



## Kentucky COVID-19 Vaccination Plan

### Frequently Asked Questions 1.4

March 5, 2021

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### General COVID-19 Vaccine Information

**Pfizer and its partner BioNTech announced that its final interim efficacy analysis has found its vaccine candidate is more than 95% effective. The study enrolled 43,931 participants in which 42,722 have received their second vaccination. No serious safety concerns have been uncovered.**

- After conducting final efficacy analysis in the ongoing Phase 3 study, the vaccine met all of the study's primary efficacy endpoints.
- Clinical trial is going to continue through to final analysis at 162 confirmed cases in order to collect further data and characterize the vaccine candidate's performance against other study endpoints.
- Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use in persons 16 or older as of 12/13/2020.

### **Pfizer Resources**

- [News | Pfizer](#)
- Pfizer Fact Sheet: [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) \(fda.gov\)](#)
- Pfizer Fact Sheet for Recipients: [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers \(fda.gov\)](#)
- For all updated details on the Pfizer vaccine: <https://www.cvdvaccine.com/>
- Pfizer has 2 hotlines available for vaccine questions that are staffed 8 am-11 pm EST, 7 days a week.
  - General Product Questions: storage & handling, basic dilution and administration 877-829-2619.
  - Medical Information: efficacy, safety, stability, dosage, mechanism of action, and vaccine ingredients 800-438-1985.
  - Pfizer's Shipping and Handling hotline will be staffed 8 am-8pm EST, 5 days a week. Shipping and Maintaining the Cold-Chain: dry ice, ordering, vaccine quantities, obtaining diluent 800-666-7248.

**Moderna announced that its first interim efficacy analysis has found its vaccine candidate is 94.5% effective. The study enrolled over 30,000 participants and has not uncovered any serious safety concerns.**

- The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under

an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older. All vaccines are currently under EUA.

- The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.
- The Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States.
- By the end of 2020, Moderna expects to have approximately 20 million doses ready to ship in the U.S. and remains on track to manufacture 500 million to 1 billion doses globally in 2021.

### **Moderna Resources**

The Moderna Call Center is available from 8am to 8pm EST, Monday through Friday and can be reached at 1-866-MODERNA (1-866-663-3762). We are here to support you as you begin vaccinations and can assist in answering questions in real-time.

[Vaccination Provider Fact Sheet | EUA | Moderna COVID-19 Vaccine \(modernatx.com\)](#)

[Press Releases | Moderna, Inc. \(modernatx.com\)](#)

### **Is the vaccine live? Does it contain fetal-tissue cells?**

mRNA vaccines are a new type of vaccine to protect against infectious diseases. To trigger an immune response, many vaccines put a weakened or inactivated germ into our bodies. Not mRNA vaccines. Instead, they teach our cells how to make a protein—or even just a piece of a protein—that triggers an immune response inside our bodies. That immune response, which produces antibodies, is what protects us from being infected if the real virus enters our bodies.

To learn more: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>

### **If an employee cannot take a flu shot due to an egg allergy, can they receive the Covid-19 vaccine (either Pfizer or Moderna)?**

Both brands (Pfizer and Moderna) are cell-based vaccines (RNA). Therefore, they do not contain any human or animal cells in their development. Since they aren't grown in eggs like some flu vaccines, your employee should be safe. However, if your employee has experienced an allergic reaction other than a rash, they should discuss with their provider and receive the vaccine in a setting that is prepared for medical intervention (doctor's office, etc.).

### **Janssen COVID-19 Vaccine**

**The safety of the Janssen (Johnson & Johnson) COVID-19 Vaccine has been assessed in an ongoing Phase 3 Study (COV3001). A total of 43,783 individuals were enrolled in this study, of whom 21,895 adults aged 18 years and older received the Janssen COVID-19 Vaccine. During the clinical trial, the vaccine was 85% effective at preventing severe infections and highly effective at preventing hospitalizations and death**

- On February 27th the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Janssen (Johnson & Johnson) single-dose COVID-19 vaccine, to prevent COVID-19 in individuals 18 years of age and older.
- The EUA follows a unanimous vote by the U.S. FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on February 26, 2021.
- On February 28th the CDC's Advisory Committee on Immunization Practices (ACIP) voted 12-0 (with one abstention) to recommend it for adults ages 18 and older. Shortly afterwards, CDC director, Rochelle Walensky, MD, announced the official CDC backing and endorsed the vaccine.

[Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers \(fda.gov\)](#)

<http://www.janssencovid19vaccine.com/>

### **Emergency Use Authorization (EUA) Fact Sheets**

#### **What is the difference between an EUA, an EUA Fact Sheet for Healthcare Providers and an EUA Fact Sheet for Patients?**

The term "EUA" can refer to either the legal authority itself or to the regulatory status of a medical product, such as COVID-19 vaccine. When FDA authorizes emergency use of a medical product such as an anticipated COVID-19 vaccine, an EUA Fact Sheet for Healthcare Providers and an EUA Fact Sheet for Recipients must be provided to the healthcare providers prescribing and/or administering the authorized medical product.

### **Provider Enrollment**

#### **How can providers enroll to administer COVID-19 vaccine?**

Enrollment Checklist: <https://chfs.ky.gov/agencies/dph/covid19/CovidEnrollmentChecklist.pdf>

Enrollment Form: <https://redcap.link/COVID19VaccineProvider>

#### **COVID-19 Provider Enrollment questions should be directed to:**

[COVID19VaccineHelp@ky.gov](mailto:COVID19VaccineHelp@ky.gov)

**Does every point of dispensing (POD) need a provider agreement, or can an organization have one provider agreement and host multiple PODs at different locations?**

When an enrolled provider (e.g., local public clinic) takes vaccine offsite to a temporary location for a one-day vaccination clinic, it is not necessary to complete a provider agreement for that location. The provider named in Section B of the provider agreement should have indicated that a temporary/off-site setting would be used for vaccine administration. However, if an enrolled provider is taking vaccine two or more consecutive days to a particular location, then Section B must be completed for that location. Additional Section Bs of the provider agreement can be submitted at any time.

They (enrolled provider) would need to ensure that the vaccine is being recorded as administered in Kentucky Immunization Registry (KYIR).

If they transfer doses to another enrolled provider, they will need to create an inventory transfer in KYIR along with following all of the required storage & handling guidelines and documentation requirements.

**Additional Information:**

If a Health Department is going to record doses in KYIR for a closed Point of Dispensing (POD), then Kentucky Department for Public Health (KDPH) will need a list of the individuals who are physically vaccinating at the event so they can be added to the *Administered By* drop-down list. KDPH will need first and last name and the professional title of the vaccinators.

If the POD site is administering in KYIR and NOT the health department, we will need the list of vaccinators plus a list of individuals who will be documenting in KYIR. The individuals documenting in KYIR will need to complete a Cabinet for Health and Family Services (CHFS) form. The health department should collect this information, including the CHFS forms for the closed PODs and they should be the ones submitting to the KYIR helpdesk (to link the records).

**Will VFC providers need to have a COVID-19 agreement signed as well as their VFC agreement or will the VFC agreement supersede a pandemic agreement?**

Any provider receiving and administering COVID-19 vaccine will need to sign the COVID-19 agreement.

**Can an organization with a provider agreement redistribute vaccine to a provider without an agreement?**

The organization doing the redistribution may sign the provider agreement (Section A) and the redistribution agreement on behalf of all locations under its umbrella. Any location or site

receiving redistributed vaccine from the organization must abide by all conditions of the provider agreement and submit a Section B form. If the organization is redistributing vaccine to a completely separate entity, the receiving entity must sign or be covered under a provider agreement (Section A).

### **How should Section B of the provider agreement be completed for a mass vaccinator that will be operating at a different site each day but receiving vaccine at a single location?**

Section B is only required for the location where the vaccine will be received, and when a mobile vaccinator will hold multiple clinics at a single location. Transport records must be kept by the mobile vaccinator.

### **How do I re-enter my completed provider enrollment form to make edits, add more locations, or complete section B?**

- Follow this link: <https://redcap.link/COVID19VaccineProvider>
- At the upper right of the screen, click on **Returning User**.
- Enter the return code. This code is specific to the Section A that you've already started.
- If all of Section A is complete, scroll to the bottom of the screen and click on Submit.
- Your screen will then display Section B of the enrollment. Complete Section B for the first location you wish to enroll. If you have more locations, you can complete another Section B by clicking on **Add Another Location** button at the end of the first Section B page.

## **Inventory Management**

### **Will providers be required to perform vaccine inventory reconciliations and, if so, how often?**

Providers will be required to report vaccine inventory to *VaccineFinder*. Vaccines must be reported daily.

### **How does my clinic enroll in vaccine finder?**

Facilities will be "pre-registered" in *VaccineFinder* using the clinic information submitted on the Provider Enrollment. Once we process your enrollment form, we send that information to Center for Disease Control and Prevention (CDC). *VaccineFinder* will then send an email to the individual who completed the *RedCap* provider agreement which will give directions on how to complete your provider profile in *VaccineFinder*. You will need to wait to do anything in *VaccineFinder* until you receive an email from them.

### **Is there a point of contact for vaccinefinder.org?**

If you have any other questions, please contact *VaccineFinder* directly at [vaccinefinder@castlighthhealth.com](mailto:vaccinefinder@castlighthhealth.com). For information, please visit <https://vaccinefinder.org/covid-provider-resources>.

## **Vaccine Allocation and Supply**

### **How will the vaccine be allocated to jurisdictions?**

Allocations will be made based on population and how much vaccine is available from the manufacturers.

### **Who will define the subgroups of critical populations?**

Starting March 1<sup>st</sup> 2021, phase 1C will begin with:

- Anyone age 60 or older.
- Anyone age 16 or older with CDC highest COVID-19 risk conditions (ages 16-17 only authorized for Pfizer vaccine).
- All essential workers.

### **Since there will be a limited supply of vaccine initially, how is Kentucky using a phased approach to COVID-19 vaccination? What are the phases and who will get the vaccine first?**

<https://chfs.ky.gov/agencies/dph/covid19/Phasesgraphic1-4.pdf>

[The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020 | MMWR \(cdc.gov\)](#)

### **Will vaccine be available for children and adolescents in the initial phase?**

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 16 years of age and older. The U.S. Food and Drug Administration (FDA) has also issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, MODERNA COVID-19 VACCINE, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

## **Vaccine Distribution**

### **How many vaccine doses will each shipment contain in the initial phase?**

The minimum order size and increment for centrally distributed vaccines will be 100 doses for Moderna and 1,170 (as of 1/26/2021) doses for Pfizer per order; though early in the response,

some ultra-cold (60°C to -80°C) vaccine, if authorized for use or approved, may be shipped directly from the manufacturer in larger quantities.

**How will jurisdictions or providers know they'll receive the same vaccine for both doses?  
Should jurisdictions or providers hold back stock for second doses to ensure they have a matching product?**

Neither jurisdictions nor providers should hold vaccine for a second dose, especially in the first month.

**Pfizer's Thermal Shipping Container**

Each thermal shipping container has a temperature-monitoring device. All shipments will be tracked to monitor end-to-end distribution within required temperatures. Temperature records of the shipment will be provided to the Vaccination Center within 1 hour of pushing the STOP button of the temperature-monitoring device.

**How many weeks before receiving the COVID-19 vaccine in the clinic will we be notified of the allocation?**

Approved COVID-19 orders are determined by the allocation committee. KDPH will reach out to those providers to confirm they are ready to receive allocations.

**Once we place the order, how long does it take to get accepted or rejected?**

COVID-19 orders are approved or rejected based on allocation committee guidance. Due to the limited resources at this times no orders can be entered into KYIR for COVID19 vaccine.

**If we are on the list to receive the vaccine, do we order it or is it automatically shipped?**

Due to limited resources at this time, no orders can be entered into KYIR for COVID19 vaccine. Being an approved provider identifies the facility as being eligible to receive vaccine when vaccine availability increases to a level where additional providers can be allocated vaccine. No additional action is needed upon completion of the enrollment process.

**Is that why our order history was deleted from our account?**

COVID-19 orders for providers that are not able to receive vaccine will be automatically deleted from the order history. When COVID-19 orders are rejected in KYIR, that order must be deleted out of the ordering system.

**How will the Janssen COVID-19 Vaccine (Johnson & Johnson) be distributed to the public?**



This vaccine will be allocated in the same manner as the Pfizer/BioNTech and Moderna vaccines which is proportional to a state's population. CDC will also be monitoring distribution of vaccines across a range of metrics, including zip codes and the Social Vulnerability Index.

### Ancillary Kits/Supplies

#### **What supplies will be provided with COVID-19 vaccine?**

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. Each kit will contain supplies to administer 1,170 (as of 1/26/2021) doses of Pfizer vaccine or 100 doses of Moderna vaccine.

For complete information by manufacturer: <https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>

### Vaccine Storage and Handling

#### **Will there be different storage and handling requirements for COVID-19 vaccine?**

Yes, the Pfizer vaccine requires ultra-cold storage conditions. CDC is working on ways to support ultra-cold chain vaccine storage and handling needs.

#### **Can vaccine be stored in a combo storage unit (refrigerator only)? Do they need to purchase a separate refrigerator for COVID vaccine?**

The vaccine must be stored separately in a single unit. Do NOT store in a freezer, refrigerator combination. Temporary thermal coolers with dry ice will be provided.

#### **Will there be additional funding for jurisdictions to purchase ultra-cold storage units?**

Because CDC does not recommend jurisdictions invest in ultra-cold storage units at this time, there will be no additional funding available.

#### **What are the on-site storage requirements and warm-up protocols for the Pfizer vaccine that must be stored at ultra-cold temperatures?**

CDC anticipates jurisdictions will receive direct shipment to the vaccination provider site on a real-time, day-to-day basis. Currently, the Pfizer vaccine candidate can be stored at -60°C to -80°C up to 6 months, -25°C to -15°C (-13°F to 5°F) for up to 2 weeks, or vials (undiluted) in the refrigerator can be stored at 2–8°C (35-46°F) for up to 5 days. Thawing: 3 hours at 2° to 8°C or 30 min at room temperature. Post-dilution in use period is 6 hours. However, stability testing is still ongoing and storage temperatures may change.

#### **Will ultra-cold vaccine need to be stored on site or can it be transported on the day vaccine is being administered?**

We do not recommend transporting the Pfizer vaccine at ultra-cold temperatures. We recommend you bring the people to the vaccine. However, the thermal shipping container may be used as temporary storage for the vaccine for up to 30 days between -80° and -60°C if it is replenished with dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every five days or as indicated by the Controlant TMD. Open the container no more than two times per day for up to three minutes each time and protect from the vaccine from light. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F). Upon receipt and after opening, the box should be inspected/replenished with dry ice within 24 hours. The shipping container should be re-iced every 5 days after initial icing. It is recommended that the container not be opened more than 2 times a day and shouldn't be opened for more than 3 minutes at a time.

#### **Storage for Ultra-cold Pfizer vaccine:**

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Do not refreeze thawed vials. Frozen Vials Prior to Use Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks. If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage within this temperature range is not considered an excursion from the recommended storage condition.

#### **Storage for Moderna Vaccine:**

Prior to Use:

- The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light.
- Do not store on dry ice or below -40°C (-40°F).
- Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
- Un-punctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours.
- Do not refreeze once thawed.

#### Storage After First Puncture of the Vaccine Vial:

- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

#### Storage for Janssen (Johnson & Johnson) Vaccine:

##### Prior to Use:

- Store un-punctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.
- Un-punctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

##### Storage After First Puncture of Vaccine Vial:

- After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

#### Storage and Handling Resources:

[Vaccines Storage and Handling Toolkit | CDC](#)

[COVID-19 Vaccine Handling Toolkit \(usp.org\)](#)

<https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>

#### Vaccine Transport

Guidance for storage, handling, preparation, and administration is different for each COVID-19 vaccine product. **It is *critical* that healthcare professionals and other staff are familiar with the COVID-19 vaccine product in their facility's inventory.**

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

#### Transportation Temperatures for Pfizer Vaccine

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F).

#### Pre-Planning

Providers vaccinating homebound persons should carefully pre-plan to understand how they can most efficiently prevent vaccine wastage and ensure safe and effective vaccination by:

1. Estimate the number of doses needed as accurately as possible.

Contact recipients or their caregivers in advance to determine those who wish to be vaccinated to best estimate how many doses will be needed. Plan to use all doses in a vial transported for home vaccination to minimize wasting vaccine doses, such as having contingency plans for vaccination of caregivers, or other persons in the home to avoid vaccine wastage.

2. Map out travel plans.

Plan out route to ensure vaccine is utilized within the approved time frames for use of vaccine at different temperatures, including factoring in pre-vaccination preparation time, and post-vaccination observation time.

3. Ensure readiness to maintain, monitor, and report temperature of vaccine.

From the time the vaccine is taken out of a clinic facility, during transportation, and up to the time that vaccine is administered it must be at appropriate temperatures.

Transport vaccine using a portable vaccine refrigerator or qualified packout. Soft-sided containers specifically engineered for vaccine transport are also acceptable. Emergency packout setups are not approved for vaccine transport.

A qualified packout includes a container and supplies specifically designed for use when packing vaccines for transport. A qualified packout does not require a power source and is “qualified” through laboratory testing under controlled conditions to ensure it can achieve and maintain desired temperatures for a set amount of time.

- Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures.

Document the min/max temperatures when transport begins, every time the container is opened, and upon return to the facility.

- Each temperature reading should be documented on a temperature log.

Transport units must be kept in passenger compartment of vehicle. The units cannot be placed in the trunk or truck bed.

- Move transport containers directly to a vehicle that is already at a comfortable temperature—neither too hot nor too cold.
- Keep containers out of direct sunlight.
  - Vial(s) must be kept protected from light and secured in bubble wrap (or other dunnage) to prevent shaking or vibration.
  - Never leave the container unattended in the vehicle.

Bring the appropriate supplies needed to mix and administer the vaccine, including diluent and mixing supplies (if needed), administration needles/syringes, sterile alcohol prep pads, proper sharps disposal equipment, a pre-vaccination checklist for contraindications and precautions, and [EUA fact sheets for recipients](#) and caregivers.

- ***A punctured vial may be transported from one home to another by the same health care professional if the cold chain is properly maintained.***

- Punctured vials must be labeled with the time of puncture. Doses cannot be administered past 6 hours of initial vial puncture.
- ***However, a partially used vial cannot be transferred from one provider to another.***
- Any unused doses in a punctured vial cannot be returned to the clinic.
- **Vaccine Administration**
- Vaccine administration involves a series of actions: assessing patient vaccination status and determining needed vaccines, screening for contraindications and precautions, educating patients, preparing and administering vaccines properly, and documenting the vaccines administered.

Vaccines should be prepared and administered following aseptic technique. Prepare the injection in a designated, clean medication preparation area that is not adjacent to potential sources of contamination, including sinks or other water sources. Keep in mind that water can splash or spread as droplets more than a meter from a sink. In addition, any item that could have come in contact with blood or body fluids, such as soiled equipment used in a procedure, should not be in the medication preparation area.

1. Give each recipient a copy of the EUA fact sheet ([Pfizer](#), [Moderna](#), or [Janssen](#)) for recipients and/or caregivers.
  - [V-safe](#) is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins for recipients after COVID-19 vaccination. Through v-safe, recipients can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on the answers, someone from CDC may call to check on recipients that have signed up for the program.
3. Ask the patient if he or she has any questions or concerns prior to vaccination, and address them, as appropriate.
4. Although there are no federal requirements for documenting informed consent (or assent for people who work with a medical proxy), best practices are to document consent/assent in the medical records.
5. Before administering vaccine, screen recipients for contraindications and precautions (use the prevaccination checklist for COVID-19 vaccination in [English](#) or [Español](#)), even if you are administering the second dose. The recipient's health condition or recommendations regarding contraindications and precautions for vaccination may change from one visit to the next.
6. For homebound persons who might be at increased risk for anaphylaxis following vaccination (i.e., persons with a history of anaphylaxis due to any cause), consider whether they can be vaccinated in a setting where medical care is immediately available if they experience anaphylaxis following vaccination. If home vaccination is the only option for these persons and, through [risk assessment](#), it is determined that the benefits of vaccination outweigh the potential risk for anaphylaxis, home vaccination providers

should be able to manage anaphylaxis. This includes appropriate screening; post-vaccination observation; medications and supplies; staff qualifications for recognition and treatment of anaphylaxis; and ability to contact and availability of emergency medical services in the area.

COVID-19 vaccination provider should have at least 3 doses of epinephrine on hand when administering vaccine. CDC currently recommends that persons without contraindications to vaccination who receive an mRNA COVID-19 vaccine be observed after vaccination for the following time periods:

- **30 minutes:** Persons with a history of an immediate allergic reaction (within 4 hours) of any severity to a vaccine or injectable therapy, and persons with a history of anaphylaxis due to any cause.)
- **15 minutes:** All other persons

Additional information about potentially managing an anaphylactic reaction is available.

7. 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., immunization information system) as soon as practicable and no later than 72 hours after administration.
8. Adverse events that occur in a recipient after COVID-19 vaccination must be reported to the Vaccine Adverse Event Reporting System (VAERS). FDA requires vaccination providers to report vaccine administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under an EUA. Reporting is encouraged for other clinically significant adverse events, even if it is not clear that a vaccine caused the adverse event. Complete and submit reports to [VAERS online](#).

### **COVID-19 Vaccine Prep & Administration**

#### **Will patients be able to receive the COVID-19 vaccine at the same time as other vaccines?**

If possible, people should separate their COVID-19 vaccinations by at least 14 days from any other vaccine (before or after). This recommendation is based on the fact that we currently do not have data regarding whether the COVID-19 vaccines will affect, or be affected by, other vaccines. Studies to determine whether COVID-19 vaccines can be given with the flu vaccine or the shingles vaccine will be completed; these types of studies are called “concomitant use studies.”

#### **Pfizer**

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen, 0.45 mL suspension that does not contain preservative and must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] (see Storage and Handling).
- Refer to thawing instructions: [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) \(fda.gov\)](https://www.fda.gov/oc/ohrt/pfizer-biontech-covid-19-vaccine-eua-fact-sheet-for-healthcare-providers-administering-vaccine)

**The Pfizer vaccine (after dilution) is supposed to contain five 30mcg doses in 0.3ml doses, but what if I can get a 6<sup>th</sup> dose?**

Pfizer has updated their information to reflect up to 6 doses per vial / dosage: 0.3 mL 6-dose vials. 1,170 doses per 195 vial trays. <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

#### **Pfizer Thawing and Dilution Steps:**

##### Thawed Vials Before Dilution

- Thawed Under Refrigeration:

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

- Thawed at Room Temperature:

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution. Undiluted vials may be stored at room temperature for no more than 2 hours.

##### Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

#### **Pfizer Dosing Schedule:**

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart. There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

### **Pfizer Vaccine Administration:**

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- Verify the final dosing volume of 0.3 mL.
- Confirm there are no particulates and that no discoloration is observed.
- Do not administer if vaccine is discolored or contains particulate matter.
- Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

Contraindications: Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine (see Full EUA Prescribing Information). *Red swelling of the injection site can appear after 7 days for the Moderna vaccine, this is an immunogenic reaction, and will go away shortly.*

[Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) \(fda.gov\)](#)

### **Moderna Thawing Steps:**

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. Do not shake. Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Each dose is 0.5 mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

### **Moderna Dosing Schedule:**

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart. There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals



who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

#### **Moderna Vaccine Administration:**

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product related particulates. During the visual inspection:

- Verify the final dosing volume of 0.5 mL.
- Confirm there are no other particulates and that no discoloration is observed.
- Do not administer if vaccine is discolored or contains other particulate matter.
- Administer the Moderna COVID-19 Vaccine intramuscularly. *Red swelling of the injection site can appear after 7 days for the Moderna vaccine, this is an immunogenic reaction, and will go away shortly.*

#### **Janssen (Johnson & Johnson) Dose Preparation:**

- The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.
- The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exists, do not administer the vaccine.
- Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. Do not shake.
- Each dose is 0.5 mL. Each vial contains five doses. Do not pool excess vaccine from multiple vials.
- The Janssen COVID-19 Vaccine does not contain a preservative. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard if vaccine is not used within these times.

#### **Janssen (Johnson & Johnson) Dosing Schedule:**

The Janssen COVID-19 Vaccine is administered intramuscularly as a single dose (0.5 mL). There are no data available on the use of the Janssen COVID-19 Vaccine to complete a vaccination series initiated with another COVID-19 Vaccine.

### **Janssen (Johnson & Johnson) Vaccine Administration:**

Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. During the visual inspection;

- Verify the final dosing volume of 0.5 mL.
- Confirm there are no particulates and that no discoloration is observed.
- Do not administer if vaccine is discolored or contains particulate matter.
- Administer the Janssen COVID-19 Vaccine intramuscularly.
- Contraindications and Warnings;
  - Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine ([see Full EUA Prescribing Information](#)).
  - Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 Vaccine.
  - Monitor Janssen COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).
  - Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Janssen COVID-19 Vaccine. The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.
  - There is no information on the co-administration of the Janssen COVID-19 Vaccine with other vaccines.
- Adverse Reactions
  - Adverse reactions reported in a clinical trial following administration of the Janssen COVID-19 Vaccine include injection site pain, headache, fatigue, myalgia, nausea, fever, injection site erythema and injection site swelling. In clinical studies, severe allergic reactions, including anaphylaxis, have been reported following the administration of the Janssen COVID-19 Vaccine ([see Full EUA Prescribing Information](#)).
  - Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Janssen COVID-19 Vaccine.

### **Will there be guidance for mass vaccination clinics?**

Yes. CDC has updated guidance for satellite, temporary, and off-site clinics and it is available at <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html>.

### **What are the PPE requirements when administering vaccines during the COVID-19 pandemic?**

CDC has issued “Interim Guidance for Immunization Services during the COVID-19 Pandemic” to help immunization providers in a variety of clinical settings plan for safe vaccine administration during the COVID-19 pandemic (see <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>). For information on PPE for healthcare workers, see [Using Personal Protective Equipment \(PPE\) | CDC](#).

### **Does CDC recommend an observation period after vaccination?**

The Advisory Committee on Immunization Practices (ACIP) currently recommends that providers should consider observing vaccine recipients for 15 minutes after receipt of a vaccine.

### **Can I pre-draw syringes for mass vaccinations?**

The provider has the option to pre-draw syringes for immediate use in the mass vaccination setting. Each syringe would then need to be labeled with the time of vial puncture so that it doesn't exceed the 6 hour time frame. Do NOT pre-draw all estimated doses for the day at one time and/or transport a pre-drawn dose. If conducting a clinic, whether that is mobile or in the office, the full vial can be pre-drawn if patients are lined up to receive the vaccine. Providers should not pre-draw more than 1 vial at a time per administering staff member. Example: If there are 3 lines for vaccines, staff may have 3 separate vials (1 for each staff member) pre-drawn. The pre-drawn doses cannot be returned to the vial or transported to another location.

For additional information please see: <https://www.usp.org/covid-19/vaccine-handling-toolkit>

### **Important Information:**

- People who have had COVID-19 should still be vaccinated. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.
- Persons who previously received passive antibody therapy: Currently, there are no data on the safety and efficacy of mRNA COVID-19 vaccines in persons who received

monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies as well as [evidence](#) suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to persons who receive passive antibody therapy before receiving any vaccine doses as well as those who receive passive antibody therapy after the first dose but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy.

- Wait at least 14 days before getting any other vaccine, including a flu or shingles vaccine, if you get your COVID-19 vaccine first. If you get another vaccine first, wait at least 14 days before getting your COVID-19 vaccine. If a COVID-19 vaccine is inadvertently given within 14 days of another vaccine, you do **not** need to restart the COVID-19 vaccine series; you should still complete the series on schedule. When more data are available on the safety and effectiveness of COVID-19 vaccines administered simultaneously with other vaccines, CDC may update this recommendation.
- Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccine.
- Persons with HIV or other immunocompromised conditions may receive vaccine and should be counseled about unknown safety data in immunocompromised people.
- Pregnant women or lactating women may choose to receive vaccine and should be counseled about unknown safety data.
- Before vaccination, recipients should be counseled about expected local and systemic post-vaccination symptoms.
- 2 doses are required to achieve high efficacy (95%). Masks should still be worn after vaccination for both doses to provide maximum protection.
- As of Tuesday, January 19, there have been confirmed cases of anaphylaxis after receipt of Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine in the United States. Appropriate medical treatment for severe allergic reactions **MUST** be immediately available in the event that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 vaccine. CDC considers a history of severe allergic reaction to another vaccine or to any injectable therapy as a precaution, but not a reason to forgo, receiving the vaccine.

- CDC currently recommends that persons without contraindications to vaccination who receive an mRNA COVID-19 vaccine be observed after vaccination for the following time periods:
  - 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause.
  - 15 minutes: All other persons

For complete information visit: [Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC](#)

Please speak to your provider regarding any of the above issues. For more information regarding ACIP recommendations:

<https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm>

### **Billing, Costs and Reimbursement**

#### **Who will pay for COVID-19 vaccine? Can it be ordered privately?**

COVID-19 vaccine will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. It cannot be ordered privately.

#### **Can a client be turned away if they owe a previous balance to the provider?**

COVID-19 vaccine is being provided at no cost to participating vaccine providers and should be provided regardless of ability to pay.

#### **Will providers be able to charge a COVID-19 vaccine administration fee?**

Providers can bill for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient's plan. However, participating vaccine providers must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees or coverage status, as stated in the CDC Provider Agreement. Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient. Vaccine providers may not seek any reimbursement, including through balance billing, from the vaccine recipient. For uninsured patients, the vaccine provider can seek reimbursement for an administration fee from the Health Resources and Services Administration (HRSA) Provider Relief Fund.

<https://www.hrsa.gov/CovidUninsuredClaim>

Billing Information Toolkit for Providers: <https://www.cms.gov/COVIDvax>

### Pharmacies and Long-term Care Facilities

#### **For independent pharmacies, can the pharmacists sign the CDC provider agreement even though they do not have prescribing authority?**

Yes, per the [PREP Act](#), pharmacists may sign the provider agreement.

#### **Is CDC considering using private contractors, such as pharmacy chains, as PODs in future phases?**

In Phase 2, once we have adequate supply of COVID-19 vaccine(s) to support broader vaccination efforts. The U.S. Department of Health and Human Services is partnering with CVS and Walgreens to offer on-site COVID-19 vaccination services for nursing homes and assisted living facilities residents once they are recommended to receive vaccine. The Pharmacy Partnership for Long-term Care (LTC) Program provides end-to-end management of the COVID-19 vaccination process, including cold-chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this prioritized patient population, while reducing burden on facilities and jurisdictional health departments.

#### **How can Long-term Care Facilities (LTCF) using CVS for their vaccine clinic get answers or specifics about what is needed to conduct the clinic from their local CVS location?**

The following is a list of documents needed to conduct a vaccine clinic by CVS at a Long-term Care Facility (LTCF):

- COVID-19 Vaccine Clinic Guide
- COVID-19 Vaccine Intake Consent Form
- COVID-19 Vaccine Webinar Deck
- COVID-19 Introductory Email
- COVID-19 Vaccine Resource

The EUA Fact Sheet for Recipients and Caregivers **must** be provided to the person being vaccinated at the time of vaccination. The LTCF should provide a copy of the insurance card for every person vaccinated for CVS to bill for their administration fee. If the person being vaccinated does not have insurance, mark “no insurance” and vaccinate.

Contact information for facilities:

- Walgreens: [immunizeltc@walgreens.com](mailto:immunizeltc@walgreens.com)
- CVS: [CovidVaccineClinicsLTCF@CVSHealth.com](mailto:CovidVaccineClinicsLTCF@CVSHealth.com)

## Second-dose Reminders

### **What assistance will jurisdictions receive to ensure the same vaccine is administered for the first and second doses? How will the type of vaccine and intervals between doses be tracked?**

COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. In addition to recording information in the Kentucky Immunization Registry (KYIR) and/or Electronic Health Record (EHR), vaccination providers are required to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each vaccine recipient who receives vaccine to ensure a basic vaccination record is provided. Several of the vaccines in clinical trials will require 2 doses, separated by 3 weeks (Pfizer) or 1 month (Moderna). The different vaccine products are NOT interchangeable. The second dose must be completed with the same vaccine brand as the first dose. Vaccination providers will provide the completed vaccination record to each vaccine recipient. Recipients are to keep the card in case the KYIR or other system is not available when they return for their second dose. There are second reminder tools available from the CDC in the form of V-safe and VaxText<sup>SM</sup>.

V-safe: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

VaxText: <https://www.cdc.gov/vaccines/covid-19/reporting/vaxtext/index.html>

### **Is social distancing necessary when an individual receives their second dose of vaccine?**

Yes. The CDC recommends following the “Vaccination Guidance during a Pandemic” for all routine vaccination as well as for planning for COVID-19 vaccination clinics (see [COVID-19 Vaccination | CDC](#)).

### **If a patient has tested positive or received other treatment in between the first and second dose, should they wait the recommended 90 days?**

The second dose should be administered as close to the recommended interval as possible. However, there is no maximum interval between the first and second dose for either vaccine, meaning that receiving a delayed second dose of vaccine as described above will be valid and will **not** require the vaccine series to be restarted.

### **If a patient develops shingles after receiving the COVID-19 vaccine, what steps should be taken?**

Persons who develop shingles or any significant adverse event after receiving the first vaccine dose should engage their healthcare provider in discussion prior to receiving the second dose. Developing shingles after receiving the first dose of either the Pfizer-BioNTech or Moderna mRNA COVID-19 vaccines is not a contraindication to receiving the second dose of the vaccine ([see this link](#)). The Advisory Committee on Immunization Practices (ACIP) General

Best Practice Guidelines states, “*The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines. The decision to administer or delay vaccination because of a current or recent acute illness depends on the severity of symptoms and etiology of the condition* ([ACIP Contraindications Guidelines for Immunization | Recommendations | CDC](#)). Postponing the second dose of COVID-19 vaccine would be indicated until shingles resolves.

**Important Information:**

If you have not already done so, we encourage you to report the symptoms your patients had after vaccination to the Vaccine Adverse Event Reporting System (VAERS) (patients can report their own adverse reactions in VAERS if they desire). Reports to VAERS are important to help CDC and the Food and Drug Administration (FDA) detect new or unusual reactions that could indicate a problem with vaccines. Reporting is encouraged for any clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Instructions for reporting are available at <https://vaers.hhs.gov/>.

**Vaccine Safety Monitoring**

CDC will use established and new systems to monitor vaccine safety:

- V-safe, is a new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys to check in with vaccine recipients and will also provide telephone follow up to anyone who reports medically important adverse events. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>.
- The [Vaccine Adverse Event Reporting System \(VAERS\)](#), an early warning system, co-managed by CDC and FDA, which monitors for potential vaccine safety problems; anyone can report possible vaccine side effects to VAERS.
- The [Vaccine Safety Datalink \(VSD\)](#), a collaboration between CDC and nine healthcare organizations that conducts vaccine safety monitoring and research.
- The [Clinical Immunization Safety Assessment \(CISA\) Project](#), a partnership between CDC and several medical centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.

**Communication Toolkit for Medical Centers, Clinics, and Clinicians**

<http://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>



## **Regional Response and Coordination Center**

14 Regional Response and Coordination Centers (RRCC) have been established across the state in order to support ongoing response efforts to COVID-19. These centers will serve to enhance planning, collaboration and information sharing with regional stakeholders, including all enrolled vaccine providers, to support equitable and efficient distribution of COVID vaccine and improved situational awareness at local, regional and state levels.

### **Objectives:**

- Establish client relationships with enrolled providers to enhance collaboration and information sharing.
- Maintain situational awareness in each region.
- Monitor vaccine administration for priority populations' progress.
- Survey local healthcare entities on existing plans for reaching and vaccinating priority populations.
- Serve as a resource for local stakeholders and providers.
- Brief local stakeholders on RRCC activities and collaborate to develop weekly IAP and situation reports.
- Expand and Contract RRCC operational objections as needed for each region

### **Core Members:**

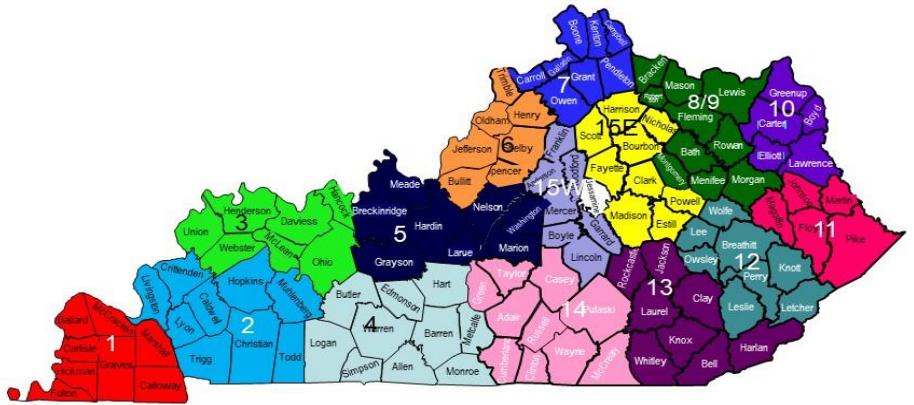
- Regional Preparedness Coordinator—Lead
- Healthcare Coalition Coordinator
- Immunization Field Staff
- Regional Epidemiologists
- Infection Prevention Field Staff
- KYEM Area Managers
- KYNG

### **The Immunization Field Staff can assist you with the following issues:**

- All inventory transfers – coordination and approvals
- Temperature issues, questions, and excursions
- Inventory reconciliations in KYIR including wasted dose and bonus dose recording
- KYIR questions/issues
- Provider enrollment questions/issues
- Contacting providers who haven't been submitting to VaccineFinder

### **Contact Emails for Each Region:**

1. [RRCC.1@ky.gov](mailto:RRCC.1@ky.gov)
2. [RRCC.2@ky.gov](mailto:RRCC.2@ky.gov)
3. [RRCC.3@ky.gov](mailto:RRCC.3@ky.gov)
4. [RRCC.4@ky.gov](mailto:RRCC.4@ky.gov)
5. [RRCC.5@ky.gov](mailto:RRCC.5@ky.gov)
6. [RRCC.6@ky.gov](mailto:RRCC.6@ky.gov)
7. [RRCC.7@ky.gov](mailto:RRCC.7@ky.gov)
8. [RRCC.89@ky.gov](mailto:RRCC.89@ky.gov)
9. [RRCC.89@ky.gov](mailto:RRCC.89@ky.gov)
10. [RRCC.10@ky.gov](mailto:RRCC.10@ky.gov)
11. [RRCC.11@ky.gov](mailto:RRCC.11@ky.gov)
12. [RRCC.12@kygov](mailto:RRCC.12@kygov)
13. [RRCC.13@ky.gov](mailto:RRCC.13@ky.gov)
14. [RRCC.14@ky.gov](mailto:RRCC.14@ky.gov)
15. [RRCC.15@ky.gov](mailto:RRCC.15@ky.gov)



**For KY TRAIN COVID-19 Vaccine Provider Training:**

[https://www.train.org/ky/training\\_plan/4832](https://www.train.org/ky/training_plan/4832).

- Every Tuesday from 2-3pm EST “How to Manually Document in KYIR” live training. This training also covers the mass event module for manual data entry of large vaccination clinics. Join from PC, Mac, Linux, iOS or Android: <https://us02web.zoom.us/j/82443239385>.
- Every Wednesday from 2-3pm EST “Inventory Management” live training includes the reconciliation process. Your weekly reconciliations are now due every Thursday by COB. This live training can help you get your reconciliation closed and submitted in KYIR. Join from PC, Mac, Linux, iOS or Android: <https://us02web.zoom.us/j/84836587260>.
- Every Friday from 1-2 PM EST “COVID-19 Vaccine Provider Office Hours” live question and answer session every week. Immunization Branch will answer the questions you have. Join from PC, Mac, Linux, iOS or Android: <https://us02web.zoom.us/j/83231550361>.

**Handling of COVID-19 Vaccine during Inclement Weather**

1. Track inclement weather conditions. Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create a shut down in power. An alarm/notification system is recommended.

2. Assure the appropriate handling of the vaccine during a power outage. Troubleshoot to get your vaccine to the proper temperature.
3. Contact your local Immunization Field Representative or the appropriate vaccine manufacturer for temperature issues / concerns.
  - To locate the Immunization Field Representative map click here: [Field Staff Map](#). They are available 24 hours / 7 week for temperature emergencies.
  - Moderna – Temperature Viability Questions: [excursions@modernatx.com](mailto:excursions@modernatx.com)
  - Pfizer - Storage and Handling: 877-829-2619 8am-11pm EST 7 days a week

#### [KDPH Immunizations Program Vaccine Management Plan](#)

#### [CDC-Handling a Temperature Excursion in Your Vaccine Storage Unit](#)

##### Preparedness Actions:

- Conduct a call down test for all personnel via use of ReadyOp (LHD/Hospitals Only) and/or phone trees.
- Check the fuel levels and operational status of generator(s).
- Test the functionality of your communications systems.
- Continue to monitor weather information and keep personnel informed of the weather status.
- (LHDs) Identify personnel to conduct environmental/epidemiological inspections of designated shelter sites and have copies of the most current shelter surveillance forms available.

##### Helpful Contacts:

- COVID-19 Provider Assistance (M-F 8:00am-5:00pm EST):(888) 705-0059 or [COVID19VaccineProviderHelp@ky.gov](mailto:COVID19VaccineProviderHelp@ky.gov)
- COVID-19 Storage and Handling: [VaxColdChain@ky.gov](mailto:VaxColdChain@ky.gov)
- Kentucky Immunization Program: (502) 564-4478
- Kentucky Immunization Registry Helpdesk: (502) 564-0038

#### [Other Resources](#)

KDPH Provider Call Center (Mon-Fri 8:00am-5:00pm): **1-888-705-0059**

Norton's non-Provider Call Center (public questions) (Mon-Fri 8:00am-4:30pm): **1-800-722-5725**

For the most up-to-date Pfizer vaccine information, please go to <https://www.cvdvaccine.com/>.

For the most up-to-date Moderna vaccine information, please go to [Press Releases | Moderna, Inc. \(modernatx.com\)](#).

For the most up-to-date Janssen (Johnson & Johnson) vaccine information, please go to <https://www.janssencovid19vaccine.com/>.