# COVID-19 VACCINE PROGRAM ENROLLMENT INSTRUCTIONS

- 1) Complete a CDC COVID-19 Provider Agreement (Section A) for each organization receiving COVID-19 vaccines
- 2) Complete a CDC COVID-19 Provider Profile (Section B) for each facility location that will administer the vaccines received by the organization

COVID-19 Enrollment Link and instructions for completion

3) Complete a CDC Supplemental COVID-19 Vaccine Redistribution Agreement if redistributing COVID-19 vaccines-REQUIRED IF REDISTRIBUTING VACCINE- email completed form to <a href="mailto:Rachel.odom@arkansas.gov">Rachel.odom@arkansas.gov</a>.

# CDC COVID-19 Vaccine Redistribution Agreement

There must be a signed CDC Supplemental COVID-19 Vaccine Redistribution Agreement for each facility/organization conducting vaccine redistribution and a fully completed CDC COVID-19 Vaccination Provider Profile Information form for each receiving vaccination location.

4) Complete a WebIZ registration for the facility and a WebIZ registration for each staff member at the facility (REQUIRED). If your facility or staff member is already registered in WebIZ, please do not submit a new registration.

Register for WebIZ

### All COVID-19 vaccinations must be entered into WebIZ within 24 hours of administration.

- 5) Identify a Primary and Back-up Vaccine Coordinator to monitor and manage the vaccine inventory.
- 6) Complete required trainings
  - WebIZ training

WebIZ website

Complete the following trainings. These trainings are also found in the WebIZ Reports section under "Arkansas WebIZ Training Materials and Documents".

- WebIZ General User Training
- WebIZ Inventory Reconciliation Power Point
- WebIZ Inventory Reconciliation Instructions and Tips
- WebIZ Inventory Training
- Vaccine Storage and Handling Training- You Call the Shots (at a minimum, the primary and back-up vaccine coordinators must complete these trainings)

CDC's You Call the Shots website

- Complete the module "Vaccine Storage and Handling" and submit certificate of completion to <u>rachel.odom@arkansas.gov</u> or the ADH WebIZ help desk at <a href="http://adhimmiregistry.hesk.com">http://adhimmiregistry.hesk.com</a>.
- COVID Vaccine Training
  - CDC Storage and Handling Toolkit- COVID Vaccine Addendum Vaccines Storage and Handling Toolkit | CDC
  - CDC'S COVID vaccine training module https://www2.cdc.gov/vaccines/ed/covid19/
- Off-site clinic training (if applicable)
  - Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations (CDC)
  - CDC Off-Site Vaccination Clinic Checklist
- If redistributing vaccine, review information on vaccine transport from CDC.
  - CDC Vaccine Storage and Handling Website
  - Refrigerated Vaccine Transport

7) Confirm your facility has the appropriate vaccine storage and temperature-monitoring equipment

#### **Vaccine Storage Requirements**

- o Refrigerated vaccines-
  - Standalone refrigerator
  - Pharmaceutical/Purpose-built refrigerator
  - NO dorm-style refrigerators allowed, even for temporary storage
  - If using a combination refrigerator/freezer, the freezer portion of storage unit must not be used if storing refrigerated vaccines in the refrigerator portion
- Frozen vaccines-
  - Stand-alone freezer
  - Pharmaceutical/Purpose-built freezer
  - You may NOT use the freezer portion of a dorm-style refrigerator to store frozen vaccines
- o Ultra-cold vaccines-
  - Ultra-cold freezer that can maintain temperatures between -60°C and -80°C
  - Ultra-cold shipping container may be used for up to 10 days to store ultra-cold vaccines; shipping container storage instructions must be followed
    - INSERT LINK TO SHIPPING CONTAINER STORAGE INSTRUCTIONS
  - The ultra-cold shipping container MUST be returned to the manufacturer no later than 20 days after receipt.
  - Return instructions for the shipping container will be available with the shipping container

Storage Unit Resource: AAP Immunization Resource: Refrigerators, Freezers, and Vaccine Storage

## **Temperature-monitoring requirements**

- All refrigerated and frozen COVID-19 vaccines must be monitored using a digital data logger with a current Certificate of Calibration.
- Ultra-cold COVID-19 temperature-monitoring requirements are under review
- Vaccine storage temperatures must be reviewed and documented at the beginning and ending of each clinic day; vaccine storage minimum and maximum temperatures must be documented at the beginning of each clinic day and the minimum and maximum temperatures reset on the data logger.
- Temperature Logs
  - Temperature Log (F/C)

Data Logger Resource: AAP Immunization Resources: Data Loggers and Vaccine Monitoring

8) Complete a Vaccine Management Plan and post on all storage units

COVID-19 Vaccine Management Plan

9) Post a "Do Not Unplug" sign on the storage unit plug outlet and a "Do Not Turn Off" sign on the circuit breaker to the storage unit to ensure the storage unit isn't inadvertently turned off or unplugged.

<u>Do Not Unplug Sign</u> <u>Do Not Turn Off Circuit Breaker</u>

## 10) Enroll in Vaccine Finder

- All facilities administering COVID-19 vaccines must enter COVID-19 vaccine inventory into vaccine finder daily, including weekends and holidays. CDC will monitor this requirement and contact facilities that do not comply.
  - You will receive an email from vaccine finder to register for vaccine finder.
  - For more information on vaccine finder and uploading vaccine inventory, go to
    - Vaccine Finder Onboarding Information
    - Vaccine Finder Data Import Instructions

# **COVID-19 Vaccination Program Provider Agreement Guidelines**

To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:

- 1. Organization must administer COVID-19 vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).1
- 2. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine Administration Data) for reporting can be found on CDC's website.2 Organization must submit Vaccine Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.2 Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law. 3. Organization must not sell or seek reimbursement for COVID-19 vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.
- **4.** Organization must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees.
- **5.** Before administering COVID-19 vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
- **6.** Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services during the COVID-19 Pandemic for safe delivery of vaccines.
- 7. Organization must comply with CDC requirements for COVID-19 vaccine management. Those requirements include the following:
  - **a)** Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's *Vaccine Storage and Handling Toolkit*, which will be updated to include specific information related to COVID-19 vaccine;
  - **b)** Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance in CDC's *Vaccine Storage and Handling Toolkit*4;
  - c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;
  - d) Organization must monitor and comply with COVID-19 vaccine expiration dates; and
  - **e)** Organization must preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
- **8.** Organization must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.
- **9.** Organization must comply with all federal instructions and timelines for disposing of COVID-19 vaccine and adjuvant, including unused doses.
- **10.** Organization must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or <a href="http://vaers.hhs.gov/contact.html">http://vaers.hhs.gov/contact.html</a>).
- **11.** Organization must provide a completed COVID-19 vaccination record card to every COVID-19 vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 vaccine shipment will include COVID-19 vaccination record cards.
- **12. a)** Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 vaccine.
  - b) Organization must administer COVID-19 vaccine in compliance with all applicable state and territorial vaccination laws.

Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.