

**The following FAQs were taken from the Centers for Disease Control and Prevention's (CDC's) Immunization Awardee COVID-19 Frequently Asked Questions Document dated October 29, 2020.**

## **General Vaccine Information**

### Vaccines for Children (VFC)

**Q: Will VFC providers need to have a COVID19 agreement signed as well as the VFC agreement or will the VFC agreement supersede a pandemic agreement?**

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

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

A: At first, COVID-19 vaccines may not be authorized, approved, or recommended for children. The groups recommended to receive the vaccines could change in the future.

### Emergency Use Authorization (EUA) Fact Sheets

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

A: The legal authority of The U.S. Food & Drug Administration (FDA) to authorize emergency use of an investigational medical product (e.g., vaccines prior to licensure, drugs prior to approval) or an unapproved use of an approved medical product to diagnose, treat, or prevent a serious or life-threatening disease is referred to as Emergency Use Authorization (EUA). 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. For example, one could say "FDA issued an EUA" or "an EUA is in place."

When FDA authorizes emergency use of a medical product such as an anticipated COVID-19 vaccine, an EUA Fact Sheet for Healthcare Providers (in place of a package insert typical of a licensed vaccine) and an EUA Fact Sheet for Recipients (akin to product information for patients or a CDC-provided vaccine information statement (VIS) for a licensed vaccine) must be provided to the healthcare providers prescribing and/or administering the authorized medical product. The healthcare providers, in turn, provide the EUA Fact Sheet for Recipients to vaccine recipients or their guardians.

**Q: How is the EUA Fact Sheet for Recipients different from a VIS?**

A: When FDA authorizes a vaccine for use under an EUA, providers and public health entities involved in vaccine administration are legally required to provide the FDA-authorized EUA Fact Sheet for Recipients to individuals receiving vaccine or their guardians, similar to VIS's that are also required by law for certain licensed vaccines. The EUA Fact Sheet for Recipients, like the VIS, explains the benefits and risks associated with the vaccine. But unlike a VIS, the EUA fact sheet also provides vaccine product-specific information, including the vaccine's authorized use, dose/dose-series, and known information or experience with the vaccine from clinical trials that support issuance of the EUA by FDA.

**Q: Can the EUA Fact Sheet for Recipients or VIS be provided to vaccine recipients electronically or is a hard copy required?**

A: The EUA Fact Sheet for Healthcare Providers and EUA Fact Sheet for Recipients can be offered in an accessible form (e.g., printable as a hard copy) or through mass media (including print, broadcast, radio, satellite, internet, or other electronic means of dissemination), videos/DVDs, or direct communication from public health agencies.

**Q: Are there any documents (e.g., fact sheets) that explain EUAs to the general public?**

A: CDC is working with Operation Warp Speed (OWS), FDA, and manufacturers to develop public messaging materials about EUAs that will help support jurisdictions' vaccination programs.

### [Pandemic Influenza Preparedness/COVID-19 Vaccine](#)

**Q: What are the protective personal equipment (PPE) requirements when administering vaccines during the COVID-19 pandemic?**

A: 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 <https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>. Additional guidance will be provided as needed when COVID-19 vaccine is available.

**Q: Can COVID-19 and influenza vaccines be administered at the same time on the same day?**

A: Once COVID-19 vaccine(s) are authorized or approved by FDA, CDC will provide administration guidance.

### [COVID-19 Vaccine](#)

**Q: Does CDC recommend an observation period after vaccination?**

A: ACIP currently recommends that providers should consider observing vaccine recipients for 15 minutes after receipt of a vaccine.

**Q: Are data available on the efficacy of the COVID-19 candidate vaccines?**

A: Efficacy data are being collected as part of the Phase 3 clinical trials in the U.S. and other countries.

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

A: CDC recommends following the "Vaccination Guidance During a Pandemic" for all routine vaccination as well as for planning for COVID-19 vaccination clinics (see <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>).

## [Vaccine Allocation and Supply](#)

### **Q: How much space will be needed to store COVID-19 vaccines in the refrigerator or freezer?**

A: Vaccine storage and handling guidance will vary by vaccine manufacturer. More information will be shared as soon as it is available.

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

A: Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in CDC's Vaccine Tracking System (VTrckS). Each kit will contain supplies to administer 100 doses of vaccine, including 105 needles (various sizes for the population served by the ordering vaccination provider), 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.

## [Ancillary Kits/Supplies](#)

### **Q: Will the ancillary supplies in the shipments include sharps containers?**

A: No, the ancillary supplies will not include sharps containers.

### **Q: Are more details (brand, type, etc.) available about the supplies to be provided with COVID-19 vaccine?**

A: CDC will provide the brand information when it is available.

### **Q: When COVID-19 vaccine is available to the general public, will the vaccine be kitted with supplies, similar to what is being done in the initial phase?**

A: Yes, ancillary kits will ship to coincide or arrive just before shipments of vaccine throughout the response.

### **Q: Will ultra-cold vaccine come with gloves for use in unpacking the vaccine?**

A: Gloves are not currently planned to be provided for unpacking ultra-cold vaccine; however, this is subject to change.

## [Billing, Costs and Reimbursement](#)

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

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

### **Q: Can providers bill for an office visit when administering COVID-19 vaccine?**

A: Yes, 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.

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

A: Yes, vaccine providers will be able to charge an administration fee. 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. For uninsured patients, the vaccine provider can seek reimbursement for an administration fee from the HRSA Provider Relief Fund.

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

A: COVID-19 vaccine will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. More information will be shared as soon as it is available.

[Vaccine Distribution](#)

**Q: How will COVID-19 vaccine be ordered?**

A: Vaccination providers will follow their jurisdiction's vaccine ordering procedures. Vaccine orders will be approved and transmitted in VTrckS by jurisdiction immunization programs for vaccination providers they enroll.

**Q: Will vaccine orders go to McKesson and be sent directly to providers?**

A: CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.

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

A: Vaccine shipment amounts will vary based on the vaccine. The minimum order size and increment for centrally distributed vaccines will be 100 doses 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. CDC will share more information on these shipments as it becomes available.

**Q: Are there planning considerations for distributing ultra-cold vaccines to high-temperature areas?**

A: Ultra-cold vaccines will ship to the vaccination provider location directly from the manufacturer in a pack-out that contains dry ice. CDC will confirm with the manufacturer about the ambient temperature conditions under which the packout was qualified to determine if there are specific considerations for jurisdictions. The thermal shipper is the way to get vaccine to clinics/sites with temperature extremes.

**Q: The provider profile only asks for business hours M-F. Does this mean McKesson won't ship on the weekends or should we still collect expanded business hours?**

A: COVID-19 vaccine shipments are planned for Monday-Friday. In the event of an urgent situation, Saturday shipments can be arranged on a case by case basis. In those circumstances, provider locations

would need to be available on Saturday during the timeframe in which the shipment is expected to arrive.

**Q: How will jurisdictions 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?**

A: 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. (This strategy may change as vaccine becomes more widely available.) Neither jurisdictions nor providers should hold vaccine for a second dose, especially in the first month.

**Q: Is there a tip sheet to support COVID-19 vaccine confidence for providers to use when talking with patients?**

A: Focus groups are being conducted and materials will be developed. More information will be shared as soon as it is available.

**Q: Will private providers have access to COVID-19 vaccine?**

A: Public and private providers enrolled in the COVID-19 Vaccination Program will have access to vaccine, based on supply, state and local need, and their jurisdiction's enrollment procedures.

**Q: Will immunization programs need to conduct site visits with providers who are administering only COVID-19 vaccine?**

A: Immunization programs will not be required to conduct site visits with COVID-19 vaccination providers. However, programs will be responsible for ensuring the provider agreement and profile forms are fully completed and that the provider has appropriate storage and temperature monitoring equipment to maintain the required temperature range for the vaccine product(s) the provider receives. Programs will also be responsible for ensuring providers are familiar with the ACIP recommendations and trained in key areas:

- COVID-19 vaccine administration, storage, and handling requirements
- Documenting and reporting wastage and temperature excursions
- Reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Providing EUA fact sheets or VISs
- Reporting information to the Immunization Information System (IIS) and/or other vaccine administration reporting systems

CDC will provide materials that awardees can use in their training efforts.

**Q: Will CDC provide a consent form for vaccination?**

A: No, informed consent is not a federal requirement. An EUA vaccine recipient fact sheet will be available online, and providers are required to provide those to vaccine recipients prior to vaccine administration. Immunization programs will be required to ensure providers are aware of the fact sheet requirements.

## [Provider Recruitment and Enrollment](#)

### **Q: Can providers enroll in the COVID-19 Vaccination program directly with CDC or do they have to enroll through their immunizations program?**

A: To receive and administer COVID-19 vaccine, vaccination providers must enroll in the COVID-19 Vaccination Program through their immunization program. CDC is exploring coordination with some multijurisdictional entities (e.g., certain federal entities and national chain pharmacies) to receive vaccine outside of this process. CDC is working to ensure that jurisdictions have full visibility of this process.

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

A: To receive and administer COVID-19 vaccine, vaccination providers must enroll in the COVID-19 Vaccination Program through their jurisdiction's immunization program. Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement. (Note: Federal clinicians working in federal facilities may have professional licensure from a different jurisdiction. Out-of-state licensure is also allowed when a corporation is enrolling and the chief medical officer is located in another state; however, those who will be administering vaccine in this scenario should be licensed to possess and administer vaccine within the jurisdiction.) Enrolled COVID-19 vaccination providers must also fully complete the CDC COVID-19 Vaccination Provider Profile form for each location where COVID-19 vaccine will be administered. Some national pharmacy chains and federal entities will be instructed to enroll directly with CDC.

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

A: 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).

### **Q: Who should sign the redistribution agreement when vaccine is redistributed? The original recipient or the recipient of the redistributed vaccine or both?**

A: The organization that is redistributing vaccine to a secondary recipient should sign the redistribution agreement. The chief medical officer and chief fiduciary officer are responsible for all affiliated sites (to which vaccine is redistributed to) and must document and submit details of vaccine movement to the awardee jurisdiction.

### **Q: 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?**

A: 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 (aside from repeat clinics for completing the vaccination series' first and second doses). Transport records must be kept by the mobile vaccinator.

## Pharmacies and Long-Term Care Facilities

**Q: Does U.S. Department of Health and Human Services (HHS) or CDC have Memoranda of Agreement (MOAs) in place with large pharmacy networks? When and how will HHS or CDC share planning assumptions for the large chain pharmacy chains?**

A: CDC is working with OWS and national chain pharmacy organizations on COVID-19 vaccine distribution and administration planning. CDC will share details of the plans and information on coordination with jurisdictions as soon as it is available.

**Q: Will clinics that reside in the same building as a pharmacy but are staffed by nurses (i.e., minute clinics and little clinics) receive direct shipments of vaccine or will vaccine only be shipped for administration by a pharmacist?**

A: CDC is working closely with jurisdictions and partners, including pharmacy chains, and details about how vaccines will be administered at pharmacy locations are still being finalized.

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

A: Yes, pharmacists may sign the provider agreement. Per the Public Readiness and Emergency Preparedness (PREP) Act, state-licensed pharmacists have authority to order and administer COVID-19 vaccinations that have been authorized or licensed by FDA.

<https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>

**Q: Is CDC considering using private contractors, such as pharmacy chains, as points of dispensing (PODs) in future phases?**

A: In Phase 2, once we have adequate supply of COVID-19 vaccine(s) to support broader vaccination efforts, select pharmacy partners will receive a direct allocation of COVID-19 vaccine in order to increase the public's access to vaccines. Through the Federal Pharmacy Partnership Strategy for COVID-19 Vaccination Program, select pharmacy partners will receive a direct allocation of COVID-19 vaccine. Vaccine will be administered at partners' retail locations at no cost to recipients. This will be done through a provider agreement between the federal government and the pharmacy partner. CDC will share information on pharmacy partners as soon as it is available.

**Q: During which phase will pharmacy chains begin receiving vaccines?**

A: HHS 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. There may be other pharmacy partners that will be added to this program. Any updates will be shared with as soon as it is available.

In Phase 2, once we have adequate supply of COVID-19 vaccine(s) to support broader vaccination efforts, additional pharmacy partners will receive a direct allocation of COVID-19 vaccine in order to increase the public's access to vaccines. The program will be open to all jurisdictions willing to participate. Participating pharmacy partners will be required to share information on vaccine supply and doses administered to states and CDC. CDC will share information on pharmacy partners as soon as it is available.

## [Second-dose reminders](#)

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

A: COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. In addition to recording information in the IIS, Electronic Health Record (EHR), and/or Vaccine Administration Management System (VAMS), 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 21 or 28 days. IISs will be critical for reporting and tracking intervals. Jurisdictions should also be planning for redundant methods of providing second-dose reminders to vaccine recipients.

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 IIS or other system is not available when they return for their second dose.

**Q: Will vaccine recipients be required to show their COVID-19 vaccination record card in order to get their second does?**

A: No. However, all vaccine recipients should be encouraged to keep their card and show it at their follow-up vaccination appointment. Retaining the COVID-19 vaccination record card is important to ensure that the first and second doses match when internet connectivity problems prevent access to the vaccine recipient's record at the time of vaccination.

## [Vaccine Storage and Handling](#)

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

A: Yes, at least one vaccine requires ultra-cold storage conditions. CDC is working on ways to support ultra-cold chain vaccine storage and handling needs. We will provide more information and guidance as they become available.

**Q: Should jurisdictions invest in ultra-cold storage units at this time?**

A: Jurisdictions are not advised to purchase ultra-cold storage equipment at this time. Ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice. Storage and handling instructions for ultra-cold vaccine will address repacking these coolers for extended storage.

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

A: CDC anticipates jurisdictions will receive direct shipment to the vaccination provider site on a real-time, day-to-day basis. Currently, one vaccine candidate requires storage at -60°C to -80°C or at 2–8°C for up to 5 days (i.e., 120 hours). Once reconstituted, the vaccine can be at room temperature for up to six hours. However, stability testing is still ongoing and storage temperatures may change. We

understand and appreciate the operational complexities ultra-cold storage poses at the vaccination provider site. Some COVID-19 vaccine products will require a very different storage and handling approach than a normal cold-state vaccine.

**Q: Does CDC know what percentage of the vaccine will require ultra-cold storage?**

A: We do not currently have this information. However, at least one vaccine candidate requires ultra-cold storage.

**Q: Will vaccine be shipped with a temperature monitoring device or phase change indicator?**

A: Yes

**Q: Will CDC provide guidance on how to handle vaccines that require an ultra-cold chain?**

A: Yes, CDC will provide specific education and training materials to facilitate storage and handling of ultra-cold vaccine based on guidance from the vaccine's manufacturer.

**Q: Should awardees plan to use digital data loggers to monitor storage unit temperatures?**

A: It will be important to monitor storage unit temperatures to ensure vaccines are stored at appropriate temperatures at all times. Because of the differing storage requirements of the various COVID-19 vaccine candidates, we continue to assess the best options for monitoring vaccine temperatures. More information will be provided as it becomes available.

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

A: We do not recommend transporting vaccine at ultra-cold temperatures. However, the vaccine can be kept for 5 days (120 hours) between 2 and 8°C. Therefore, the amount needed to conduct off-site clinics may be removed, stored, and transported following guidance for vaccines stored between 2°C and 8°C. CDC's Vaccine Storage and Handling Toolkit is being updated to provide detailed guidance and key considerations for COVID-19 vaccine.

## **IIS and Technology**

### **[Vaccine Finder](#)**

**Q: Will CDC or OWS have a public-facing vaccine locator at the national level?**

A: As COVID-19 vaccine becomes widely available, providers will self-report to the website [www.vaccinefinder.org](http://www.vaccinefinder.org).

**Q: Will VaccineFinder have real-time information? For example, can a provider change their status if they run out of vaccine and update it when they have vaccine in stock?**

A: Yes, VaccineFinder relies on providers to keep their location details up to date. The system will reflect the information and supply details entered by providers for their location (with an approximately 15- to 30-minute delay to reflect changes on the external website).

**Q: Will VaccineFinder be active in Phase 1 when vaccine availability is limited?**

A: This is under discussion. However, because VaccineFinder is for use by the general public to locate vaccination services, VaccineFinder may not be active for public search of COVID-19 vaccine until vaccine is more widely available.

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

A: The point of contact for VaccineFinder is [locatinghealth@healthmap.org](mailto:locatinghealth@healthmap.org).