 1a, 1b and 1c.	Vaccination Section
			Section 5: Added SIREN notification registration for providers.	
			Section 7: Flow chart for notification of distribution and allocation steps.	
			Added Redistribution graphic.	

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.	Vaccination Section
			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.	
01/25/2021	5.0	01/25-27, 2021	Section 1: Added CDC link to vaccination toolkits & mRNA.	Vaccination Section
			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 PODs.	
			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 &	
02/03/2021	6.0	02/03-12, 2021	review. 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 6 th dose.	
			Section 8: Added language on redistribution form being updated to a link.	
			Section 10: Added language on 2 nd dose clinical considerations (CDC). Performed final copy edit & review.	
02/16/2021	7	02/16 – 3/20	Throughout: Added CDC toolkit hyperlinks, Pfizer, Moderna, & Janssen EUA hyperlinks. Added updated 1B Plus language & phase 2 to Section 3/4. Updated language on second doses. Updated Pfizer trays from 975 to 1,170.	Vaccination Section
			Section 6: Added IDFPR Pharmacist Proclamation hyperlink. Added IDFPR Dentist Proclamation hyperlink. Added additional language on vaccination administration fees guidance.	
			Section 7: Added additional language on not holding doses for extended periods of time & tracking order status in I-CARE. Updated Pfizer cold chain language.	
			Added hyperlink on emerging variants & made various updates.	

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
05/03/2021	7.1	03/22 – 5/3	Section 7: Added language on Pfizer low dead-volume syringes, CDC's Quick Reference Guide for Healthcare Professionals & Moderna EUA amendment. Added HCP & Recipient fact sheets hyperlinks. Added language on shipping processes (Pfizer from RSS) & Janssen EUA amendment. Added information & hyperlink on VTrckS. Section 8: Added additional language & hyperlink on vaccine packaging disposal. Section 10: Added additional language on vaccine cards & hyperlink on CDC fully vaccinated guidance.	Vaccination Section
05/07/2021	8.0	5/7 – 5/14	Section 3: Added language on vaccine wastage. Section 4: Added language on consent for ages 12-15 & updated Table 2 to account for 12+ population. Section 5: Added language on COVID-19 vaccine provider oversight requirements. Section 7: Added language on pediatric ancillary supply kits.	Vaccination Section
05/19/2021	8.1	5/19 - 6/20	Section 7 & throughout: Added new Pfizer 450 shipper & ancillary kits and additional language on managing vaccine expiration/inventory. Added language on process for wasting doses in I-CARE. Section 10: Added language on guidance on people vaccinated outside the US & coadministration. Section 14: Added additional language on V-safe after vaccination health checker.	Vaccination Section

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
			Appendix B: Added CDC COVID-19 Public Data Sets hyperlink. Throughout: Updated Pfizer 2c to 8c storage duration language from 5 days to 31 days.	

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 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/guidance 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 operations and tracking of the SARS-CoV-2/COVID-19 vaccine administration 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 indicated.
- 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 <u>training to vaccine providers</u> 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.
 - o Managing and reporting vaccine inventory via I-CARE and VaccineFinder.
 - Documenting and reporting vaccine wastage and spoilage.
 - o 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 LHDs to provide to vaccine recipients.
 - o 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.
 - Hotline: General Questions about COVID-19: 1-800-889-3931
 - o Hotline: COVID-19 Appointments: 833-621-1284 (TTY compatible)

Available Vaccines as of May 12, 2021

	Janssen (Johnson and Johnson)	Moderna	Pfizer (Pfizer-BioNTech)
Number of Doses Per Individual	1	2	2
Date of EUA	27-Feb-21	18-Dec-20	11-Dec-20
Diluent Requirement	No	No	Yes
Number of Doses Per Vial	5	10 up to 15*	6*
Storage Temperature Requirement	Refrigerated 2c to 8 c	Frozen -15c to -25c Refrigerated 2c to 8c	Ultra Cold -60c to -80c Frozen -15c to -25c Refrigerated 2c to 8c
Age Requirement	18 and Up	18 and Up	12 and Up

^{*}Please see Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management for more information.

Figure 1: Available Vaccines

Figure 1 shows the vaccine characteristics of the three approved vaccines, <u>Janssen (Johnson and Johnson) vaccine</u>, <u>Moderna vaccine</u>, and <u>Pfizer-BioNTech (Pfizer) vaccine</u>, issued EUA by the Food and Drug Administration (FDA).

Section 1: COVID-19 Vaccination Preparedness Planning

Initial 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 and state guidance on vaccine administration, storage, and handling by signing the COVID-19 Vaccination Program Provider Agreement with the CDC and the State of Illinois.
 - Vaccine providers will be allocated vaccine as it becomes available based on the overall jurisdiction's population size and disease burden, while ensuring <u>equity</u>.
 - Vaccine will be delivered via the Vaccines for Children (VFC) model, i.e., shipped directly to providers, when possible.

- o In the early phases of vaccine distribution for vaccines requiring ultra-cold (-80°C) temperature controls and the inability to distribute less than 1,170 doses, IDPH and IEMA will coordinate a centralized distribution model by modifying the state's SNS plan.
- o Vaccine providers will be required to enroll in VaccineFinder 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 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
 - The rest of the population aged 16 years and older. (Note: On May 12, 2021, the CDC adopted the recommendation of ACIP to expand use of the Pfizer vaccine for those 12 years and older)
 - 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.
- o 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 1,170-dose increments kitted with ancillary supplies.
- As of the date of this plan, COVID-19 vaccines are available in single dose or two dose increments depending on the type of vaccine administered.
- COVID-19 vaccines that require two doses, 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 be 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.
- o 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.
- o Demand for the pandemic vaccine may be high throughout the response.
- o Providers will follow state and 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 may be 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 2). With IDPH as the lead agency, 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 2, functions that interface with IEMA are signified 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 general staff 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 and federal government. 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.

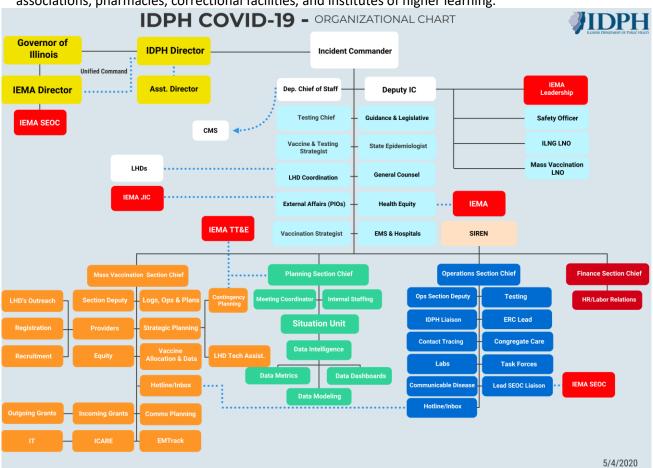


Figure 2: Illinois Department of Public Health Organizational Chart

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 response and vaccination operations 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.

Initially, IDPH utilized the recommendations from National Academies of Science, Engineering, and Medicine's (NASEM) <u>A Framework for Equitable Allocation of COVID-19 Vaccine</u> to inform the phased approach, before ACIP had released their recommendations. 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. Once ACIP released their recommendations, the COVID-19 Community Vulnerability Index (CCVI) was then leveraged to ensure an equity lens was utilized in vaccine allocation to pharmacies and other partners to provide vaccine access to hard-to-reach communities.

The following explains the phased approach per CDC and ACIP guidance, which are recommended based on "science, implementation, and ethics." Further ACIP recommendations were provided after the issuance of the EUA for vaccine candidates, which altered the phased approach by adding phases and/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 subphases: (Note: Phases may be adjusted based on continued guidance from CDC/ACIP)

Phase 1A

- Healthcare personnel
 - Hospital Settings
 - Non-hospital healthcare
 - Other Congregate Care
- Long-Term Care Facility residents and staff

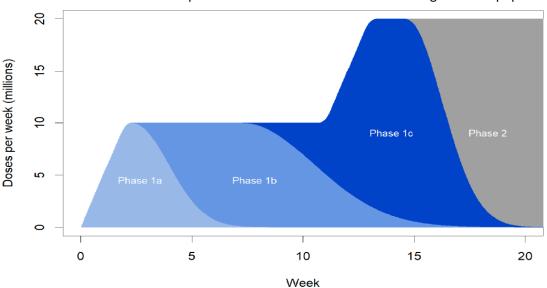
> Phase 1B

- Persons aged 65 years and older
- Frontline essential workers
- Incarcerated individuals

o Phase 1B Plus

- Persons aged 16 to 64 years with high-risk medical conditions
- Additional identified essential workers
- **Phase 2:** Larger number of vaccines are available. The focus is on ensuring access to vaccine for all populations 12 years of age and older.
- (Note: As of the date of this plan, only <u>Pfizer</u> has been authorized for those ages 12 years and older, whereas <u>Moderna</u> and <u>Johnson & Johnson</u> were authorized for those ages 18 years and up.)

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 lowincome 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, and as vaccine supply transitions from scarce to ample, jurisdictions should monitor their supply and adjust strategies to avoid vaccine waste and protect the valuable resource. Examples of this could be 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. As of the SIREN dated May 11, 2021, with updated guidance from IDPH & the CDC, providers should make every effort to vaccinate all eligible persons who present at vaccination locations. If providers need to puncture a multi-dose vial to administer vaccine to only one or a couple of patients, the provider should. Ultimately, the provider may need to waste some or all remaining doses in that vial; but at this stage in the pandemic response, it is critical that opportunities to vaccinate are not missed. 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 3: Example of a Phased Approach Provided by the ACIP

Section 4: Critical Populations

The CDC 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. Initially, IDPH utilized the recommendations from NASEM to ensure equity and inform the phased approach, before ACIP had released their recommendations. Once ACIP released their recommendations, the COVID-19 Community Vulnerability Index (CCVI) was then leveraged to ensure an equity lens was utilized in vaccine allocation to pharmacies and other partners to provide vaccine access to hard-to-reach communities. 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. All residents of Illinois, regardless of citizenship status, should have the opportunity to receive the vaccine, if they so choose, free of charge.

Ariadne Labs and the Surgo Foundation have developed a free <u>Vaccine Allocation Planner for COVID-19</u>, 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 utilized this tool for planning and 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 provide vaccine access to underserved populations for vaccinations within the priority groups. Community partners could include community-based organizations (CBOs) or social service organizations, faith-based organizations, YMCAs/YWCAs, fraternities/sororities, school organizations, meal delivery services, or senior centers. 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 immediately 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/region.
- 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. Outreach could include providing LTCFs with resources regarding <u>building vaccine confidence for LTCF residents and staff</u>.
- Partners that will be necessary to accomplish all aspects of the local plan (e.g., local law enforcement, local emergency management, local hospitals, municipal resources for snow removal, etc.).
- 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 PODs/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 nontraditional work hours.

Recommendations for Phase 1 subset groups include the following:

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. See Table 1 below for full list of
 Phase 1A eligible locations in LTC.
 - LTCF Staff: Nurses (RN, LPN), Nursing Assistants, Nursing Practitioners, Nurse's Aides, 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 Surveyors, 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 Aides, Physicians (DO, MD), Physicians Assistants, Medical Assistants, Respiratory Technicians, Pharmacists, Emergency Medical Technicians (EMTs) (including Fire Department 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 religious leaders.
 - Non-hospital health care: Nurses (RN, LPN), Nursing Assistants, Nursing Practitioners, Nurse's Aides, 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, Optometrists, COVID-19 Testing Staff, Dermatologists, Dialysis Staff, Urgent Care Workers, Corrections Nurses/Aides, Physical/Occupational/Speech Therapists, Vaccine Clinic Workers, and EMTs (including Fire Department EMTs and Air Medical Transport [rotor and fixed wing]).
 - Other Congregate Care: Nurses (RN, LPN), Nursing Assistants, Nursing Practitioners, Nurse's Aides, Physicians (DO, MD), Physicians Assistants, Medical Assistants, Respiratory Technicians, Group Home/Residential Staff, Pharmacists, Environmental Services Staff, Reception Staff, Home Aides/Caregivers, Corrections Nurses/Assistants, Congregate Care Surveyors, Hospice and Palliative Care Staff, and Community Health Workers when acting as health aids or health translators.
 - Note: See Table 1 below for Phase 1A eligible locations in LTC and Congregate Care.
- 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:

- o Cerebral Palsy
- o Down Syndrome
- o Epilepsy
- Specialized healthcare needs, including dependence upon ventilators, oxygen, and other technology

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

	Hospitals
Hospital Settings:	
Non-hospital Settings:	 Medical Outpatient Clinics Public Health Clinics Local Health Department Points of Dispensing (PODs)
Long Term Care	 Federally Qualified Health Centers (FQHCs) 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
Facilities:	 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 in "Other Congregate Care" are eligible for vaccination in 1A.

Adjusted for ACIP and CDC recommendations, Phase 1B has been split into two parts, Phase 1B and Phase 1B Plus

(Note: As of the date of this plan, only <u>Pfizer</u> has been authorized for those ages 12 and up, whereas <u>Moderna</u> and <u>Johnson & Johnson</u> were authorized for those ages 18 and up.)

- **Phase 1B:** 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, and 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 Service Drivers.
 - Education Workers (Congregate Childcare, Pre-K through 12th grade): Teachers, Principals, Support Staff, 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 Plus: 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, and <u>Pregnancy</u>.
 - o Persons with a disability (not otherwise covered in previous categories).
- As of March 22, 2021, the following priority groups will be eligible:
 - **Government Employees:** Federal, state, local, or municipal government employees not eligible under previous phases.
 - Higher Education Staff: Workers in educational institutions, including junior colleges, four-year colleges and universities, technical schools, trade schools, educational support services, and administration of education programs.

- News Media: Newspaper, television, radio, and other media services.
- As of March 29, 2021, the following priority groups will be eligible:
 - Food and Beverage Service Workers: Restaurants and other facilities that prepare and serve food (including bars) and entities that provide food services.
 - Religious Leaders
 - Construction Trades and Businesses Supporting Building and Infrastructure Repair

(Note: As of the date of this plan, only <u>Pfizer</u> has been authorized for those ages 12 and up, whereas <u>Moderna and Johnson & Johnson</u> were authorized for those ages 18 and up.)

- Phase 2: Effective April 12, 2021, all populations not specified above will be eligible for vaccine. On May 12, 2021, the CDC approved the Pfizer vaccine to include persons 12 through 15 years of age.
 - The rest of the population aged 12 years and older.

(Note: Once Phase 2 is opened, documentation for priority groups is no longer required.)

(Note: Individuals should check with their LHD or healthcare provider about whether a parent or guardian must be present for an individual under the age of 18 to receive the vaccine, or whether some other form of written consent is required.)

(Note: As of the date of this plan, only <u>Pfizer</u> has been authorized for those ages 12 and up, whereas <u>Moderna</u> and <u>Johnson & Johnson</u> were authorized for those 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	Health care personnel	Est. 540,000
1A	Long-term care facility residents & staff	Est. 340,000
1B	Frontline essential workers including first responders	Est. 1,400,000
1B	Persons aged 65 and older	Est. 2,000,000
1B Plus	People with high-risk comorbid conditions aged 16 to 64	Est. 3,400,000
2	Rest of population (aged 12+)	Est. 3,160,000

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 Care Facility Staff" and under "Healthcare Personnel"). Please note, the populations calculations do not include children under the age of 12.

Figure 4 below shows critical population by vaccine supply. Phase allocations may change based on further guidance from the CDC.

.2021	Critical Populations for Vaccine Allocation				
	Limited suppl	y of vaccine		Increased Supply of vaccine	
	Healthcare Workers & Long Term Care Facility Residents & Staff.	Persons 65+, Front Workers & Persons 16 risk medical co	6 to 64 with high-	The rest of the population aged 12 & up.	
	Phase 1a	Phase 1b P	art 1	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.	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 Plus Persons aged 16 to 64 years with high-risk medical conditions, which include; Obesity, Diabetes, Pulmonary Disease, Smoking, Heart Condition, Chronic Kidney Disease, Cancer, Immunocompromised State from a Solid Organ Transplant, Sickle Cell Disease, Pregnancy. Persons with Disability. (Not otherwise covered in previous categories.)		Note: As of the date of this document, only Pfizer has been authorized for those ages 1: and up, whereas Moderna and Janssen were authorized for those ages 18 and up.	
	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				
Pop.	880,000	3,400,000	3,400,000	3,160,000	

Figure 4: 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 focused on Federally Qualified Health Centers (FQHCs) and pharmacies, especially those in <u>rural areas</u> 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 access to many priority patients. In coordination with LHDs, the State of Illinois will also support the deployment of mobile vaccination teams able to conduct on-site vaccination events for populations that may not have ready access to another vaccine provider. Once hospitals and pharmacies are on-boarded, IDPH will begin focusing on 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. Visit the hyperlink for information on <u>vaccination locations in Illinois</u>. If a provider has a POD open to the public, it will be listed on that website.

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 two agreements: (1) the CDC and (2) the IDPH COVID-19 Vaccination Program Provider Agreements 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 <u>Pfizer vaccine</u>, 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." <u>Providers must complete the COVID-19 Provider Agreement as a requirement to administer the COVID-19 vaccination.</u>
- 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, as outlined in Section 4: Critical Populations.
- All entities must provide <u>training to staff</u> 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. 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 indicated, 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, that those fields should be sent to I-CARE. This data **is mandatory** for those entering data manually into I-CARE.

- All vaccine providers must report daily vaccine administration and on-hand inventory to IDPH through VaccineFinder 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, and all COVID-19 vaccine providers will receive an email from CDC/VaccineFinder on how to enroll into this program. The option for a site/POD to be visible on the VaccineFinder public-facing website is available; however, this is optional for the provider as a method 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 program.

CDC updated the *COVID-19 Vaccination Program Site Visit Reviewer Guides* for provider and depot locations. Training, site visits, and other oversight measures are essential for maintaining or improving providers' adherence to program requirements. Site visits to COVID-19 Vaccination Program locations within the State of Illinois will be conducted by IDPH.

Site Visit Requirements:

- IDPH will conduct on-site visits with a CDC-determined target number of enrolled provider locations with COVID-19 vaccine inventory by December 31, 2021.
- IDPH will visit all depots used to store or redistribute COVID-19 vaccine to multiple locations.
 - Per the CDC, IDPH is **not** required to visit providers receiving direct vaccine allocations from the federal government (e.g., LTCFs, federal pharmacy partners, IHS, VA, HRSA, etc.).
 - Per the CDC, IDPH is **not** required to visit provider locations receiving direct federal or split awardee/federal allocations.

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. This system is not intended for use by the general public.

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 COVID-19 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. Approximately ninety-nine percent of the long-term care providers in the State of Illinois were enrolled in the Federal Retail Pharmacy Partnership Program established by CDC and selected pharmacies to ensure residents and staff are vaccinated. As of the date of this plan, LTCFs across the state have received first doses and second doses are projected to be completed by March 31, 2021.

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

To assist with vaccination operations at POD sites, COVID-19 vaccine providers can use <u>Illinois Helps</u> 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 who 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.

Per CDC's updated <u>COVID-19 Vaccine Administration Fees Guidance</u>, all organizations and providers participating in the CDC COVID-19 Vaccination Program:

- **Must** administer COVID-19 vaccine at no out-of-pocket cost to the recipient.
- May not deny anyone vaccination based on the vaccine recipient's coverage status or network status.
- May not charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided.
- May not require additional medical services to receive COVID-19 vaccination.
- May seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient.
 - Vaccine recipient's private insurance company.
 - Medicare or Medicaid reimbursement.
 - o <u>HRSA COVID-19 Uninsured Program</u> for non-insured vaccine recipients.
 - Note: Providers may not charge the patient a Co-Pay.
- May **not** seek any reimbursement, including through balance billing, from the vaccine recipient.

For additional information on filing claims for reimbursement of COVID-19 vaccine administration fees, go to:

 CMS Guidance, which states: "Providers administering the vaccine to people without health insurance or whose insurance does not provide coverage of the vaccine can request reimbursement for the administration of the COVID-19 vaccine through the Provider Relief Fund."

CDC COVID-19 Training

The CDC has released <u>immunization education & training</u> for COVID-19 vaccine administration. The training includes four modules:

- 1. <u>COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare</u>
 Providers
- 2. Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know
- 3. Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know
- 4. Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Professionals Need to Know

Illinois National Guard

The Illinois National Guard (ILNG) Mass Vaccination Augmentation Team (MVAT) is capable of augmenting county public mass vaccination operations or deployable as a standalone package for remote vaccination, established under the oversight 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 mass vaccination surge capability. During the initial phases of state vaccination operations, the ILNG has the capability to deploy 25 teams of military personnel and medics providing up to 47,250 vaccinations per week. As operations continue, the ILNG has the capability to activate another 75 teams, augmented with contract medical personnel, to provide an additional capacity of 141,750 vaccinations a week. Oversight to the distribution of these resources across the state are made by the Illinois Department of Public Health in collaboration with other state partners and take direct orders from the Governor of Illinois. On the ground oversight is the responsibility of the respective Local Health Department, as the site functions under the LHD's COVID-19 Provider Agreement. Part of the oversight of the LHD is ensuring training/orientation and quality improvement methodologies are in place that are in line with established CDC guidelines and standards. The ILNG mission will be evolving over the course of the vaccination program and is tailored to best serve the residents of Illinois, such as ILNG mobile missions in rural counties across the state.

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 to evolve. On the ground oversight is the responsibility of the respective Local Health Department, as the site functions under the LHD's COVID-19 Provider Agreement. Part of the oversight of the LHD is ensuring training/orientation and quality improvement methodologies are in place that are in line with established CDC guidelines and standards.

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 <u>pharmacists</u>. Dentists can administer COVID-19 vaccines under supervision of the administering body upon completion of training outlined in the IDFPR proclamation.

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/Paramedic) and Emergency Medical Technicians – Intermediate (EMT-I), to vaccinate as approved by their EMS System Medical Director. According to an IDPH <u>Proclamation</u>, 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 <u>Pfizer</u> has been authorized for those ages 12 and up, whereas <u>Moderna</u> and <u>Johnson & Johnson</u> were authorized for those ages 18 and up.)

Additionally, EMS Systems should consider the need for just-in-time training that may specifically address the type of vaccine 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 COVID-19 vaccines from the CDC, or from the designated manufacturers. 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 or as operations dictate.

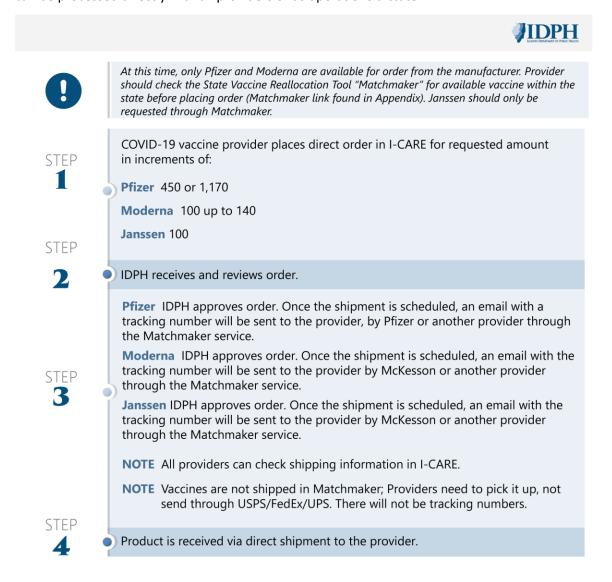


Figure 5: Illinois Department of Public Health COVID-19 Vaccination Allocation Steps

If COVID-19 Vaccine Providers have vaccine that they have identified are not needed for local operations, or if providers need additional vaccine, before placing an order through I-CARE, they should first consult the State Vaccine Reallocation Tool "Matchmaker" to receive or reallocate vaccine already in the state to prevent wastage.

See below on tracking order status in I-CARE:

- 1) In I-CARE, click on the COVID tab followed by the Vaccine Requests View. This section will list all orders that have been placed.
- 2) "Approved" means the order has been placed in I-CARE.

"Transmitted" means the order has been sent to CDC.

"Complete" means the order has been shipped by the distribution center.

Note: All of these processes are manual and require uploading and downloading files. They are **not** automatic.

For refrigerated and/or frozen vaccine, approved vaccine orders—including the adjuvant/diluent, 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 the Vaccine Tracking System (VTrckS). The <u>Vaccine Tracking System (VTrckS)</u> is a secure, federal, web-based information technology system that integrates the entire publicly funded vaccine supply chain from purchasing and ordering through distribution to participating state, local, and territorial health departments and healthcare providers. However, this timeframe is dependent on vaccine availability and on McKesson and the vaccine manufacturer's ability 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.

Per the CDC, adult ancillary supply kits shipped by McKesson will include the following:

Johnson & Johnson Vaccine adult 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 (sterile, individually sealed)

- 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.

Note: On April 13, 2021, the CDC issued a pause to the administration of the Johnson & Johnson Waccine in the USA, out of an abundance of caution. Effective April 23, 2021, the CDC and FDA lifted the recommended pause on Johnson & Johnson COVID-19 vaccine; use of the vaccine as of this date may resume. The FDA issued an EUA amendment for the Johnson & Johnson COVID-19 vaccine that includes warnings and precautions.

Moderna Vaccine adult ancillary supply kit for 100 up to 140 doses:

- 85 needles (22-25G x 1")
- 20 needles (22-25G x 1.5")
- 105 syringes (1mL or 3mL)
- 210 alcohol pads (sterile, individually sealed)
- 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 adult ancillary supply kit for 1,170 doses:

(Note: The original dose count of 975 was increased due to the 6th dose to 1,170 the week of February 15, 2021. As of May 25, 2021, Pfizer added the option of a new shipment of 450 doses; shipments will come as ordered in dose increments of 450 or 1,170. Note: If multiple 450 trays are ordered, the manufacturer may consolidate them into 1,170 trays)

- 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 mixing syringes (3mL or 5mL)
- 2,900 alcohol pads (sterile, individually sealed)
- 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.

Pfizer Vaccine ancillary supply kit for 450 doses:

(Note: As of May 25, 2021, Pfizer added the option of a new shipment of 450 doses; shipments will come as ordered in dose increments of 450 or 1,170. Vials will be shipped in the same thermal shipping container as the 1,170-dose orders and will include the same Controlant temperature monitor. Note: If multiple 450 trays are ordered, the manufacturer may consolidate them into 1,170 trays)

- 390 needles (22-25G x 1")
- 85 needles (22-25G x 1.5")
- 80 mixing needles (21-25G x 1.5")
- 475 syringes (1mL)
- 80 mixing syringes (3mL or 5mL)
- 1,200 alcohol pads (sterile, individually sealed)
- 450 vaccination record cards, for each vaccine recipient
- 75 diluent vials
- 4 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 20 surgical masks and 10 face shields.

Per the CDC, specifically for the Pfizer vaccine, the ancillary kit is designed to include 3 low dead-volume syringes (that permit an extra dose to be drawn) and 3 normal (non-low dead-volume) syringes with each vial. As long as 3 low dead-volume syringes are used per vial, an extra dose will be able to be drawn.

Beginning March 31, Pfizer started to provide retail pharmacies with 10mL single-use vials of diluent rather than the typical 2mL vials. Pharmacies will receive these 10mL diluent vials until inventory runs down, which will take approximately 9 weeks. The single-use vials cannot be punctured more than once due to the potential risk for cross-contamination. Per Pfizer, the vials should be discarded after withdrawing 1.8mL of diluent. Per Pfizer, these vials will be distributed through the retail pharmacy channel only.

Per the CDC, pediatric ancillary supply kits shipped by McKesson will include the following:

<u>Pfizer Vaccine</u> pediatric ancillary supply kit for 450 doses: (Note: As of May 12, 2021, the CDC approved the Pfizer vaccine to include those aged 12 through 15 years. The pediatric ancillary kit contains only 1" needles. Pediatric kits are only available with the 450 configuration. There are no pediatric kits with the Pfizer 1,170 configuration. All other supplies in the kit remain the same.)

- 475 needles (25G x 1")
- 80 mixing needles (21-25G x 1")
- 475 syringes (1mL)
- 80 mixing syringes (3mL or 5mL)
- 1,200 alcohol pads (sterile, individually sealed)

- 450 vaccination record cards, for each vaccine recipient
- 4 needle gauge and length charts
- 10 face shields
- 20 surgical masks
- 75 diluent vials

When placing orders, awardees should select an order intention of Adult or Pediatric for their Pfizer order. This information will determine which ancillary kit is shipped with the vaccine. This is a change from COVID-19 vaccine ordering since the program first started, for which all vaccines had to be ordered with an Adult order intention.

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. Minimum orders for ultra-cold vaccines that are shipped directly from the manufacturer will be 450 or 1,170 doses per package and will be shipped in special shipping containers containing dry ice to maintain the ultra-cold temperature. The new 450-dose pack includes 3 trays of 25 vials each. Vials will be shipped in the same thermal shipping container as the 1,170-dose orders and will include the same Controlant temperature monitor. The newly extended refrigerator storage temperatures (up to 31 days at 2°C to 8°C) should decrease the need for dry ice. Therefore, Pfizer asks that the shippers and Controlant monitors be returned within 10 days. There will be no dry ice replenishment for the 450-dose pack. Due to the limited allocations of the initial doses of ultra-cold vaccine, IDPH received most initial orders at a central location and re-distributed to LHDs, depending on their allocation, at refrigerated (2°C to 8°C) temperatures. The Pfizer COVID-19 vaccine vials must remain undiluted to remain at 2°C to 8°C for 31 days. The up to 31 days 2°C to 8°C storage duration must be within the labeled expiration date (i.e., not cumulative). Per the CDC, total cumulative storage time for Pfizer in freezer (-15°C to -25°C) and refrigerator (2°C to 8°C) should not exceed 45 days. Providers should use the entire first dose allocation and not hold back first doses of vaccine for a second dose, as the second doses will be provided closer to the time of its expected administration, per CDC guidance. It is important that providers do not hold second doses for an extended period of time; to accomplish this, planning is needed when ordering second doses to ensure they are not held for extended periods of time. If a vaccinator is unable to pull a full 6th dose for the Pfizer vaccine, it must be listed as "wasted" in I-CARE to ensure the inventory is accurate. The process for wasting doses in I-CARE can be found in the quick reference guide on the I-CARE homepage. It should be noted that Pfizer vaccine tray numbers were increased to 1,170 doses from 975 by the CDC, as of the week of February 15, 2021, which changed the 5-dose vial to a 6-dose vial. As of May 25, 2021, Pfizer added the option of a new shipment of 450 doses; so shipments may come in dose increments of 450 or 1,170. 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 or Johnson & Johnson vaccine with a diluent and do not pool vaccine to make additional full doses. Follow the hyperlinks for more information from the CDC regarding vaccine preparation and administration for Pfizer, Moderna and Johnson & Johnson vaccine.

Note: Ultra-cold Pfizer shipping containers should be returned to Pfizer once they are no longer in use.

Pfizer provides these instructions on the return process.

Note: If multiple 450 trays are ordered, the manufacturer may consolidate them into 1,170 trays

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 COVID-19 vaccine providers. During initial rollout when vaccine is scarce, LHDs will determine the allocations 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 Health Departments 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 for Phase 1A, and then total population from Phase 1B forward.
- 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 COVID-19 vaccination operations in the state. 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/strategy 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 are 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 as required by the CDC 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 immunization 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.

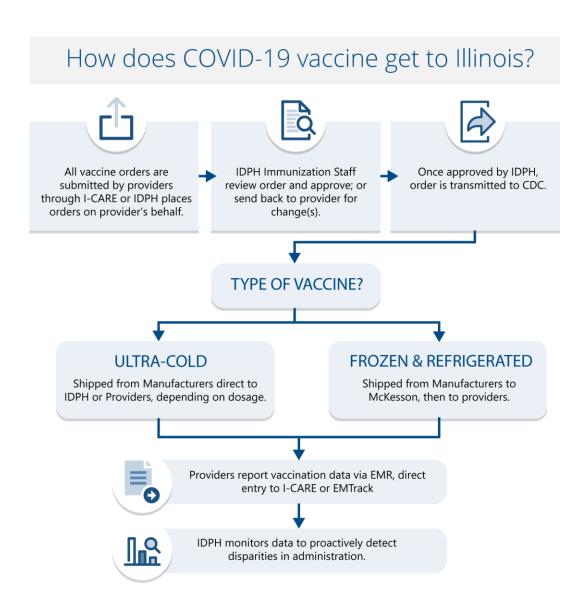


Figure 6: COVID-19 Vaccinations Transportation

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

Tier 1 for refrigerated, frozen & ultra-cold 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 redistribution 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 for refrigerated & frozen vaccine.
- 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 redistribution for administration.
- LHDs may redistribute vaccines while maintaining the cold chain. With the challenge of meeting cold chain requirements, LHDs should limit any redistribution to refrigerated vaccines only, unless specialized equipment is available.
- Any necessary further redistribution to sub-sites within the local jurisdictions is determined by the LHD and its community partners as part of that agency's COVID-19 vaccination plan.
- o 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 vaccine 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") was executed for initial distribution of ultra-cold vaccine using a modified version of the State Strategic National Stockpile Plan, due to the scarcity of vaccine supply to the State of Illinois and the initial minimum order size of 975 doses, which was updated to 1,170 doses the week of February 15, 2021, to ensure widescale vaccine distribution without vaccine waste. As of May 25, 2021, Pfizer added the option of a new shipment of 450 doses; so shipments may come in dose increments of 450 or 1,170. This model also ensured 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. (Note: Pfizer 450 doses trays will be packed on dry ice, but will not include dry ice replenishment.)
 - Jurisdictions not meeting the 450 or 1,170 minimum dose allocation can still receive vaccine.
- For providers that will be allocated at least 450 or 1,170 doses of the <u>Pfizer vaccine</u> and/or in increments of 450 or 1,170, 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. (Note: Pfizer 450 doses trays will be packed on dry ice, but will not include dry ice replenishment.)

- For those receiving direct shipment of Pfizer, approximately 1 day after vaccine arrival, an additional shipment will arrive and will consist of:
 - Dry Ice Pellets for 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 450-dose or 1,170-dose level. Otherwise, the vaccine 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-RSS.
 - 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 warehouse management system (WMS) 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 team the allocations of vaccines to begin repackaging for delivery.
- The IDPH RSS has implemented revised shipping processes for Pfizer vaccine that will allow expanded storage and shipping options. Effective as of April 12, 2021, Pfizer from the RSS will be shipped **frozen** (-25°C to -15°C) on dry ice. (Note: Pfizer 450 doses trays will be packed on dry ice, but will **not** include dry ice replenishment.) This allows the following storage options upon receiving Pfizer vaccine from the RSS:
 - 1) **RETURN to ULTRA-LOW TEMPERATURE FREEZER (-80°C to -60°C):** Vials shipped/stored at frozen temperatures may be returned 1 time to the recommended storage condition of -80°C to -60°C until the expiry date printed on the label, as per Pfizer. A temporary option would be to store the vaccine in the Pfizer thermal shipper with regular dry ice replenishment.
 - 2) VACCINE FREEZER (-15°C to -25°C): Vials may be stored frozen for up to 2 weeks. Any hours used for transport from the RSS count against the 2-week limit for storage at -15°C to -25°C. Total cumulative time the vials are transported and/or stored at -15°C to -25°C should be tracked and should not exceed 2 weeks, as per Pfizer.

3) VACCINE REFRIGERATOR (2°C to 8°C): Thawed, undiluted vials can be stored in the refrigerator (2°C to 8°C) for up to 31 days, as of May 19, 2021 (previously 5 days or 120 hours). Do not refreeze thawed vials, as per Pfizer.

Note: Vaccine shipping from the RSS will likely have DDL temperature readings below -25°C to -15°C. This is expected as the temperature is rising from -80°C to -60°C ultra-low temperature freezers at the RSS. The 2-week countdown starts as soon as the vaccine is removed from ultra-low temperature freezer at the RSS, which is written with date and time on a label affixed to the outside of the shipping box. Total storage time for Pfizer in freezer and refrigerator should not exceed 45 days.

- o 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 1-month window to use the Pfizer vaccine at the refrigerated temperature of 2°C to 8°C. Vaccine cannot be re-frozen. The date and time of packaging will be noted on the shipper.
 - 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.)

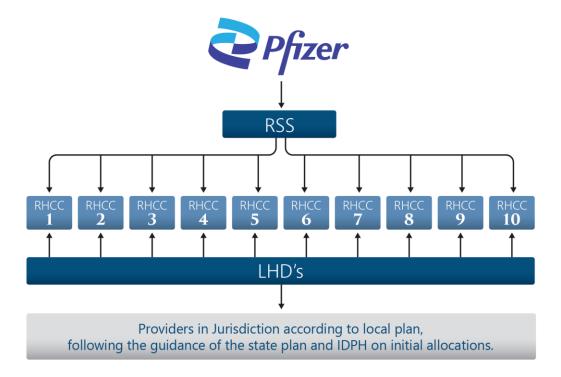


Figure 7: Vaccine Distribution

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 daily inventory of COVID-19 vaccines in VaccineFinder. Additional doses gained from vaccine vials should also be reported in I-CARE to ensure inventory is increased to account for additional doses drawn from vaccine vials (as of the date of this plan, the CDC has only approved the use of extra doses from Pfizer & Moderna 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.

In order to minimize the number of unused expired doses and manage expired doses correctly, CDC encourages jurisdictions and providers to:

 Monitor expiration dates weekly, rotate stock as needed, and follow a "first in, first out" strategy to manage inventory.

- If nearing expiration, check posted manufacturer information for the most up to date expiration/extension information for vaccine lots.
- Based on the latest expiration information, REMOVE expired vaccine from the storage unit IMMEDIATELY. Do not give staff opportunity to administer expired vaccine.
 - o If expired vaccine is inadvertently administered, it is considered a vaccine administration error and requires remediation including a VAERS report, contacting the recipient to inform them of the error, and may or may not require revaccination based on the manufacturer's guidance. Guidance on vaccine administration errors can be found in Appendix A of the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.
 - Expired vaccine should be wasted according to wastage protocols and not sent back to the manufacturer in the vaccine shippers.
- Check vaccine stock using CDC's Vaccine Lot Number and Expiration Date webpage.

If COVID-19 Vaccine Providers have vaccine that they have identified are not needed for local operations, or if providers need additional vaccine, before placing an order through I-CARE, they should first consult the State Vaccine Reallocation Tool "Matchmaker" to receive or reallocate vaccine already in the state to prevent wastage.

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).



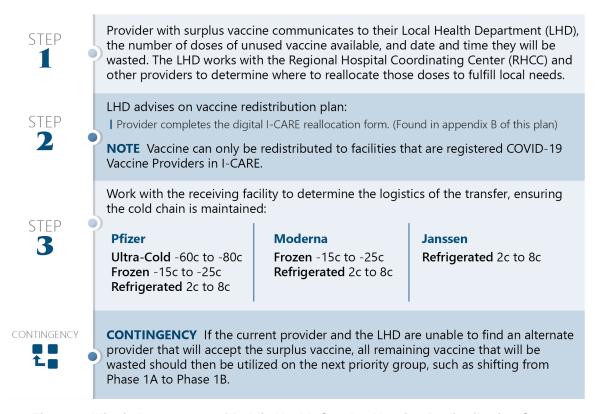


Figure 8: Illinois Department of Public Health Surplus Vaccine Redistribution Steps

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 to providers within the state. 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.

If COVID-19 Vaccine Providers have vaccine that they have identified are not needed for local operations, or if providers need additional vaccine, before placing an order through I-CARE, they

should first consult the <u>State Vaccine Reallocation Tool</u> "Matchmaker" to receive or reallocate vaccine already in the state to prevent wastage.

Note: If providers are contacted by research firms requesting vaccine, they should be directed to the US Health and Human Services (HHS).

Pfizer Thermal Shipping Containers

Ultra-cold Pfizer shipping containers should be returned to Pfizer once they are no longer in use. Pfizer provides these instructions on the return process.

Additional Doses

According to the FDA, the <u>Pfizer vaccine</u> comes in multidose 6-dose vials. Vials of Pfizer COVID-19 Vaccine may contain 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. As of March 31, 2021, per the <u>HCP Fact Sheet</u>, there is a new maximum 15-dose vial presentation with ranges for the Moderna vaccine (see table attached to hyperlink). Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum 11-dose vial or more than 14 doses from the maximum 15-dose vial. Irrespective of the type of syringe and needle, each dose must contain 0.5 mL of vaccine. Do **not** pool excess vaccine from multiple vials. Pierce the stopper at a different site each time.

Other key changes from the Moderna EUA Provider fact sheet:

- Lower limit for frozen temperature now -50°C (previously -25°C). **WARNING:** Use of dry ice may subject vials to temperatures colder than -50°C.
- Unpunctured vials may be stored between 8°C and 25°C for a total of 24 hours (previously 12 hours).
- After puncture, the vial should be held between 2°C and 25°C. Discard 12 hours after the first puncture (previously 6 hours).
- Thawed vials can be handled in room light conditions.

See the updated Recipient Fact Sheet for updates for Moderna vaccine recipients.

Per the FDA and the CDC:

- If the amount remaining in the vial, after the 6 doses (Pfizer) or 10 up to 15 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.
- As of the date of this plan, the CDC has not authorized the use of additional doses of <u>Johnson & Johnson vaccine</u> above the 5 doses in the vial. Do NOT use extra doses from Johnson & Johnson vials.

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. See this Department of Defense memo for more information.

- Action 1: All used/depleted vials should be disposed of in medical sharp's container following disposal protocol.
- Action 2: Destroy/shred/deface all materials (packaging/boxes/items with logos) so it cannot be reintroduced or reproduced. After the products are sufficiently destroyed/defaced, then dispose with regular waste.
- Pfizer trays "pizza boxes" should be destroyed/shredded before being disposed.
- All Pfizer shipper boxes should be shipped back to Pfizer utilizing the return mail label included with the shipment. Pfizer provides these <u>instructions</u> on the return process.

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, specific to each vaccine (Pfizer, Moderna, and Johnson & Johnson). 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 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. See CDC's Quick Reference Guide for Healthcare Professionals for basic information on proper storage, preparation, and administration of the currently authorized COVID-19 vaccine products in the United States.

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. (Note: Pfizer 450 doses trays will be packed on dry ice, but will **not** include dry ice replenishment.) 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. The majority of 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 within the State of Illinois. 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 first dose allocation and **not** hold back first dose 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. When notified second doses are available for order, only order second doses when they can be administered to ensure they are not held for long periods of time.

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 centralized distribution of ultra-cold vaccine and can also act as contingency should ultra-cold vaccines need to be stored.

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

- The quantity of COVID-19 vaccine transported to a satellite, temporary, or off-site COVID-19 vaccination clinic will be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and possibly transport the vaccine appropriately. This is essential to minimizing vaccine wastage and spoilage.
- COVID-19 vaccines may be transported—not shipped—to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. The procedures will include transporting vaccines to and from the provider site at appropriate temperatures, using appropriate equipment, and monitoring and documenting temperatures. Visit the hyperlink for more information on transporting Johnson & Johnson vaccine for vaccination clinics held at satellite, temporary, or off-site locations.
- 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. The vaccine should be segregated until cleared for use by the manufacturer or the CDC.

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

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

Unplanned Vaccine Repositioning

Before movement of any vaccine for redistribution, providers must submit a request to the immunization program by filling out the <u>I-CARE Redistribution Form</u> (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 always remain with the vaccine 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 #8 above "Surplus Vaccine Redistribution Steps").

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 discussed above. 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 from the CDC and daily inventory reported by COVID-19 Vaccine Providers in the VaccineFinder system. These numbers are 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 the 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:
 - o 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 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 and 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, regional, 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 approved COVID-19 providers in the State of Illinois and includes:

- 1. A portal for individuals/patients, who qualify in the given phase, to register and self-attest to the priority group they belong to and pick an appointment time. 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, if a second dose is indicated depending on the type of vaccine.
- 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, please visit the <u>IDPH Point of Dispensing Online Training Center</u>. The password for initial POD registration was distributed via a SIREN on January 6th. You can request the password from <u>DPH.Covid.Vaccination@Illinois.gov</u> via your agency email account, if needed.

Note: If you are having trouble with EMTrack app functioning at your POD, first try logging off, closing the app, restarting the app and logging back on before contacting technical support.

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.
- While vaccine supply is limited, LHDs should ensure that individuals in earlier priority groups have an opportunity to be vaccinated prior to using vaccine for closed PODs for lower risk groups.

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, if a second dose is indicated.

POD Flow – Standard Registration / Check In Screening Vaccination Observation Check out / Discharge • Each Station Requires at least staff member • Best separation of tasks • Can optimize based on throughput • Each station can be scaled • One Registration station • One Screening station • Three Vaccination stations (etc)

Figure 9: Providers' Process at the Point of Dispensing

Process Review

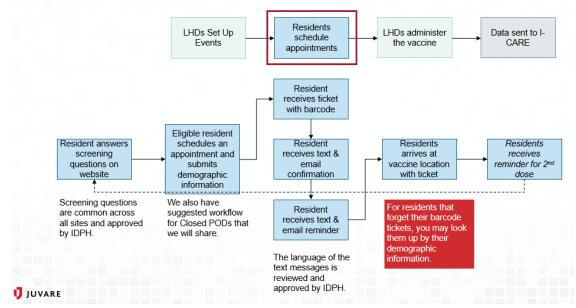


Figure 10: Individual's Process in Registering to Receive Vaccine and Reminder for 2nd Dose

Visit the CDC <u>Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site</u> 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 first dose allocation from the state vaccine distribution program completely without the concern of preserving a second dose. The goal for IDPH is to limit waste and give access to vaccine to as many people as possible. If a provider is done with the current phase of the Vaccination Program within their jurisdiction to the appropriate priority group and vaccine will be wasted/expire, 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] 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 and Moderna COVID-19 vaccines may be scheduled up to 6 weeks (42 days) after the first dose. There is 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, and IDPH will provide technical assistance as needed to the LHDs. 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.

As of June 2, 2021, COVID-19 vaccines may be coadministered with other vaccines without regard to timing. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, as well as coadministration within 14 days. Per the CDC, it is unknown whether reactogenicity of COVID-19 vaccine is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines. When deciding whether to coadminister vaccine(s) with a COVID-19 vaccine, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

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, if a second dose is needed. 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 included vaccination record cards with vaccine shipments. Providers will be required to provide vaccination cards to those receiving their COVID-19 vaccination. The card will include the vaccine manufacturer name, vaccine lot number, date of vaccination, and the date to return for your second dose, if required. If the COVID-19 vaccine you receive requires two doses, patients should bring their vaccination record card to their second appointment. To obtain vaccination records, patients may:

• Vaccination records can be requested via a <u>form on the I-CARE website</u>

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.

Visit the hyperlink for CDC guidance on once you have been fully vaccinated.

In addition, visit the hyperlink for <u>CDC guidance on people vaccinated outside the United States</u>.

VaxText

The <u>VaxText</u> text messaging resource is a free/voluntary service offered to vaccine recipients by the CDC. The <u>VaxText</u> 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). Per the CDC, the <u>VaxText</u> 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 8, 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 data. 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 the inventory. Additionally, daily on-hand inventory must be reported through VaccineFinder. 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.).

Note: EMTrack will continue to function if I-CARE is not available.

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 VaccineFinder 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, resources for employers and employees, potential impacts of emerging variants, 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.

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. The toll-free Vaccine Appointment Call Center phone number is **833-621-1284** and it can take TTY calls.

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 <u>FDA</u> 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 and COVID-19 Vaccine Providers 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 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 <u>CDC</u> <u>guidance for anaphylaxis</u>, including having the necessary supplies available to manage anaphylaxis.
- o Communicate with patients on vaccine safety.
- o Communicate with patients on <u>vaccine effectiveness</u>.

V-safe

<u>V-safe</u> 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 <u>V-safe</u>, 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 <u>V-safe</u>, reminders will be sent to the individual that it is time for their second COVID-19 vaccine dose, if necessary. V-safe information is translated into <u>English</u>, <u>Korean</u>, <u>Chinese</u> (<u>Simplified</u>), <u>Spanish</u>, and <u>Vietnamese</u>.

COVID-19 vaccine providers should **encourage** their vaccine recipients to use V-safe to report adverse events. To do this, vaccine providers are strongly encouraged to include the V-safe handout with the vaccine EUA fact sheet and VAERS handout in vaccine recipient materials.

As of May 20, 2021, parents and guardians can enroll adolescents (ages 12 and older) in the <u>V-safe after</u> vaccination health checkersM and complete health check-ins on their behalf after COVID-19 vaccination.

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, per CDC requirements, will perform quality control reviews of 25% of COVID-19 vaccine providers by December 31, 2021. Additionally, IDPH will provide site assessments to 100% of COVID-19 vaccine providers by the date the CDC requires, which as of the date of this plan is forthcoming.

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 is a federal system, which 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 run reports using IIS data to generate a list of providers who have not accepted an order into their inventory within 7 business days, as needed/indicated. This information will be sent to ordering staff for follow-up with the provider. The staff will 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 procedures 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 CDC and 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

CBO - Community-Based Organization

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

FDA - Emergency Use Authorization

FDA - U.S. Food and Drug Administration

FEMA - Federal Emergency Management Agency

FQHC - Federally Qualified Health Centers

GIS - Geographic Information System

HHS - Health and Human Services

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: Useful Resources

CDC Toolkits:

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

CDC COVID-19 Public Data Sets:

Data | Centers for Disease Control and Prevention (cdc.gov)

COVID-19 Vaccine Reallocation Tool "Matchmaker:"

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

State of Illinois Vaccination Statistics Dashboard:

https://www.dph.illinois.gov/covid19/vaccinedata?county=Illinois

Statewide Metrics: http://dph.illinois.gov/statewidemetrics

Vaccine Allocations: https://www.dph.illinois.gov/covid19/vaccineallocations

State of Illinois COVID-19 Statistics:

https://www.dph.illinois.gov/covid19/covid19-statistics

Future Versions of this plan will be posted at:

https://www.dph.illinois.gov/covid19/vaccination-plan