



# COVID-19 Vaccination Frequently Asked Questions

**Keep informed about the COVID-19 Vaccination Clinic Program.**

**Please note: due to the fluidity of the situation, we are continuously updating these FAQs. Please visit [www.omnicare.com/covid-19-vaccine-resource](http://www.omnicare.com/covid-19-vaccine-resource) routinely, to access and download the latest version of this FAQ document.**

CVS Health® is actively monitoring the global COVID-19 pandemic, including guidance from trusted sources of clinical information such as the Centers for Disease Control (CDC) and World Health Organization (WHO). Below is information about policies and procedures that CVS Health has implemented that focus on the health and safety of our colleagues, customers, members, and patients. For more information about the virus, please visit the [CDC](https://www.cdc.gov) and/or [WHO](https://www.who.int) websites dedicated to this issue.



CVS Health® is an enterprise comprised of many business units that are coming together to support this vaccination effort. It is possible that you may receive outreach from Omnicare®, our long-term care pharmacy team, as well as our retail CVS Pharmacy® and MinuteClinic® teams. Know that we are connected and are all part of the CVS Health enterprise. Our shared mission is to help you and your patients on the path to better health.

**What is COVID-19?**

COVID-19 is an infectious disease caused by a novel respiratory coronavirus. COVID-19 poses a serious public health risk and is highly contagious. For more information about the virus, please visit the [CDC](#) and/or [WHO websites](#) dedicated to this issue. Visit the [CDC Traveler's Health website](#) for travel notices and precautions.

**How does COVID-19 spread?**

Human coronaviruses are usually spread from an infected person to others through the air by coughing and sneezing and through close personal contact, such as touching or shaking hands. It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose or possibly their eyes, but this is not thought to be the main way the virus spreads.

For more information about the transmission of COVID-19, please see the CDC website.

**How would a COVID-19 vaccine work?**

As with any vaccine, the goal of a COVID-19 vaccine is to expose the body to an antigen that won't cause disease but will provoke an immune response that can block or kill the virus if a person becomes infected. Vaccines contain either the whole virus or a component. After receiving a vaccine, a person develops immunity to that disease without having to get the disease. The immunity varies based on the type of vaccine you receive. Some vaccines last a year (like the flu vaccine) and others last longer (like the polio vaccine). Current science suggests that the COVID-19 vaccine will be more like the flu vaccine requiring annual dosing, but research will be required to fully answer this question.

**What are the different technologies being used to develop a COVID-19 vaccine?**

Manufacturers are taking different approaches toward developing a COVID-19 vaccine including using portions of the virus, genetic material or other vectors.

Traditional technology

A traditional vaccine technology is to use protein sub-units that can be injected into cells to stimulate a response. Such vaccines usually need adjuvants—or immune-stimulating molecules—delivered in conjunction with the vaccine and may also require multiple doses. Some of the candidates in development using this technique are from Novavax and Sanofi/GSK.

Novel technologies

Viral vector vaccines use another virus that has been engineered to express the S protein to generate an immune response. Some of the candidates in development using this category are from AstraZeneca/Oxford, Johnson & Johnson, Merck and Vaxart.

Nucleic acid vaccines deliver genetic material into the cell which is then translated into a protein – usually the S protein. However, this method – and the way the genetic material (RNA or DNA) is delivered into the cell – requires that these vaccines be stored and transported at ultracold temperatures of -20 to -70 degrees Celsius. Some candidates in development in this category are from BioNTech/Pfizer, Inovio and Moderna.

***What is the FDA's Emergency Use Authorization and how does the process work?***

In order to help make a vaccine available as soon as possible, the Food and Drug Administration (FDA) would need to authorize its distribution under an Emergency Use Authorization (EUA). The agency has issued guidance for the criteria that will be used to evaluate any EUA application. The FDA evaluates the following criteria when determining whether to issue an EUA:

- **Safety:** Whether the chemical, biological, radiological or nuclear (CBRN) agent can cause a serious or life-threatening disease or condition. The known and potential benefits of the product, when used to diagnose, prevent or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- **Efficacy:** If the product is determined to be effective in preventing SARS-CoV-2.
- There is no adequate, approved and available alternative to the product for diagnosing, preventing or treating the disease or condition.

Under the EUA, any investigational vaccines developed to prevent COVID-19 will be assessed on a case-by-case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product and the totality of the available scientific evidence relevant to the product. The final guidance specific to EUA for vaccines to prevent COVID-19 can be found [here](#).

***What are some of the clinical considerations or uncertainties concerning a potential vaccine?***

Given each vaccine will have different clinical profiles, there are a number of important criteria to evaluate as part of overall planning efforts. Understanding these criteria will help the clinical community plan for safe and effective administration of the vaccine. Some of these considerations include:

- Efficacy, safety, age of vaccine recipient, duration of immunity and route of administration (e.g., intramuscular, intradermal injection, oral, other)
- Dosing frequency and tracking (e.g., single dose vs. multiple doses, time between doses)
- Shipping/storage requirements (e.g., room temperature, refrigerated, frozen, deep-frozen)
- Compounding requirements (e.g., reconstitution, ready-to-use)

Most COVID-19 vaccines under development are likely to require a second booster shot a month or so after the initial dose. Providers will need to ensure that individuals who got the first shot receive a second shot of the right vaccine at the right time. Educating the population about the importance of receiving the booster shot will be critical.

***Is it safe to receive the vaccine?***

CVS Health's COVID-19 vaccination services will be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines. CVS Health will only be administering vaccines that have been approved for emergency use by the FDA.

***How is CVS Health working with the CDC to make the COVID-19 vaccine available?***

As announced by the HHS and Department of Defense, CVS Health has entered into a contract with the CDC to be one of the official COVID-19 Vaccination Program Providers in the Pharmacy Partnership for Long-Term Care Program. As a result, once a COVID-19 vaccine is approved and available, the U.S. government will make a supply of the publicly funded vaccine available to CVS Health to provide on-site vaccination clinic services to residents and staff of long-term care facilities.

***Who is eligible to receive the COVID-19 vaccination under this contract?***

Under this contract, CVS Health will receive a supply of the publicly funded COVID-19 vaccine and necessary supplies for administration once the vaccine is authorized and available. This supply of vaccine will be used to provide vaccinations to patients and staff of long-term care facilities.

***When will CVS Pharmacy begin offering the COVID-19 vaccine?***

Once a COVID-19 vaccine (or vaccines) is available, CVS Health will work rapidly to make vaccinations available to staff and residents of long-term care facilities, consistent with governmental priorities.

***How will CVS Health identify/select the long-term care facilities that it will support through this vaccination program?***

CVS Health will not select facilities. Rather, facilities will select their preferred pharmacy partner through the CDC's survey process. CDC will then provide a list of facilities to CVS Health where onsite clinics will be scheduled and conducted.

***Will patients be charged for the vaccine?***

No. Section 3203 of the CARES Act generally requires issuers offering non-grandfathered group or individual health insurance coverage to cover any qualifying coronavirus preventive service, including a COVID-19 vaccine, without imposing any cost sharing requirements, such as a copay, coinsurance or deductible.

No patient will be charged for the vaccine or its administration. The federal government will provide the vaccine itself, and CVS Health will be reimbursed by the patient's insurance or, in the case of uninsured patients, the Health Resources and Services Administration (HRSA) program for uninsured patients, for the administration of the vaccine. The Centers for Medicare & Medicaid Services (CMS) has established the reimbursement rates for administration of the vaccine for patients covered by Medicare as well as those covered by the program for the uninsured.

***How many doses of vaccine will be made available to CVS Health?***

The volume to be made available to CVS Health will be determined by the federal government's allocation methodology.

***Which vaccines will be offered? Will there be more than one type?***

The type of vaccine made available to CVS Health will be determined by the federal government's allocation methodology.

***In how many states will CVS Pharmacy be able to offer these clinics?***

CVS Health is prepared to provide vaccination clinics for long term care facilities in all 50 states.

***Where will the vaccinations take place? Will they take place at CVS Pharmacy locations or on-site at the selected long-term care facilities?***

For this specific program, CVS Health will coordinate and schedule a series of vaccination clinics on-site at the identified long-term care facilities.

***Will you be vaccinating both residents and staff members at these long-term care facilities?***

Yes, through this program we will be vaccinating both residents and staff members at identified long-term care facilities.

***Is CVS Health ready to provide appropriate temperature-controlled storage of the vaccine, even if the approved vaccine requires extreme cold storage and cold-chain standards?***

Yes. CVS Health will be able to appropriately store vaccines at the manufacturer's required temperature range.

***Who administers the vaccines at on-site clinics?***

Appropriate trained personnel under applicable state and federal laws and guidance will administer vaccines to facility patients and employees at the on-site clinics. CVS Health immunizers are trained and certified according to company and state specific regulations. These immunizers may include pharmacists, pharmacy interns, and trained pharmacy technicians, as well as other qualified healthcare professionals. All CVS Health immunizers are trained in the administration of immunizations and hold an active CPR certification.

***Will CVS Health be able to use the COVID-19 vaccine provide through this program for other populations outside of long-term care facility settings?***

Under the Pharmacy Partnership for Long-Term Care Program, the federal government will supply vaccine for use only to vaccinate residents and staff of long-term care facilities. Under the separate agreement CVS Health has entered into with HHS, CVS Pharmacies will receive vaccine supply to administer vaccines in our retail locations in accordance with the government's prioritization guidelines.

***How do I schedule an on-site COVID-19 vaccine clinic?***

To accommodate all interested facilities and to streamline operations for a positive experience, COVID-19 vaccine clinics will be automatically scheduled for pre-selected clinic dates and times, based on location, staffing and vaccine availability into specific geographies.

Three clinics will be scheduled for each facility, to accommodate both vaccine doses and potential new admissions and/or new hires.

Please note that facilities will not have the ability to request a reschedule, nor adjust their pre-selected clinic dates and times.

***If my facility did not complete the CDC survey for enrollment in this program, am I able to still register and sign up for a clinic?***

No. If a response was not provided on the CDC survey during the allotted window to enroll in this program, you will need to work directly with you state and/or local jurisdictions to determine a plan for receiving COVID-19 vaccine.

***What will the CVS pharmacy team bring to the clinic?***

The pharmacist will bring all requested vaccine product and other supplies necessary (including all appropriate Personal Protective Equipment, PPE) for administration, according to vaccination protocol.

***PPE & Cleaning Procedures***

CVS Health will follow CDC guidance to ensure vaccines are administered as safely as possible. We will abide by any state specific requirements regarding COVID-19 protocols, as well as CMS guidance.

***How are we ensuring discharged residents get booster administration?***

Close coordination between CVS Health and the Long-Term Care facility will be utilized to provide access to the next clinic dates for the discharged residents to complete their vaccination.

***What if a new admission comes in between the clinic dates?***

New admissions between clinics dates should be incorporated into the next available on-site clinic to begin the vaccination process if they choose to.

***What if a new admission comes from another setting that has received an alternative vaccine?***

CVS Health is not responsible for completing the booster dose for vaccinations of an alternative vaccine to what CVS Health was provided by the federal government and that patient should seek resolution with their care providers.

***If we get new admissions the day of the clinic can we add them to the clinic?***

In most instances the new admission will be able to receive the vaccine at that day's clinic as long as all paperwork is appropriately complete and vaccine is available. In some cases the patient will need to wait until the next on-site clinic to begin the vaccination process.

***Will there be consent forms available?***

Yes. Each individual planning to participate in the clinic and receive a COVID-19 vaccination (patient and facility staff) will need to complete a vaccine administration consent form. A packet of consent forms will be mail directly to your facility in advance of the clinic.

***What if a patient refuses consent?***

It is each patient's and/or responsible party's right to refuse the COVID 19 vaccination.

***Do participants need to provide their insurance cards?***

Yes, FRONT and BACK photocopies of each participant's current insurance cards will need to be obtained and attached to their consent form, to allow our teams access to unique claim billing details and avoid interruptions to your staff at point of care.

***Can patients receive other vaccines at the time of COVID-19 vaccine administration?***

Other vaccinations will not be offered at the time of COVID-19 vaccine administration and no patient should receive the COVID vaccine having received other vaccinations within 14 days

***Are the immunizers going to be vaccinated?***

CVS Health immunizer teams will be offered the opportunity to be vaccinated when available but are not required to be part of the vaccination effort

***How will CVS communicate with my facility?***

CVS plans on utilizing multiple communication channels but it will be important that they have the appropriate contact information, both email and phone, for the people responsible for the facilities clinics.

**How will the disposal of waste be handled at on-site clinics?**

CVS colleagues will bag waste from the clinics (trash bag provided by CVS) and dispose of the bagged waste in the facility's dumpster. Waste is defined as gloves, mask, gown, band-aids, used alcohol wipes, cotton balls., etc.

Please note that items such as empty vaccine vials, immunization supplies (needles, syringe), etc. would still be put into a Sharps container and transported back to CVS Pharmacy for disposal.

**How do I contact CVS if I have questions?**

Please reference [www.omnicare.com/covid-19-vaccine-resource](http://www.omnicare.com/covid-19-vaccine-resource) with questions or reach out to [CovidVaccineClinicsLTCF@CVSHealth.com](mailto:CovidVaccineClinicsLTCF@CVSHealth.com). You will also be receiving numerous communications and other material throughout the process that should help answer most questions.

Consent Form Requirements & Process:

**What are the requirements for consent?**

Three (3) copies of a signed, completed consent form is required in order to participate in the vaccination clinic and receive a COVID-19 vaccine.

**Are both physical and electronic versions of the consent form available?**

A packet of physical, triplicate consent forms will be mailed directly to your facility and is the preferred method of obtaining consent.

However, electronic consent is available via the following two options:

1. COVID-19 Vaccine Consent Responsible Party Form (*abridged*)
2. COVID-19 Vaccine Full Intake Consent Form

Both of the electronic, editable PDF versions are available for download on our webpage.

**What is needed in order to use the COVID-19 Vaccine Responsible Party cover sheet form?**

The facility will need to email the Responsible Party Form (*abridged*) to the patient's responsible party (RP)/Power of Attorney (PoA) where the patient is unable to complete the form themselves. The form will need to be completed, signed, and returned to the facility and three (3) copies will need to be printed. One copy of the printed, completed form will need to be attached to each copy of the physical triplicate COVID-19 Vaccine Consent Form. Facility staff are responsible for completion of the remainder of the physical triplicate COVID-19 Vaccine Consent Form and a signature by facility staff is required, to indicate alignment to RP authority. The CVS immunizer will complete the bottom section on the physical form, which carbon copies to the other 2 for documentation, RP cover sheet attached to each.

**What is needed in order to use the electronic, editable PDF COVID-19 Vaccine Full Intake Consent form?**

The facility will need to email the editable COVID-19 Vaccine Full intake Consent form to the patient's responsible party (RP)/Power of Attorney (PoA) where the patient is unable to complete the form themselves. The form will need to be completed, signed, and returned to the facility and three (3) copies will need to be printed. Verified electronic signature should be present on all three copies. The facility must confirm health status prior to the clinic and the facility is responsible for complete all incomplete fields not populated by the patient's RP/PoA. The CVS immunizer will complete the bottom section on the printed 3 forms.

**Is verbal consent accepted?**

For individuals who do not have physical or cognitive ability to consent through alternate means (or minors), verbal consent by the patient's responsible party is permitted. For patients who have the ability to offer written consent, that process should be used.

If consent from the patient's responsible party is collected verbally by the facility, a facility representative signature is required to indicate that verbal consent to treat has been documented in the medical record. Further, the facility is authorizing CVS to bill on behalf of the individual. In such instances, the facility must complete and sign the consent form.

**Do participants need a completed consent form for each dose of the COVID-19 vaccine?**

Yes. Two (2) complete sets of the consent forms will be required for each individual participating in the vaccination clinic (one for the first dosing/clinic and a second set for the second dosing/clinic).

**In the event that the facility doesn't intend to provide a form back to patient, are they able to only print two copies?**

We require three signed and completed forms. If a facility elects not to share the third form with a patient, that is a choice at the discretion of the facility, but our process is designed to fully complete three forms per immunized individual.

The purpose of three signed and completed forms is for full documentation to be provided to the vaccine recipient, the LTC facility, and CVS Health.

Adverse Events:

**What is the recommended observation time following administration of a COVID-19 vaccine?**

The CDC published an observation time of 15 minutes, for most people. For those with a history of severe allergic reactions (e.g., anaphylaxis), a 30 minute observation period is recommended. This is the responsibility of the LTC facility.

**In the event of a severe allergic reaction to the COVID-19 vaccine, will the CVS immunizing team bring anaphylactic response?**

Yes, our immunizers will come prepared with emergency kits (e.g. a minimum of 6 Epipens) in the event of any reactions.

**How should reporting of adverse events be reported?**

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under Emergency Use Authorization:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

In the event of any COVID-19 Vaccine Administration Error and/or Adverse Event (whether identified at the time of the clinic or at a later date) the facility should call the CVS store team that performed their clinic. A pharmacist at the store will speak with the facility, provide guidance on next steps, and offer support for reporting in VAERS.

Pfizer-BioNTech COVID-19 Vaccine:

**Should someone who was previously infected with COVID-19 receive the Pfizer vaccine?**

Yes. Data from clinical trials suggest that the Pfizer vaccine is safe and likely efficacious in persons with evidence of a prior COVID-19 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic COVID-19 infection.<sup>1</sup>

**Should someone who is currently infected with COVID-19 receive the Pfizer vaccine?**

Vaccination of persons with known current COVID-19 infection (meaning infection with symptoms) should be deferred until the person has recovered from the acute illness and criteria have been met for them to discontinue isolation. While there is 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 COVID-19 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.<sup>1</sup> Those who have tested positive for the virus but are not exhibiting acute symptoms may receive the vaccine.

**Should someone with known exposed to COVID-19 receive the Pfizer vaccine?**

Yes. For persons residing in congregate healthcare settings (e.g., long-term care facilities) where exposure and transmission of COVID-19 can occur repeatedly for long periods of time, residents with a known COVID-19 exposure may be vaccinated. In these settings, healthcare personnel are already in close contact with residents (e.g., entering patient rooms for evaluation and treatment) and should employ appropriate [infection prevention and control procedures](#), so administering COVID-19 vaccine should not result in additional exposures.<sup>1</sup>

**How is the Pfizer vaccine administered?**

The Pfizer-BioNTech COVID-19 vaccine series is administered intramuscularly.

**What is the dosage of the Pfizer vaccine?**

The Pfizer-BioNTech COVID-19 vaccine series consists of two doses (30 µg, 0.3 ml each) administered three weeks apart. Doses within a grace period of ≤4 days (i.e., between day 17 and 21) are considered clinically effective.

**What is the clinical guidance for someone who misses the recommended second dose window?**

If the second dose is administered earlier than day 17, it does not need to be repeated. If more than 21 days have elapsed since the first dose, the second dose should be given at the earliest opportunity; the series does not need to be repeated.<sup>1</sup>

**Are there any known age restrictions for receiving the Pfizer vaccine?**

The Pfizer-BioNTech COVID-19 vaccine can be administered to persons age 16 years and older.

**Is the Pfizer vaccine interchangeable with other COVID-19 vaccine products?**

No. The Pfizer-BioNTech COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products and the safety and efficacy of a mixed-product series have not been evaluated. Persons initiating vaccination with the Pfizer vaccine should complete the series with this product. If two doses of different COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. Recommendations may be updated as further information becomes available or other vaccine types (e.g., viral vector, protein subunit vaccines) are authorized.<sup>1</sup>

**Are individuals able to receive other vaccines simultaneously with the COVID-19 vaccine?**

Given the lack of data on the safety and efficacy of the COVID-19 vaccine administered simultaneously with other vaccines, the Pfizer vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. If the COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.<sup>1</sup>

**What is the efficacy of the Pfizer COVID-19 vaccine?**

Preliminary data suggest that vaccine efficacy of the Pfizer COVID-19 vaccine is 95.0% following two doses in healthy adults. Vaccine efficacy following a single dose is estimated at 52.4%; however, one-dose efficacy was based on few cases and a short median follow-up time. Thus, patients should be counseled on the importance of completing the two-dose series to optimize protection.

**Can a resident be vaccinated with the Pfizer COVID-19 Vaccine if they received a monoclonal antibody infusion?**

Current guidance states that vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.

State Activation Plans:

**How do we know if our state has activated with the federal program?**

Facilities are encouraged to refer to their state Department of Health for activation status and timelines.

**What specific process/operational details are preventing CVS Health from participating in West Virginia?**

There is no single operational detail that is individually preventing CVS Health from participating in the state program. However, due to the large number of operational changes required to support the state requirements (versus federal program), the management of these adjustments introduces risk into the overall / national operation. At this stage of deployment, we are committed to launching the federal vaccine program as top focus.

Reference:

1 [https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F covid-19%2Finfo-by-manufacturer%2Fpfizer%2Fclinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F covid-19%2Finfo-by-manufacturer%2Fpfizer%2Fclinical-considerations.html)

