Kentucky Public Health
Prevent. Promote. Protect.
Immunization Branch

Kentucky COVID-19 Vaccination Plan

Frequently Asked Questions 1.1

December 29, 2020

Contents

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: https://selfservehosteu.pfizer.com/pfrrdownload/file/fid/77056
- Pfizer Fact Sheet for Recipients: https://selfservehosteu.pfizer.com/pfrrdownload/file/fid/77411
- 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.).

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

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*. During Phase 1A, inventory information 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@castlighthealth.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?

The Advisory Committee on Immunization Practices (ACIP) is recommending two groups for the COVID-19 vaccination in the first phase when supply is limited:

- Healthcare personnel (Learn who is included under the broad term "healthcare personnel".)
- Residents of Long-term care facilities

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?

Each jurisdiction should plan for high-demand and low-demand scenarios and should be planning in terms of three phases.

- Phase 1: Potentially limited supply of COVID-19 vaccine doses available. Focus initial efforts on reaching the critical populations listed in Section 4: Critical Populations of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html
- Phase 2: Large number of vaccine doses available. Focus on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the general population; expand provider network.
- Phase 3: Sufficient supply of vaccine doses for entire population (surplus of doses). Focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.

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 975 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?

In the early phases when vaccine is limited, the second dose will be held at the federal level to ensure availability of a matching dose to complete the vaccine series. 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.

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 975 doses of Pfizer vaccine or 100 doses of Moderna vaccine. Moderna's will include 105 needles, 105 syringes, 210 alcohol prep pads, four surgical masks and two face shields (per kit) for vaccinators, and 100 COVID-19 vaccination record cards for vaccine recipients.

For complete information on Ancillary Kits please see:

Product information guide_12.04.20_C.pdf (msu.edu)

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 requires storage at -60°C to -80°C up to 6 months 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 2 and 8°C. Upon receipt and after opening, the box should be replenished/ inspected 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). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use. 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 -40ºC (-40ºF).
- Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
- Unpunctured 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.

COVID-19 Vaccine Prep & Administration

Pfizer

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen 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: https://selfservehosteu.pfizer.com/pfrrdownload/file/fid/77056

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

As you are likely aware, vaccine administration sites across the nation are reporting that many or all Pfizer-BioNTech COVID-19 vaccine vials contain material sufficient to provide 6 full doses of vaccine, rather than the 5 doses described in the FDA EUA for the product. While we await official FDA confirmation, we are advising that as long as each individually administered vaccine dose is of the appropriate volume and quality as described in the FDA EUA, hospital-based vaccine administration sites may be permitted to use every full dose contained in these vials. Anticipating that the FDA will promptly issue clarifying guidance and since the federal long-term care facility immunization program does not begin until December 21, 2020, this guidance applies only to hospital-based vaccine administration sites where on-site pharmacist oversight is available to provide quality assurance oversight.

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).

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.

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.

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 for COVID-19, vaccination should be deferred for at least 90 days.
- 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.

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.

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

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, pharmacists may sign the provider agreement. Per the PREP Act.

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
- CVS: 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 each vaccine recipient to ensure a basic vaccination record is provided and to keep the card in case the KYIR or other system is not available when they return for their second dose.

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

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).

There are second reminder tools available from the CDC in the form of V-safe and VaxText[SM]

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

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

Other Resources

KDPH Provider Call Canter (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/.