Vaccine Administration: At a Glance

COVID-19 Vaccine

Refer to the EUA fact sheets or product inserts for vaccine-specific storage and handling and administration guidance. This guide outlines requirements in CDC’s COVID-19 Vaccination Program Provider Agreement and Vaccine Storage & Handling Toolkit.

Resources will be posted to COVID-19 BioNTech Vaccine Resources as they become available.

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<th>Topic</th>
<th>Requirements &amp; Guidance</th>
<th>Resource Links</th>
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<tr>
<td>Pre-Vaccination Screening</td>
<td>CDC has provided a COVID-19 Screening Form for facilities to assist with patient screening.</td>
<td>Pre-Vaccination Form for Pfizer-BioNTech COVID-19 Vaccine</td>
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| Vaccine Preparation          | Vaccine preparation is the final step in the cold chain before administration. Handling vaccines with care is equally important as storing them properly. It is important to follow vaccine preparation instructions provided in the vaccine product’s EUA Fact Sheet for Healthcare Providers, or the vaccine package insert. COVID-19 vaccine products may have different preparation requirements. Some should not be shaken, or the vaccine will be compromised and cannot be used. Carefully follow the manufacturer’s vaccine preparation guidance. Diluents: They are not interchangeable unless specified by the manufacturer. Vaccine mixed with the wrong diluent should never be administered. | • Pfizer Standing Orders Template  
• Pfizer Vaccine Preparation and Administration Summary  
• Pfizer Vaccine Preparation: Mixing Diluent and Vaccine  
• Moderna Standing Orders Template  
• Moderna Vaccine Preparation & Administration Summary                                                                                                     |
<table>
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<tr>
<th>Vaccine Administration</th>
<th>Organization must administer COVID-19 vaccine in accordance with all requirements and recommendations of CDC and CDC’s Advisory Committee on Immunization Practices (ACIP). (CDC Provider Agreement #1).</th>
<th>• ACIP Interim Recommendations</th>
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<tr>
<td></td>
<td>Organization must administer COVID-19 vaccine in compliance with all applicable state and territorial vaccination laws. (P.A. #12b)</td>
<td>• IM Injection Children 7-18 years</td>
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<td>• IM Injection Adults 19 years and older</td>
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<td>• Needle Gauge and Length</td>
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<td>Organization’s COVID-19 vaccination services must be conducted in compliance with CDC’s Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines. (P.A. #6)</td>
<td>Interim Guidance for Routine and Influenza Immunization Services During the COVID-19 Pandemic</td>
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<td>Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 vaccine. (P.A. #12a)</td>
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<td><strong>Emergency Use Authorization:</strong> The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met as requirements of authorized vaccine use. FDA will coordinate with CDC to confirm these “conditions of authorization.”</td>
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<td><strong>What is an EUA?</strong> <a href="#">Video</a></td>
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</table>
| EUA Fact Sheet or VIS | Before administering COVID-19 vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. (P.A. #5)  

**EUA Fact Sheets:** Specific, detailed protocols for individual vaccines are provided in manufacturer package inserts for vaccines licensed by the Food and Drug Administration (FDA). However, because COVID-19 vaccines may initially be authorized for use under an EUA, COVID-19 vaccination providers should refer to the EUA Fact Sheets for Consumers and Healthcare Providers for detailed information on each vaccine. Both sets of EUA fact sheets will be available after FDA approval.  

**Pfizer EUA Website:** [cvd vaccine.com](http://cvd vaccine.com) was developed to provide specific information for HCPs and Fact Sheets for consumers. Will go live and materials will be posted after EUA is granted to Pfizer by FDA. Vial trays in thermal shippers have a QR code used to access this website.  

**Moderna EUA Website:** The [EUA website](http://EUA website) has multi-language resources including fact sheets for HCPs and recipients, storage & handling resources, and a lookup tool for expiration dates. | Pfizer-BioNTech COVID-19 Vaccine |
| --- | --- |
| **Vaccination Card** | Organization must provide a completed COVID-19 vaccination record card to every COVID-19 vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 vaccine shipment will include COVID-19 vaccination record cards. (P.A. #11)  

COVID-19 Vaccination Record Cards are included in the ancillary kits. Vaccination providers should encourage vaccine recipients to keep the card in case the IIS or other system is not available when they return for their second dose. The card provides room for a written reminder for a second-dose appointment. If vaccine recipients have a smartphone, they may consider documenting their vaccine administration with a photo of their vaccination record and entering the date the next vaccine dose is due on their electronic calendar. |
**Second-Dose Reminders**

Second-dose reminders for vaccine recipients will be critical to ensure compliance with vaccine dosing intervals and to achieve optimal vaccine effectiveness.

- **Pfizer:** Schedule 2\textsuperscript{nd}-dose appointment at least 21 days after first dose. See EUA fact sheet (cvd vaccine.com) for details. There are no data available on interchangeability of vaccine products. Individuals who receive one dose of Pfizer vaccine should receive a second dose of Pfizer vaccine to complete the vaccination series.

- **Moderna:** Schedule 2\textsuperscript{nd}-dose appointment at least 28 days after first dose. See EUA fact sheet for details.

**Record & Report Administration**

- **Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient’s record and report required information to the relevant state, local, or territorial public health authority.** Details of required information (collectively, Vaccine Administration Data) for reporting can be found on CDC’s website. (P.A. #2)

- Organization must submit Vaccine Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements. (P.A. #2)

- **Pfizer EUA Website:** Vial trays will be labeled with QR code that links to EUA website for lot numbers and expiration dates. All vials in a tray share the same lot number and expiration date; if multiple vial trays are in a shipper, lot numbers and expiration dates could be different.

**Record Keeping**

- **Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law.** Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law. (P.A. #2)
| Billing for Vaccine Administration | Organization must not sell or seek reimbursement for COVID-19 vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization. (P.A. #3)  

CMS released a set of toolkits for providers, states and insurers to help the health care system prepare to swiftly administer the vaccine once it is available. These resources are designed to increase the number of providers that can administer the vaccine and ensure adequate reimbursement for administering the vaccine in Medicare, while making it clear to private  

| VAERS Reporting | Organization must administer COVID-19 vaccine regardless of the vaccine recipient’s ability to pay COVID-19 vaccine administration fees or coverage status. Organization may seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient. Organization may not seek any reimbursement, including through balance billing, from the vaccine recipient. (P.A. #4)  

Organization must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or http://vaers.hhs.gov/contact.html). (P.A. #10).  

The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):  

- vaccine administration errors whether or not associated with an adverse event,  
- serious adverse events* (irrespective of attribution to vaccination),  
- cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and  
- cases of COVID-19 that result in hospitalization or death. | • CMS – COVID-19 Vaccine Policies & Guidance  
• CMS - COVIDvax Provider Toolkit  
Report an Adverse Event to VAERS |
### VAERS Reporting

*Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report.

Consumers may report an adverse reaction to Pfizer products by calling (800) 438-1985 (US only). When reporting an adverse reaction or vaccine administration error to VAERS, consumers should identify the product as Pfizer-BioNTech COVID-19 Vaccine and note that the product was used under Emergency Use Authorization.

### V-safe

The v-safe poster is now available in multiple languages, including English, Spanish, Korean, Vietnamese, and Simplified Chinese. Other translations are coming soon.

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through v-safe, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And v-safe will remind you to get your second COVID-19 vaccine dose.

**Suggested script:** “CDC has created a way for you to report how you feel after COVID-19 vaccination through a smartphone-based tool that uses text messaging and web surveys to check in with you. Here (or in your packet) is a v-safe information sheet with more details and simple instructions to sign up.”

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**v-safe app**  
**v-safe Poster**  
**V-safe printable information sheet**  
(select Languages)
### Off-Site Clinic Considerations

Satellite, temporary, and off-site clinics in collaboration with community or mobile vaccinators may assist jurisdictions in providing equitable access for COVID-19 vaccination. However, these situations require additional oversight and enhanced storage and handling practices. Refer to resource links for guidance.

- Guidance for Satellite, Temporary, and Off-Site Clinics
- Infection Control Guidance for Healthcare Professionals about Coronavirus
- Interim Guidance for Routine and Influenza Immunization Services during the Pandemic
- Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations
- Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations