Reporting Requirements

Lesson 8

Guidance on Reporting Requirements

Note: Formalized training will be released after vaccine product approval to provide vaccine-specific storage and handling, vaccine administration, and operational guidelines.

Vaccine Administration Documentation and Reporting

CDC requires that vaccination providers enrolled in the COVID-19 Vaccination Program report certain data elements for each dose administered within 24 hours of administration. COVID-19 vaccination providers may view the data requirements on **CDC's IIS website**.

Local health departments will facilitate and monitor IIS reporting by enrolled COVID-19 providers. Each vaccination location should be ready (including trained staff, necessary equipment, and Internet access) to report vaccine administration data to California's Immunization Registry (CAIR) at the time of vaccination. If data will be entered off-site, vaccination providers must ensure the required data are reported to CAIR within 24 hours.

Providers may record dose-level vaccination data in CAIR using any of our proven and established methods:

- ✔ Data interface with providers' Electronic Health Records (EHR) systems
- ✔ PrepMod (which includes vaccine inventory control)
- ✔ California Immunization Registry (CAIR2) Mass Vax online tools
- ✔ Manual data entry into one of California's CAIR software applications

Except for manual entry, all the other methods provide real time submission directly into CAIR.

Resources are being developed to assist providers. Enrolled providers will be notified as new materials are posted.

- ✔ COVIDReadi application and user guide (coming soon)
- ✔ **CAIR2/Mass Vax tool** and **user guide**
- ✔ PrepMod™ application and user guide (coming soon)
- ✔ **CAIR2 Guidance for Sites with EHRs**
- ✔ CAIR2 Manual Use—**CAIR Training**
- ✔ Non-CAIR2 IIS Info
    - SDIR: **SDIR email, website**
    - RIDE: **Healthy Futures email, website**

Report On-Hand Inventory

COVID-19 vaccination providers must report COVID-19 vaccine inventory daily using CDC's **VaccineFinder**. Once providers are enrolled, they will be preregistered for a **VaccineFinder** account and provided instructions via email on how to submit daily supply information.

CDC will collect data from pharmacies and providers to help understand the demand and supply of COVID-19 vaccines. Inventory quantities will not be made publicly available. Organizations will have the option to report daily inventory for all provider locations, or allow each location to report their own daily inventory.

Providers who are enrolled in the California COVID-19 Vaccination Program must report inventory of on-hand COVID-19 vaccines as part of each submitted order. State officials who approve orders from local health departments and providers will monitor these levels as well as doses administered.

California is building systems, processes, and step-by-step reporting resources to help providers comply.

Report Doses Wasted, Spoiled, and Expired

Providers must report COVID-19 vaccines and diluents that were unused, spoiled, expired, or wasted, and comply with federal instruction regarding disposal of unused COVID-19 vaccines and diluents. Disposal guidance will be provided once available from CDC.

Early in the COVID-19 Vaccination Program, there may be a limited supply of COVID-19 vaccines. Providers must understand the storage and handling and vaccine administration guidelines for the approved vaccines and manage their inventory to minimize wasted, spoiled, and expired doses. To reduce shipping incidents, providers must ensure shipping information (e.g., shipment address, provider contact information, shipping hours) is accurate and complete.

California is building systems, processes, and step-by-step reporting resources to help providers comply.

Report Temperature Excursions

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 vaccines with reduced effectiveness.

Providers must comply with CDC requirements for vaccine management, including temperature monitoring, at all times, and comply with California Immunization Branch instructions for reporting temperature excursions including contacting the vaccine manufacturers, who determine vaccine viability.

California is building systems, processes, and step-by-step reporting resources to help providers comply.

Vaccine Adverse Event Reporting System

VAERS is a national early warning system to detect possible safety problems with vaccines. Anyone—a doctor, nurse, pharmacist, or any member of the general public—can submit a report to VAERS. VAERS is not designed to detect whether a vaccine caused an adverse event, but it can identify signals that might indicate possible safety problems requiring additional investigation.

Per the *CDC COVID-19 Vaccination Program Provider Agreement,* COVID-19 vaccination providers are required to report the following to VAERS:

- ✔ vaccine administration errors (whether associated with an adverse event or not)
- ✔ serious adverse events (even if they are not sure if the vaccination caused the event)
- ✔ multisystem inflammatory syndrome (MIS) in children or adults
- ✔ cases of COVID-19 that result in hospitalization or death

They are also required to report to VAERS any additional adverse events and/or adhere to any revised safety reporting requirements per FDA's conditions of authorized vaccine use posted on FDA's website throughout the duration of the EUA, as applicable. Vaccination providers should also report any additional clinically significant adverse events following COVID-19 vaccination to VAERS, even if they are not sure if the vaccination caused the event. More information on submitting a VAERS report electronically can be found at the **VAERS website**.

v-safe

CDC will implement v-safe, a new smartphone-based tool that uses text messaging and web surveys to check in with vaccinated individuals for adverse events after a COVID-19 vaccination. v-safe will also provide second-dose reminders (if needed) and live telephone follow up by CDC if vaccinated individuals report a medically significant event during a v-safe check-in. v-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. Medically significant events will be identified if the vaccinated individual reports that they missed work, were unable to complete normal daily activities, or had to seek care from a health provider or healthcare professional. The information will be used to analyze common side effects (soreness in the arm, muscle aches, etc.) and to detect unexpected, serious health problems if they occur.

CDC will create a v-safe information sheet that contains background on the v-safe program and instructions for enrolling. Healthcare professionals and healthcare facilities that are giving COVID-19 vaccines are asked to provide printed hard copies of the v-safe information sheet to each vaccinated individual and counsel them on the importance of enrolling in v-safe. The v-safe information sheet and counseling script are in development and will be made available electronically when competed. It is critically important for vaccine safety monitoring and assessment that healthcare professionals give each patient a v-safe information sheet at the time of vaccination and encourage patients to enroll.