

# FAQs and Resources on COVID-19 Vaccines and Issues Surrounding Vaccinations

March 1, 2021

We have received numerous inquiries about potential vaccines for COVID-19 as well as operational and practical questions involving vaccinating employees and residents. Below are answers to frequently asked questions as well as a list of resources on COVID-19 vaccines and vaccinations. We will update these FAQs when more information becomes available.

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#### **VACCINE APPROVAL**

#### When will a COVID-19 vaccine be available in the United States?

The first vaccines for use in the United States have been approved. The Pfizer-BioNTech COVID-19 vaccine has been granted Emergency Use Authorization (EUA) by the government and has already begun shipment. The Moderna COVID-19 vaccine was issued an EUA on December 17, 2020.

The Johnson & Johnson (Janssen Biotech) one-shot COVID-19 vaccine was given FDA EUA approval on February 27, 2021.

(updated 3/01/2021)

### How is a vaccine developed and tested?

Approval of a vaccine for use in people involves multiple phases with different goals for assessing effectiveness and safety in different populations. There are a total of 4 phases and the vaccine must meet very intense safety criteria before completing each phase. Once a vaccine is approved for use after phase 3, it has been tested in tens of thousands of people and if no significant harmful side effects are noted, it is considered safe for use. Phase 4 involves continued monitoring and gathering of safety data. This

type of clinical trial has been used for decades to approve medications and vaccines. See AMDA Questions and Answers About the COVID-19 Vaccine.

(updated 12/15/2020)

# What are the Food and Drug Administration (FDA) requirements for the safety and efficacy of a COVID-19 vaccine?

FDA requires 50% efficacy of a COVID-19 vaccine (the COVID-19 vaccines from Pfizer and Moderna are showing 94-95% efficacy in preventing COVID-19 disease during this trial phase). Many other companies are working on a vaccine and we expect that the FDA will approve additional vaccines. The FDA requires 8 weeks of safety data on the COVID-19 vaccine. See <a href="MMDA Questions and Answers About the COVID-19 Vaccine">AMDA Questions and Answers About the COVID-19 Vaccine</a>.

(updated 12/15/2020)

### What is an Emergency Use Authorization (EUA) and if the vaccine is approved for an EUA, what does that mean?

An EUA is based on the need to use a vaccine quickly to save lives during an urgent health crisis or pandemic. While the EUA is a shorter process, no steps are skipped in the safety evaluation process. This approval can still take weeks and the FDA will reevaluate the numbers and data to ensure that the calculations are correct. The FDA will assess if the vaccine's known and potential benefits outweigh the known and potential risks. See <a href="MDDA Questions and Answers About the COVID-19 Vaccine.">MDDA Questions and Answers About the COVID-19 Vaccine.</a>

(updated 12/15/2020)

# Are the Emergency Use Authorizations Fact Sheets in languages in addition to English?

The FDA has <u>posted</u> the Pfizer-BioNTech COVID-19 Vaccine Fact Sheet in languages including: Arabic, Burmese, Cherokee, Chinese (Simplified and Traditional), Chuukese, German, Haitian Creole, Hindi, Hmong, Korean, Mam, Polish, Portuguese, Russian, Spanish, Somali, Tagalog, Vietnamese, and Yiddish. We will post additional language translations of the fact sheet for recipients and caregivers to this page as we receive the translations.

(updated 12/29/2020)

#### Will there be a one-dose vaccine approved soon?

Johnson & Johnson (Janssen Biotech) conducted trials of a one-dose vaccine and the FDA granted EUA approval of the vaccine on February 27, 2021.

(updated 03/01/2021)

### PRIORITIZATION AND DISTRIBUTION

### Who is making recommendations and determinations on the priority for COVID-19 vaccinations?

The Centers for Disease Control (CDC) is making coronavirus disease 2019 (COVID-19) vaccination recommendations based on input from an Advisory Committee on Immunization Practices (ACIP). ACIP is a federal advisory committee made up of medical and public health experts who develop recommendations on the use of vaccines in the U.S. public. ACIP holds regular meetings, which are open to the public and provide opportunity for public comment.

After ACIP publishes its guidance and recommendations, it is then up to the states and their governors to determine the priority of vaccinations in their respective states.

States are working in real time to develop vaccination priorities anticipating a first round of vaccines doses in the coming weeks. Many have interim plans in place for vaccine allocation, and an initial analysis of these by LeadingAge finds that states are prioritizing long-term care residents and workers in their plans. The ACIP recommendations may help inform state plan refinements and/or continued prioritization of long-term care.

# Who will be prioritized once Phase 1a healthcare workers and residents in congregate settings (nursing homes, assisted living, HUD Section 202, IDD communities) are vaccinated?

The Advisory Committee on Immunization Practices (ACIP) recommended that in phase 1b people over the age of 75 and essential frontline workers should be vaccinated. In the next tier 1c, people between the ages of 64-75, people between 16-64 with high-risk health conditions, and essential workers not yet vaccinated should receive priority. States are the final decision makers, but many follow ACIP guidance.

Keep following your state recommendations as the priorities and tier levels as well as vaccine availability are changing on a regular basis.

(updated 3/01/2021)

# Will state and pharmacy partner allocations include first AND second doses? Will pharmacies need to conserve doses to have enough for second doses?

Operation Warp Speed is holding back fifty percent of available doses to be used as second doses, i.e., if a pharmacy partner gets 10 doses, they vaccinate 10 people and will receive 10 more for the second immunization for those 10 people.

(updated 12/10/2020)

#### PHARMACY PARTNERSHIP FOR LONG-TERM CARE PROGRAM

### What is the Pharmacy Partnership for Long-Term Care Program?

The Pharmacy Partnership for Long-term Care Program provides end-to-end management of the COVID-19 vaccination process, which includes cold chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this patient population, while reducing burden on long-term care facilities and jurisdictional health departments. Long-term care facility staff members that have not received a COVID-19 vaccine can also be vaccinated as part of this program.

The pharmacy partnership program provides critical vaccination services and is free of charge to facilities. This effort will require extensive coordination with jurisdictions, long-term care communities, federal partners, including the Centers for Medicare and Medicaid Services (CMS), and professional organizations, including LeadingAge and American Health Care Association (AHCA).

# What facilities can participate in the Pharmacy Partnership for Long-Term Care Program?

Long-term care facilities are eligible to participate in the Pharmacy Partnership for Long-term Care Program, including skilled nursing facilities, nursing homes, assisted living facilities (residential long-term care facilities providing assistance and supervision to primarily elderly residents with activities of daily living and skills for independent living; this includes HUD Section 202 communities but does not include other Independent Living (see next question)), and similar congregate living settings where most individuals receiving care/supervision are older than 65 years of age.

#### Is "independent living" included in the Pharmacy Partnership or not?

The Pharmacy Partnership does not include stand alone independent living and does not *officially* include people living in IL on a LPC/CCRC campus. However, there is some flexibility in how this is carried out. For instance, jurisdictions may elect to include IL residents of LPCs. The CVS/Walgreens partners will work with states and jurisdictions on these determinations. Unofficially, it is also possible that there will be additional vaccine doses when all staff on the campus and all nursing home and assisted living residents have been immunized. Decisions might be made about how to use those doses.

It's also important to keep in mind that the Pharmacy Partnership clinics are the "kickstart" to COVID-19 vaccines; there will be other pharmacy clinics in communities after this first wave.

(updated 12/18/2020)

What if my Pharmacy Partner says they are restricted in their CDC contract from immunizing independent living residents, even though my state has included people in IL on a CCRC/LPC campus in the program?

That is not accurate. If a state includes people living in IL in the Partnership, the CVS or Walgreens (or other pharmacy partner) should include those individuals.

(updated 01/08/2021)

# CDC officials have talked about allocations to providers based on "certified" beds. Does this actually mean only Medicare and Medicaid certified beds?

No. It means all beds. Allocations for each provider will be based on the total number of beds the provider has. In addition, this is regardless of whether the bed is currently occupied.

(updated 12/18/2020)

### What needs to happen to "green light" the Partnership to start?

States must "activate" the Partnership. All states have requested to activate their programs effective December 21 or two to three weeks following, with the exception of two or three states that have opted out of the program and are handling things on their own. This Partnership program was designed to support states and jurisdictions.

(updated 12/18/2020)

### How can I check to make sure my facility is within the Pharmacy Partnership?

According to CDC, with more than 70,000 participating agencies and no public-facing database, there is no way to confirm a facility's participation.

(updated 12/10/2020)

### Is it too late to join the Partnership?

Yes. Providers should work with their state to access vaccine resources.

(updated 12/18/2020)

### I initially selected one pharmacy partner and now I want to switch. Can I do that and how?

If a provider selected Walgreens or CVS and wants to switch, that is done with the state. Similarly, as noted above, if a provider did not sign up for the Partnership but now hopes to be included, that is a conversation that has to happen at the state level, where these decisions are made.

(updated 01/08/2021)

### What happens after the three clinics that are part of this program?

The ultimate goal of the Partnership is to transition these clinics to long-term care pharmacies as well as current partners. As new vaccines come on line that don't require different freezers and can be shipped in smaller quantities, CDC hopes that qualified nursing homes, assisted living, and other providers will be able to administer vaccines themselves.

We anticipate more information about this transition to retail pharmacies soon. It is our understanding that anyone should be able to go to the CDC website and sign up once it is up and running.

(updated 01/28/2021)

### What if scheduling is still a problem with my Pharmacy Partner?

CDC is aware of this but acknowledges that working with 19 partners (40,000 pharmacies) and with close to 80,000 vaccine clinics to schedule – there will be bumps in the road. It might be helpful to know that CDC has suggested to CVS and Walgreens that they set up clinics in larger organizations in the morning and smaller organizations in the afternoon, since clinics in larger organizations often end with a few extra thawed doses.

(updated 01/08/2021)

# Does the HHS announcement on January 6 mean that anyone can go into their local drugstore and get a COVID vaccination?

Not yet. Starting next week, a state that is up to phase 1B and is ready to vaccinate essential workers can transfer doses to one of the 19 federal pharmacy partners and designate those doses for specific essential workers. For example, a state could move doses for teachers to a local drugstore, which in turn would hold clinics for teachers, with each designated, approved teacher receiving a code to get the vaccine. Or a state could provide a store like Target or Walmart with enough doses for their workers (who are essential workers).

(updated 01/08/2021)

The CDC recommendations for the Pharmacy Partnership suggest to sequential distribution: a Part A (nursing homes), and a Part B (all else). Has the CDC recommended states or Pharmacy Partners further phase vaccine distribution within Part B?

The CDC has not recommended to states or Pharmacy Partners any staggering of facility types in Part B (which includes assisted living, HUD Section 202s and other

settings). States may be prioritizing within Part B, but the CDC has not recommended this.

(updated 01/08/2021)

# If our organization participates in the Pharmacy Partnership for Long-Term Care Program, are we responsible for certain costs?

According to the CDC, there will be no cost to the facility for participation in the pharmacy partnership program. It is anticipated that participating pharmacies will bill public and private insurance for the vaccine administration fees.

### Will there be any additional administrative fees charged by CVS or Walgreens?

No, and any rumors to the contrary are incorrect. The administrative fee will be paid by the program. CVS and Walgreens are absolutely NOT sending any kind of bill or balanced billing to providers. They cannot bill providers and they cannot bill the people who are immunized. They cannot charge for onsite clinics. Some people on the ground with CVS or Walgreen's have outdated or wrong information. If members share the name of pharmacies that give them information related to billing, please send the information to Linda Couch or Ruth Katz at LeadingAge and we will send it to CDC. (updated 12/10/2020)

### Will the Pharmacy Partnership for Long-Term Care Program vaccinate staff, in addition to residents?

Yes, the pharmacy partnership program can cover both residents and staff for the vaccinations when the pharmacies schedule their visits.

However, each state determines how to vaccinate health care workers, including long-term care workers, so follow your state public health agency and governor's office guidance to get more information on how to vaccinate your staff.

### Are facility volunteers eligible to be vaccinated through the partnership (can they be counted in the staff numbers)?

Yes, volunteers can be counted as staff. The CDC has a very broad definition of health care worker – includes paid and nonpaid workers.

(updated 12/10/2020)

# Who is responsible for administering the vaccination and fulfilling the data reporting requirements of the vaccination program?

The pharmacy partners will be responsible for administering the vaccine as well as for completing all of the data reporting requirements under the program.

### Will vaccine recipients be billed?

No balance billing is permitted. Those receiving vaccines through the Partnership cannot be billed. The pharmacy partner, CVS or Walgreens, will ask for a photocopy of the individual's insurance card and then bill Medicare, Medicaid, or private insurance or the HRSA uninsured program.

(updated 12/10/2020)

### Does the Pharmacy Partner need an ACTUAL Medicare, Medicaid, or insurance card, or just the information?

Each Pharmacy Partnership pharmacy may handle this differently. For example, CVS is asking for an image of the front and back of the insurance card as they are seeing errors in transcribing numbers on the consent form. So, yes, copies of the cards are needed. If the person does not have insurance, attestation can be completed on the consent form.

(updated 12/22/2020)

### What do they do with that insurance data?

They use it to bill for administration of the vaccine. Note: there is NO charge to anyone for the vaccine itself.

(updated 12/18/2020)

# Section 202 housing has different rules and restrictions about collecting insurance information, for example. How will the variations for this type of housing be handled?

Thus far, the answer from Pharmacy Partners has been for all providers to try to conform as closely to the prescribed process as possible.

(updated 12/22/2020)

### What if the individual cannot pay?

No one will be turned away for not being able to pay. Pharmacies are not allowed to turn away people who cannot pay. The pharmacy will vaccinate the individual and then bill the HRSA uninsured program.

(updated 12/10/2020)

### Are home health aides, hospice workers, and other caregivers working outside of a facility setting included in the pharmacy partnership program?

Although these workers are considered healthcare workers, they are not part of the pharmacy partnership program. These workers should be addressed by the state priority plans, so stay tuned as more information becomes available in your state.

Which vaccine is going to be distributed to organizations under the Pharmacy Partnership for Long-Term Care Program?

Each state will determine which vaccine or vaccines are allocated to the pharmacy partnership program in their respective state.

(updated 12/10/2020)

#### How much time can there be between the first and second vaccinations?

The ACIP will issue the acceptable range of time between the first and second doses. (updated 12/10/2020)

### Can you receive the first shot with one vaccine and then get the second shot with a different vaccine?

No, it is important to use the same vaccine for both doses as these vaccines differ from one another.

(updated 01/07/2020)

### How will new residents/admissions and staff will receive the vaccine ongoing?

This issue is developing. Ideally, there will be vaccines that could be left with the provider like flu vaccines are (the Pfizer vaccine, for example, must be kept at -80 degrees and few have such deep cold storage). Also, states bringing more and more pharmacies on through which facilities can order the vaccine.

(updated 12/10/2020)

#### Does administration of the vaccine require a patient specific practitioner order?

No. According to Public Readiness and Emergency Preparedness Act (PREP Act) guidance issued by HHS Office of General Counsel in early September, this is not needed for vaccines approved under EUAs. Pharmacies can administer the vaccines under a standing order for everyone.

(updated 12/10/2020)

### What literature is coming out on the program, who will issue and distribute it and who will they send it to?

CDC will provide the pharmacy partners with the EUA fact sheet (which will also be on the FDA website) and information about safety tracking. Facilities in turn will distribute the information to those who are vaccinated. See the Pfizer-BioNTech and Moderna COVID-19 Vaccine EUA Fact Sheets below in the resources section.

#### Is CDC putting out a toolkit for providers?

Yes. The CDC has posted a Vaccination Toolkit for Long Term Care Facilities and can be found here: Long-Term Care Facility Toolkit: Preparing for COVID-19 Vaccination at

<u>Your Facility</u>. The toolkit also provides a variety of printable resources to help communicate with staff and residents:

- 1. Sample Letter to Staff About COVID-19 Vaccination
- 2. Fact Sheet Answering Common Long-Term Care Staff Questions about COVID-19 Vaccines
- 3. Sample Letter to Resident About COVID-19 Vaccination
- 4. Sample Letter to Residents' Loved Ones About COVID-19 Vaccination
- 5. <u>Fact Sheet Answering Common Long-Term Care Residents' Questions about COVID-19 Vaccines</u>

The CDC has also posted a <u>Frequently Asked Questions about COVID-19 Vaccination in Long-Term Care Facilities</u>.

A toolkit for health care providers is also available.

(updated 12/29/2020)

### After staff of LTC provider organizations get vaccinated must they continue to be tested?

Yes. There have not been changes to the testing requirements.

(updated 12/23/2020)

#### How will administration of vaccines be tracked?

The pharmacy partner will track administration and take care of all federal and state reporting. Long-term care facilities should document in residents' medical record per usual practice. HUD Section 202 communities do not maintain such records.

(updated 12/10/2020)

If residents and staff have not received a first dose of COVID-19 vaccine, should they receive their first dose at the third and final clinic scheduled as part of the Pharmacy Partnership for Long-Term Care Program?

The CDC supports optimizing vaccine access for all long-term care staff and residents. However, some jurisdictions have asked pharmacy partners not to initiate first dose vaccinations at third clinics. In this case, providers and pharmacy partners should follow jurisdictional guidance.

(updated 2/9/2021)

How can we ensure residents and staff who receive their first dose of Moderna vaccine at the third on-site clinic are able to receive their second dose of Moderna vaccine?

Some LTC pharmacies (CDC defines a LTC pharmacy as a specialized pharmacy designed specifically to support individuals living in a LTC facility or community) will be providing the Moderna vaccine to residents and staff at facilities they serve, either

through the <u>Federal Retail Pharmacy Program</u> or through enrollment as a COVID-19 vaccination provider with a specific state or territory. Providers should check to see if their regular LTC pharmacy will have access to the Moderna vaccine. If so, pharmacy staff may administer the second dose of Moderna vaccine to staff and residents at the appropriate time.

Staff or discharged residents who receive their first dose of Moderna vaccine at a third clinic can also seek their second dose in the community at a retail pharmacy location or through their local health department.

(updated 2/9/2021)

How can we ensure residents and staff who receive their first dose of Pfizer-BioNTech vaccine at the third on-site clinic are able to receive their second dose of Pfizer-BioNTech vaccine?

Many LTC pharmacies may not stock Pfizer-BioNTech vaccine because of the product's unique cold chain requirements, so it is important to determine in advance how staff and residents who receive their first dose of Pfizer-BioNTech vaccine at a third clinic will access their second dose.

**Staff members** who receive their first dose of Pfizer-BioNTech vaccine at a third clinic can contact CVS, Walgreens, or any other pharmacy locations providing the Pfizer-BioNTech vaccine in their community to schedule an appointment to get their second dose. Staff can also contact their local health department for this information. This applies to LTCF residents who are later discharged, too.

Administrators and clinical leadership should determine if there is a local provider available to administer the second dose of Pfizer-BioNTech vaccine to **residents** on site at the time it is needed, either by checking with another local pharmacy or by contacting their local health department. If all potential options for administering a second dose of Pfizer-BioNTech vaccine have been exhausted, LTCF clinical leadership may consider counseling residents to finish the vaccine series using the Moderna vaccine. The Advisory Committee on Immunization Practices (ACIP) recommends, "In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series." ACIP further recommends that "...the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose." https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

(updated 2/9/2021)

How can we ensure our facility has continued access to COVID-19 vaccine after the Pharmacy Partnership for Long-Term Care Program is over?

To ensure new staff and residents have access to COVID-19 vaccine after the federal Pharmacy Partnership for LTC Program is completed, providers should work with a LTC pharmacy that is enrolled as a COVID-19 vaccination provider. Many pharmacies are enrolled with the federal government as COVID-19 vaccination providers through the Federal Retail Pharmacy Program and will be able to order vaccine directly from the federal government. Others may enroll directly with the state or territory in which they are located. CDC will provide more detailed guidance in the coming weeks on next steps for COVID-19 vaccination in LTCFs after the federal Pharmacy Partnership for LTC Program concludes. Check the program website for updates.

(updated 2/9/2021)

### **IMMUNIZING STAFF**

### Can employers mandate that employees get the COVID vaccine when available?

The federal government cannot mandate a vaccine under an Emergency Use Authorization. The EUA, however, is silent on whether an employer, state or local jurisdiction may require vaccinations. We will continue to monitor state level actions as well as any additional federal guidance as more information becomes available that provides clarity to this issue.

The EEOC updated its guidance – What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws - on December 16, 2020. The guidance explores the requirements and considerations if employers mandate COVID-19 vaccinations for employers. Unfortunately, it does not directly answer the question of whether a mandatory vaccination policy is allowed if a vaccine only has only FDA EUA approval. See <u>EEOC Guidance</u>.

Generally, for vaccines that have gone through the full FDA process (the Biologics License Application), employers, and specifically health care providers, may require employees to get certain vaccinations as a condition of employment, but those mandates are subject to exceptions based on accommodations for disability or religious objections that might be available under state or federal law. See the <u>EEOC Guidance</u>, specifically Section K, to understand the nuances of the ADA analysis and how to address reasonable accommodation requests from employees that refuse a COVID-19 vaccine.

Even though employers might be able to mandate a vaccine for employees, employers may choose not to make vaccinations mandatory or use alternative methods for ensuring their employees get a vaccine once it becomes available. As this is a new virus and there may be multiple vaccines available, education will be critical for employers to assure their workforce is aware of the benefits of a vaccination.

If employers are exploring whether to mandate a vaccination for employees, they need to consider whether that impacts any potential worker's compensation or personal injury claim by an employee for claims resulting in adverse reactions to the vaccine. They should also consult with their human resources staff and labor and employment legal counsel.

Finally, unionized employers should look at any collective bargaining agreement in place to determine if that impacts any policy on vaccinations.

(updated 12/17/2020)

### Are employers liable for any side effects or injuries that employees may suffer from the vaccine?

As mentioned above, employers that mandate a COVID-19 vaccination for their employees might be subject to workers' compensation claims if the employee has an adverse reaction or is injured due to the vaccine.

For non-work related claims arising out of a COVID-19 vaccination, individuals may seek recovery under the <u>Countermeasures Injury Compensation Program (CICP)</u>. This program is set up to address potential claims from the COVID-19 vaccine (and other "countermeasures" relative to various illnesses and pandemics). This is separate and distinct from the <u>National Vaccine Injury Compensation Program</u> that covers many childhood and the seasonal influenza vaccinations.

### Can we provide an incentive for employees to get the vaccine?

Yes, you may offer an incentive if you institute a voluntary vaccination program and want to encourage staff members to get the vaccine.

### Should temporary staff be vaccinated?

Yes, temporary staff are within the CDC's definition of a healthcare worker. Indeed, temp agency staff that might rotate among a number of facilities could in many ways be at highest risk.

(updated 12/10/2020)

Vaccinations may cause staffing problems, either because staff experience side effects and have to miss work or because many residents experience side effects and need more staff time. What can providers do, can vaccines be staggered?

It is possible for the Partnership to vaccinate half the staff and for the other half to go through the state program at a different time. That is not an ideal solution and CDC is working on others. Doubling the number of visits to allow for staggering of staff immunizations would involve doubling the number of clinics; there are 70,000 providers participating in the program.

(updated 12/10/2020)

### How can staff demonstrate they have been immunized, especially if they go to work somewhere else?

Each vaccine dose comes with a card, which must be given to the individual or their proxy. Pharmacies may also offer additional verification on an app.

(updated 12/10/2020)

### **IMMUNIZING RESIDENTS**

### Are nursing home residents required to get a COVID-19 vaccination?

No. Under an EUA, the federal government cannot mandate that individuals get the vaccine. Residents or their representative can refuse the vaccine.

### If a person already had COVID-19, should they get a COVID-19 vaccine?

Yes. Vaccine will be offered to persons regardless of history of prior symptomatic or asymptomatic COVID-19. Data from phase 2-3 clinical trials suggest it is still efficacious.

### Should those with a known exposure to COVID-19 be vaccinated?

People in the general community who have a known COVID-19 exposure should not seek vaccine until quarantine has ended in order to prevent exposing healthcare personnel and others. In long-term care, however, healthcare personnel and residents with a known COVID exposure may be vaccinated before the quarantine period is up. In these circumstances, employ appropriate safety protocols in vaccine administration. Those in other congregate settings who have been exposed, such as correctional facilities or homeless shelters, may also be vaccinated without waiting for the end of a quarantine period.

(updated 12/15/2020)

### How would someone discharged before their second dose receive the second dose, e.g., short-term rehab patients in a nursing home?

How people who move in and out of systems and geographies present complications, but is one of the benefits to the CDC using two very large providers, CVS and Walgreens, as the pharmacy partners. CVS and Walgreens serve as their own vaccine registries. A person would remain in the CVS system, for example, as they move and could thus receive a second dose in a different setting than the original setting. The issue should be a part of the conversations between facilities, especially those that have short-stays, and their CVS or Walgreens pharmacy partner. Options are: a person who left a facility could return, staying in their car and not entering the facility, to get the second dose; or, pharmacies are working on establishing a 1-800-call center so individuals can follow up with the pharmacy and make an appointment at the CVS or

Walgreens to get their second dose outside of their original facility site. As the supply of vaccines becomes less constrained, access to doses will not always be an issue.

### How can people demonstrate they have been immunized?

Each vaccine dose comes with a card, which must be given to the individual or their proxy. Pharmacies may also offer additional verification on an app.

(updated 12/10/2020)

# How will provider staff recognize side effects versus virus symptoms in residents and evaluate them post-vaccine?

The CDC has issued some guidance on approaches to help staff evaluate and manage systemic new onset signs and symptoms for residents post-vaccination. This is critical because some post-vaccine symptoms may overlap with COVID-19 symptoms. These symptoms include fever, chills, headache, fatigue, muscle ache, and joint pain. Symptoms that are consistent with COVID-19 and are not consistent with post-vaccine symptoms include cough, shortness of breath, runny nose, sore throat, and loss of taste or smell.

All symptomatic residents should be assessed and the evaluation should be tailored to fit the clinical and epidemiologic characteristics of the specific case. For information on the suggested approaches see the CDC - Post Vaccine Considerations for Residents. See also the CDC - Post Vaccine Considerations for Healthcare Personnel and Summary of CDC Webinar on Post-Vaccine Events and Considerations.

(updated 12/15/2020)

### **CONSENT**

### Who sets the policies, materials and requirements for consent?

CDC does not require consent or dictate how providers or pharmacists handle consent. The CDC standard of practice is to have a conversation with the individual or their proxy and document it. Providers should talk with pharmacy partners about how they each plan to handle consent and there are many resources available at the end of this document.

(updated 12/18/2020)

### Can consent forms be signed before the EUA comes out?

Again, CDC does not require consent forms, but it is advised that if they are used, it should be after the EUA is available so the person knows what vaccine they are getting and fact sheets are also available.

(updated 12/10/2020)

#### Will consent forms be able to be done electronically?

CVS/Omnicare has agreed to accept an email from a resident or resident representative printed out and stapled to the triplicate consent form it is otherwise requiring. Providers should talk with their pharmacy partners about alternatives to the consent forms.

(updated 12/11/2020)

### Will consent forms be available in multiple languages?

This is up to the pharmacy or provider requiring the consent form.

(updated 12/10/2020)

#### Is verbal consent allowed?

Yes. According the CVS, verbal consent from a responsible party is allowed for patients that do not have physical or cognitive ability to consent. If patients or their responsible party are able to provide written consent, that process should be used. If consent is collected verbally by the facility, a facility representative signature is required to indicate that verbal consent to treat by patient's responsible party 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. See <a href="CVS">CVS</a>
COVID-19 Consent Requirements and Process.

Walgreens requests that facilities follow their **standard facility protocols** for obtaining consent from family members or other authorized persons. Consent can be provided verbally, via phone or email. The Walgreens vaccine consent form (VAR) still needs to be completed. The form indicates that an authorized person can complete the VAR on behalf of the patient. See the FAQs section of the <u>Walgreens Long-Term Care Facility COVID-19 Vaccination Program</u>.

(updated 12/18/2020)

### SIDE EFFECTS

### How will provider staff recognize side effects?

The ACIP plans to discuss side effects of vaccines and staggering immunizations in long-term care and information will be update once it is made available.

(updated 12/10/2020)

# I heard the COVID vaccine will harm my fertility and make it so I'm unable to get pregnant. Is this true?

No. This is false. There is not plausible biological explanation for how the vaccine would cause infertility as the spike protein in the vaccine or antibodies to it do not effect fertility. No infertility has been shown among people who have contracted COVID during

the pandemic since people who got COVID develop antibodies to the same spike protein in the vaccine. Finally, in the vaccine trial with the Pfizer vaccine, 12 women became pregnant after receiving the vaccine. See also <a href="this fact-checking article">this fact-checking article</a>.

(updated 12/11/2020)

### **Miscellaneous Questions**

We are hearing lots of news on the use of and best masks, so what is the position of the CDC on masking?

There are numerous discussions ongoing regarding whether double-masking is appropriate or recommended, but the CDC has not recommended double-masking at this time. This is the latest link to the CDC <u>Guide to Masks</u> and <u>Considerations for Wearing Masks</u>.

(updated 1/28/2021)

### If I wear a mask, do I still need to practice social distancing?

Yes, a mask is NOT a substitute for social distancing. Masks should still be worn in addition to staying at least 6 feet apart, especially when indoors around people who don't live in your household.

(updated 1/28/2021)

### Where can I find trusted information regarding the COVID-19 variants that are appearing in the United States?

The CDC is providing information on the new strains that are appearing. Here is the updated CDC information on Emerging SARS-CoV-2 Variants.

(updated 1/28/2021)

### **COVID-19 RESOURCES**

### Approval, Prioritization, and Distribution of COVID-19 Vaccines

CDC Frequently Asked Questions about COVID-19 Vaccination

CDC - COVID-19 Vaccination Communication Toolkit

<u>CDC - Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently</u> Authorized in the United States

<u>CDC - Covid-19 Interim Considerations for COVID-19 for Healthcare Personnel and Long-Term Care Facility Residents</u>

AMDA Qı	uestions	and	Answers	About the	COVID-	19	Vaccine
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Center for Disease Control (CDC) Frequently Asked Questions About COVID-19
Vaccination

How CDC is Making COVID-19 Vaccine Recommendations

Advisory Committee on Immunization Practices (ACIP)

CDC - Ensuring the Safety of COVID-19 Vaccines in the United States

Executive Summaries of State COVID-19 Vaccination Playbooks

Countermeasures Injury Compensation Program (CICP)

Vaccine Adverse Event Reporting System

### Pharmacy Partnership for Long-Term Care Program

CDC Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination

CDC Long-Term Care Facility Toolkit: Preparing for COVID-19 Vaccination at Your Facility

CVS/Omnicare COVID-19 Vaccine Resources

CVS COVID-19 Vaccine Clinic Guide

CVS COVID-19 Consent Requirements and Process

CVS COVID-19 Vaccine Intake Consent Form

CVS COVID-19 Responsible Party Consent Form

CVS Understanding and Addressing Vaccine Hesitancy White Paper

COVID-19 Vaccine Clinic Process Webinar Deck

Walgreens Long-Term Care Facility COVID-19 Vaccination Program

Walgreens Consent Guide With Instructions

Walgreens - What to Expect From Your Trusted Immunizer

Walgreens - Preparing for Your COVID-19 Immunization Clinic

#### **Education on the COVID-19 Vaccines**

CDC - Building Confidence in COVID-19 Vaccines

COVID-19 Vaccine Education and Equity Project

CDC - Benefits of Getting a COVID-19 Vaccine

CDC - Importance of COVID-19 Vaccination for Residents of Long-Term Care Facilities

CDC: Answering Patient's Questions on Vaccines

Healthcare Professionals: Preparing for COVID-19 Vaccinations

CDC - Post Vaccine Considerations for Healthcare Personnel

CDC - Post Vaccine Considerations for Residents

Summary of CDC Webinar on Post-Vaccine Events and Considerations

Summary of 3 CDC Calls on Pfizer COVID-19 Vaccine

**Encouraging COVID-19 Vaccination** 

Vaccination Clinic Tips and Tools For Housing Providers

#### Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization

Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization

Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Patients

Pfizer-BioNtech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers

#### Moderna COVID-19 Vaccine Emergency Use Authorization

Moderna COVID-19 Vaccine EUA Letter of Authorization

Moderna COVID-19 EUA Fact Sheet for Recipients and Caregivers

Moderna COVID-19 EUA Fact Sheet for Healthcare Providers Administering Vaccine

### Johnson & Johnson (Janssen Biotech) COVID-19 Vaccine Emergency Use Authorization

Johnson & Johnson (Janssen Biotech) Covid-19 Vaccine EUA Letter of Authorization

Johnson & Johnson (Janssen Biotech) EUA Fact Sheet for Recipients and Caregivers

Johnson & Johnson (Janssen Biotech) EUA Fact Sheet for Healthcare Providers