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COVID-19 Mass Vaccination Guidance for Providers

The Illinois Department of Public Health (IDPH) Office of Health Protection (OHPT) Immunization Section and the IDPH Office of Preparedness and Response (OPR) Medical Countermeasures Program are leading the development of the State of Illinois' COVID-19 Vaccination Plan (Plan), which is being implemented by state and local partners. This COVID-19 Mass Vaccination Guidance for Providers (Guidance) should be read in conjunction with Illinois' Plan, including any subsequent updates to the plan. This Guidance provides instructions for all potential provider organizations (providers), including but not limited to local health departments (LHDs), hospitals, Federally Qualified Health Centers (FQHCs), and other healthcare entities capable of administering COVID-19 vaccines and is subject to change as the vaccines become more widely available.

I. Registration for COVID-19 Mass Vaccination

All COVID-19 vaccine providers must enroll in the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE). By enrolling in I-CARE, a provider is agreeing to the terms and conditions of the I-CARE system. I-CARE will be used for enrolling providers, tracking vaccine administration, and submitting orders for additional vaccines. Providers are also required to register for SIREN notifications as described in Section VI.

Providers that are currently enrolled in I-CARE should complete the following steps:

1. Visit the I-CARE home page and follow the step-by-step instructions for providers on the application process to become a COVID-19 vaccine provider.
2. Complete the Vaccine Provider Enrollment Form on I-CARE for IDPH approval for each site/location at which the provider will administer or store the vaccines.
3. Under "announcements," follow the instructions to complete the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccine Provider Agreement (CDC Provider Agreement).
4. Access the IDPH COVID-19 Vaccine Provider Agreement (IDPH Provider Agreement) in [smartsheets](#) and upload an executed copy.

In addition to the steps outlined above, providers that are not currently enrolled in I-CARE must do the following:

1. Establish an account with I-CARE.
2. Complete the application for Web Portal Access.
3. Determine how many users at provider's site will need access to I-CARE for purposes of entering, managing, and accessing data.
4. Complete Web Portal Access for each individual I-CARE user.
5. Access the IDPH Provider Agreement in I-CARE and upload an executed copy.

Once providers are enrolled in I-CARE and have completed their CDC Provider Agreement and IDPH Provider Agreement, IDPH will review all completed forms. If IDPH approves the forms, it will assign the provider a COVID ID/PIN. Providers will know they have been assigned a COVID ID/PIN in I-CARE when it appears in I-CARE under the COVID tab after logging into the system.

Providers may also refer to the IDPH Decision Tree for Access to I-CARE for COVID Mass Vaccination Planning, which is attached to this Guidance.

II. Vaccinator Training Requirements and Modules

All providers must provide training to staff assigned as vaccinators and to other staff members assigned to assist with vaccine administration operations. Specifically, prior to administering a COVID-19 vaccine, healthcare professionals must complete comprehensive, competency-based training in vaccine administration policies and procedures. Providers should validate their healthcare professionals' knowledge and skills regarding vaccine administration using a skills checklist and should monitor such knowledge and skills using quality improvement processes. The CDC has created COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals that contain various training modules for healthcare professionals administering the vaccine available at:

<https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf>.

Healthcare professionals must be authorized within their scope of practice to administer COVID-19 vaccines, including but not limited to licensed physicians, nurses, medical assistants, dentists, pharmacists, certain EMS personnel, and other categories of healthcare personnel who are appropriately trained.¹

III. Obligations of COVID-19 Vaccine Providers

A. Compliance with the CDC COVID-19 Vaccine Provider Agreement

Providers must complete the CDC Provider Agreement and be approved by IDPH prior to receiving COVID-19 vaccines. The CDC Provider Agreement requires providers to adhere to all CDC standards and public health authorities' vaccine prioritizations.² Providers are encouraged to have their legal counsel review the CDC Provider Agreement to ensure that the provider understands all terms and obligations. Providers must institute practices to avoid any actual or potential risks to the safe, proper, and effective use of any COVID-19 vaccine during this public health crisis. The following highlights some of the CDC Provider Agreement's key requirements for providers:

- The CDC Provider Agreement contains a critical requirement relating to storage and handling of COVID-19 vaccines. Specifically, providers are required to maintain cold chain conditions and chain of custody in accordance with the manufacturer's package insert while following the CDC's Vaccination Storage and Handling Toolkit. Providers must take all necessary steps to ensure that COVID-19 vaccines are kept securely within any required temperature conditions to avoid any mishandling, contamination, or waste.

¹ <http://dph.illinois.gov/covid19/vaccine-faq>

² <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>

- The CDC Provider Agreement also mandates that **within 24 hours** of administering a COVID-19 vaccine, the provider must record the vaccination in the recipient’s record pursuant to state and local law. As discussed in Section III.D below, IDPH requires that all providers report vaccine administration within 24 hours into both I-CARE and the CDC’s VaccineFinder to keep an accurate record of vaccinations occurring throughout the State of Illinois.
- The CDC Provider Agreement also requires the provider to disclose informational materials (e.g., Emergency Use Authorization fact sheets) to vaccine recipients and comply with the prioritization plans for vaccination as determined by public health authorities (i.e., CDC/Advisory Committee on Immunization Practices (ACIP), state/territorial health departments in coordination with the state/territorial governor).

B. Compliance with the IDPH COVID-19 Vaccine Provider Agreement

In addition to the CDC Provider Agreement, providers are also required to sign and submit the IDPH Provider Agreement. Among other things, in the IDPH Provider Agreement, providers must certify that they will comply with all requirements in the CDC Provider Agreement, the Illinois Plan, IDPH SIREN Alerts, and applicable state and federal laws, regulations, and policies relating to COVID-19 vaccination. This includes but is not limited to compliance with the requirements for (a) receiving, handling, storing, and administering COVID-19 vaccines; (b) reporting complete and accurate information into any required state or federal reporting and tracking systems; and (c) prioritization for vaccine administration set forth by IDPH in the Illinois COVID-19 Vaccination Plan.

C. Compliance with Prioritization of Vaccine Allocation and Administration

The Plan, the CDC Provider Agreement, and the IDPH Provider Agreement require providers to follow prioritization plans set by CDC, ACIP, and IDPH. While the State is moving towards completion of Phase 1a by mid-January 2021, it will continue to make determinations on the next phases in light of variances from ACIP and any other state/local needs. Phases are subject to change and providers will be notified of such changes via the SIREN system and updates to the Plan. IDPH encourages all providers to ensure they and their health care worker providers are also vaccinated.

D. Compliance with Patient Tracking and Reporting Requirements

Providers are required to report vaccine administration as follows:

(1) I-CARE or EMTrack

- a. I-CARE – As stated above, all providers must enroll in I-CARE to be eligible to receive the COVID-19 vaccination. For overall patient tracking in Illinois, IDPH will use I-CARE to track individual patient information and send reminders for additional doses. Providers must report patient-level information into the I-CARE system within 24 hours of vaccine administration.
- b. EMTrack – Alternatively, providers may choose to utilize EMTrack Testing and Vaccination Module for reporting and scheduling vaccine administration. EMTrack will automatically upload the required information to I-CARE. Even if a provider reports vaccine administration via EMTrack, the provider must be enrolled in I-CARE and providers must report vaccine administration into both the I-CARE system and EMTrack within 24 hours.

- (2) CDC's Vaccine Finder- In addition to I-CARE and EMTrack, providers must use the CDC's VaccineFinder for tracking inventory to keep an accurate record of vaccinations occurring throughout the State of Illinois. VaccineFinder will prompt the provider to register upon the provider's receipt of the first shipment of the COVID-19 vaccine. Providers must ensure that data is reported into VaccineFinder within 24 hours.

IDPH will be continually monitoring the timeliness and completeness of data reports and will notify the CDC if providers fail to provide accurate information within the required timeframes. IDPH will update the required reporting frequency and data metrics as more guidance is received from CDC. Providers are expected to also comply with any other reporting obligations initiated by IDPH as mass vaccination rollout continues throughout the State. Failure to complete required surveys and report data as requested may be viewed as a violation of the IDPH Provider Agreement.

IV. Provider Vaccination Plan

All providers should have plans in place to receive COVID-19 vaccines and ancillary supplies for centralized distribution and distribution at designated sites. Providers receiving shipments through redistribution and not directly from IDPH must complete all requirements outlined in this Guidance and in accordance with DPH's Plan, including submitting all necessary and complete information on the Illinois COVID-19 Redistribution Log to IDPH. The COVID-19 Redistribution Log is attached to this Guidance.

V. Provider Requirements Regarding Administration of Second Doses of COVID-19 Vaccination

At the time of administration of the first dose of a COVID-19 vaccine, providers must provide each vaccine recipient with documentation that includes the manufacturer name, lot number, dose, site, date of the first vaccine, and the date when the second dose should be administered, if applicable. This documentation may be a COVID-19 vaccination record card provided as part of vaccine ancillary kits by the CDC, a vaccination record card provided by IDPH, or a printed copy of proof of vaccination from the provider's electronic health records or I-CARE. The CDC COVID-19 vaccine verifications and reminder cards will be included in the ancillary supply kit shipments from McKesson. IDPH encourages providers to schedule the patient's second-dose appointment at the time the first dose is delivered and to use the reminder/recall function in I-CARE.

VI. SIREN Registration Required

Providers must be registered in the Illinois Health Alert Network – HAN/SIREN (SIREN) to receive vaccine guidance and critical updates on the administration of COVID-19 vaccines. SIREN is a statewide, web-based solution for quickly and effectively disseminating health information, issuing 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 receive updates on the COVID-19 mass vaccination mission. All providers must comply with any SIREN alerts or guidance documents related to COVID-19 vaccination.

For SIREN registration, please use this link to guide you to the correct registration instructions for your public health related classification: <http://www.dph.illinois.gov/siren>. Please email dph.siren@illinois.gov for any questions or concerns.

VII. IDPH Oversight of COVID-19 Vaccination

IDPH will monitor daily reports from I-CARE, VaccineFinder, EMTrack, and the Vaccine Adverse Event Reporting System (VAERS) to ensure providers are in compliance with the necessary requirements. IDPH will regularly review reports from these systems to identify how many vaccines have been administered by each provider, how many vaccines are in current inventory, and to compare vaccination administration with documentation timestamps. IDPH may investigate any potential violations, including, but not limited to, any vaccine-related incidents, temperature excursions, unaccounted/missing inventory, waste, or improper redistribution, failure to follow prioritization plans, or receipt of redistributed vaccines without prior approval and acknowledgement of IDPH.

As stated in the IDPH Provider Agreement, IDPH may suspend or terminate providers from the I-CARE system and deny future requests for COVID-19 vaccines if providers fail to comply with the requirements of the Plan, the CDC Provider Agreement, the IDPH Provider Agreement, IDPH SIREN alerts relating to COVID-19 vaccination, and applicable state and federal laws, regulations, and policies.