

Pharmacy Partnership for Long Term Care Program

Overview and Frequently Asked Questions

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PROGRAM OVERVIEW

The Pharmacy Partnership for Long Term Care Program will facilitate COVID-19 vaccination in long term care facilities while reducing the burden on the facilities and state health departments. CDC/HHS is partnering with CVS, Walgreens and select pharmacies in the Managed Health Care Associates Network (MHA) to distribute and administer vaccine to long term care facilities. As part of this program and at no cost to the facility, these pharmacies will:

- Schedule and coordinate on-site clinic date(s) directly with each facility. Three total visits over approximately two months are likely to be needed to administer both doses of vaccine (if indicated) and vaccinate any new residents and staff.
- Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
- Ensure cold chain management for vaccine.
- Provide on-site administration of vaccine for residents and any staff not previously vaccinated.
- Report required vaccination data (approximately 20 data fields) to the local, state/territorial, and federal public health authorities within 72 hours of administering each dose.
- Adhere to all applicable Centers for Medicare & Medicaid Services requirements for COVID-19 testing for LTC staff.

In November, providers were asked to enroll in this program by selecting one of four pharmacy options (CVS, Walgreens, existing LTC provider or another entity such as your local health department). CDC then worked with states and jurisdictions to match providers with pharmacies, based on their selections.

In some cases, providers were reassigned to different pharmacies based on logistics and program requirements, such as cold chain storage.

Pharmacy partners have already started reaching out to their matched facilities.

VACCINE SELECTION AND PRIORITIZATION

Q. Who gets the vaccine first?

A. The Centers for Disease Control (CDC) [Advisory Committee on Immunization Practices](#) (ACIP) has recommended health care workers (HCW) and long-term care (LTC) residents at the highest level of priority for the first distributions of a COVID-19 vaccine. This includes nursing facility residents, assisted living residents and residents in other resident care settings.

Final decisions on vaccine allocation is ultimately up to each state or jurisdiction. States or jurisdictions can decide to activate the federal pharmacy partnership program if they are able to allocate at least 50% of the needed doses of vaccine that will be required for the pharmacy partnership program.

Q. Will assisted living and ID/DD communities receive the vaccine at the same time as skilled nursing facilities?

A. The ACIP [recommendations](#) have specified that when sub prioritization is needed in case of initial vaccine shortage, skilled nursing facilities and nursing homes should be prioritized over other long-term care settings. After nursing facilities, vaccine would be distributed to other long-term care settings, including assisted living facilities, residential care communities, intermediate care facilities for individuals with developmental disabilities and state veterans' homes.

The initial shipments of the vaccine will not be enough to cover the entire population of the priority group (healthcare workers and long-term care), which is anticipated to be approximately 25-30 million people.

As such, the pharmacy partnership program will prioritize skilled nursing facilities above other long-term care settings. However, we anticipate the supply of vaccine to quickly increase and be able to cover all long-term care settings quickly after the distribution begins.

PREPARING FOR THE VACCINATION CLINIC

Q. How can I prepare for the clinic in my facility?

A. Your matched pharmacy partner will be sharing information with you on how to prepare for clinics. Their websites are linked below.

- CVS website: www.omnicare.com/covid-19-vaccine-resource

Q. Can LTC staff get vaccinated alongside residents?

A. Yes, staff can be vaccinated alongside residents under the pharmacy partnership program and have been included in the estimates that CDC has made for the number of doses needed for each facility/state.

However, some states are taking different approaches to distribution. Your state may have alternative plans to vaccinate all healthcare workers, including long term care staff. We recommend contacting your state affiliate or state public health agency for more information on the different ways and locations that long-term care staff will receive the vaccine.

Q. Does this program cover contract staff?

A. Yes, if contract staff are working in your facility you should include them in the clinic. If you have questions, contact the pharmacy staff.

Q. Does a physician need to order the COVID-19 vaccine for residents and/or staff?

A. No. Under the authority of the PREP Act, the HHS Secretary issued guidance that overrides state and local laws to allow pharmacist to order and administer the vaccine if the pharmacist meets certain training requirements. This information is available [here](#) and an excerpt is included below:

"...as an Authority Having Jurisdiction under the Secretary's March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), the Office of the Assistant Secretary for Health (OASH) issues this guidance. Subject to satisfaction of the requirements listed below, this guidance authorizes State-licensed pharmacists to order and administer, and State-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, to persons ages three or older COVID-19 vaccinations that have been authorized or licensed by the Food and Drug Administration (FDA)." "This authorization preempts any State and local law that prohibits or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines as set forth above."

ONSITE VACCINATION CLINIC

Q. Should facilities stagger staff for vaccination?

A. This decision needs to be made on a case by case basis. Concern about staff getting systemic symptoms causing them to miss work has led some to consider staggering staff vaccinations. However, staggering staff may cause delays in vaccinating your staff and some may miss out on this program. While about half of the people getting the vaccine experience fatigue or headache, it was mild to moderate in the vast majority, which should not limit their ability to work. However, some staff may feel sick enough that they can't work. We would recommend plan for some staff to miss work for 1-2 days after the vaccine clinic.

Q. What do I need to provide for the pharmacy clinic team coming to my facility? Do I need to provide any medical supplies or PPE?

A. The pharmacy clinic team will bring the vaccine and all necessary supplies to administer the vaccine including PPE for the pharmacy team. The LTC pharmacy clinic team will let you know in their material what you need to provide.

Q. How many pharmacy team members will be at the facility during the clinic?

A. This will vary depending on the size of the facility and is a question to ask your matched pharmacy partner when they contact you.

Q: Can the facility elect to have the vaccine administered in resident rooms vs. centralized clinic location? And if so, who will be responsible for the 15-minute observation of the resident post administration?

A. This may vary depending on the pharmacy clinic team working with you. You will need to check with the pharmacy clinic team assigned to your facility.

Q. If an adverse reaction occurs after the pharmacy clinic team leaves, is the facility required to notify the pharmacy?

A. The CDC has a vaccine monitoring system called the Vaccine Adverse Event Reporting System (VAERS) as well as a smart phone-based monitoring program called V-safe. They will use these systems to actively track adverse events from the COVID-19 vaccine. Information about these programs should be provided during the onsite clinic.

Q: Is there a maximum number of individuals that can be vaccinated at each clinic?

A: The pharmacy partnership program has provided an estimate to the matched pharmacies based on the resident data you provided in the sign-up process and a 1:1 ratio of staff. However, this is a question to ask of your matched pharmacy partner when they contact you.

Q. What happens if staff or resident refuse vaccine or are not present during the onsite clinic?

A. After the initial phase of vaccinations, facilities may continue working with the federal pharmacy partner it was matched with or shift to another pharmacy provider that is enrolled with the state to provide COVID-19 vaccine. However, it is possible that those individuals may have to wait several months to get the vaccine.

Q. Will residents and staff need to follow infection control measures (e.g. PPE, social distancing, testing) post vaccination?

A. Most likely, yes. It takes about two weeks to generate antibodies after the vaccine and this vaccine requires two doses, so individuals will not achieve immunity until 2-3 weeks after the second dose. They will need to take all precautions until that time. Also, since the vaccine is not 100% effective and not everyone else in the community or other staff will take the vaccine, it may be necessary to continue basic infection control measures until enough people get the vaccine. This is why it's so important to get as many people vaccinated as possible.

Q. How should facilities handle staff members who are showing adverse effects from the vaccination?

A. CDC is developing guidance on who needs to be tested or remain out of work since some of the symptoms of the vaccination mimic COVID-19. Until CDC issues guidance, we would recommend that if staff feel so sick that they can't work, they should stay home until they feel able to work. Staff can contact their physician with specific medical questions about any symptoms they may have and for any medications such as acetaminophen or ibuprofen that may help. We are advocating to CDC that staff who feel ok to work, should be allowed to work.

Q. Will someone who receives the vaccine test positive for COVID-19 using the rapid antigen tests?

A. No. The first vaccines (Pfizer and Moderna) are RNA injections so there's been some question on whether individuals who have received the vaccine would test positive on an antigen test. However, they do not cross react with the antigen tests, the antigen measured is completely distinct of the RNA injection. As such a person will not test positive just because they received the vaccine.

Q. Will someone who received the vaccine test positive on a PCR test due to the antibodies produced from the vaccine?

A. No, the first vaccines (Pfizer and Moderna) are RNA injections and PCR tests are not impacted by them.

Q. Will the facility be responsible for ensuring that discharged residents receive the second dose of the vaccination?

A. No, this is why CVS and Walgreens are entering data into the state immunization registry to help follow up if people get the second dose. However, discuss any specific situations or concerns with your pharmacy partner directly.

CLINICAL CONSIDERATIONS

Q. What details can you give regarding the clinical trials for the Pfizer vaccine? For example, what demographic was the vaccine tested on? For how long?

A. The Pfizer vaccination was tested using a randomized trial among about 40,000 people with half getting the vaccine and half a placebo group. In both groups; there were equal percent of men and women. There were about 4,000 African American, 1,700 Asian, 10,000 Hispanic individuals. The actual numbers and additional details of the trail are available in the [FDA summary report on the Pfizer trial](#).

Q. Is there any information that can be given to our staff and residents who may be worried about long term side effects of the Pfizer vaccine?

A. In general, most adverse events to vaccines occur within a few months after receiving a vaccine. The Pfizer trial followed people for at least two months and up to four months after the second dose. The rate of adverse events in the 40,000 people in the study was extremely low and essentially not different between the vaccine group 126 (0.5%) and placebo group 111 (0.4%). Pfizer will continue to follow all of the participants for up to two years.

Q. What are the side effects of the Pfizer vaccine?

A. The side effects fall into four categories: local reactions at the site (such as pain, swelling or redness); systemic symptoms (such as fever, chills, fatigue, muscle or joint pains, or headaches); adverse events (such as heart disease, neurologic, appendicitis) and death. Local reactions are more common compared to placebo and systemic symptoms are also more common, particularly after the second dose. There is no major difference in adverse events or death. There were 0.6% of participants who got the vaccine compared to 0.5% of those getting the placebo that experienced an adverse event. There were fewer deaths in the group getting the vaccine vs placebo (2 people vs 4 people).

Q. What ages is the Pfizer vaccine approved for?

A. We anticipated the Pfizer vaccine to be approved for individuals 18 and older until more clinical trials are conducted. The Pfizer vaccine was tested in individuals 16 and older.

Q. Are there any preexisting conditions that will exclude an individual from receiving the Pfizer vaccination?

A. Individuals who are pregnant and individuals <18 years of age are excluded since individuals in these demographics were not included in the clinical trials. There is no data indicating

concerns in these groups, the vaccine has simply have not been tested. CDC is examining initial reports of anaphylaxis in three individuals in England to see if there are any additional cautions. No other cautions have been issued at this time.

Q. Should individuals who have recovered from COVID-19 get the Pfizer vaccine?

A. Yes, we anticipate CDC will recommend the vaccine for individuals who have recovered from COVID-19. In the trial 10% of the participants already had the vaccine and receiving the vaccine appeared beneficial. Also, some people who have recovered from the virus have low levels of antibodies and some have been shown to be reinfected.

Q. How long after does an individual who has recovered from COVID-19 need to wait to get the Pfizer vaccine?

A. They can get the vaccine right away after their recovery.

Q. If an individual currently has COVID-19 can they get the Pfizer vaccine?

A. CVS and Walgreens are recommending that individuals who are sick with COVID-19 do not get vaccinated during the onsite clinic, so they don't inadvertently spread the virus to others.

SIGNED CONSENT

Q. Is consent required?

A. Yes, consent is required and needs to include the use of the emergency use authorization (EUA) fact sheet on the risk and benefits of the vaccine. The fact sheet will not be available until after the EUA is issued. Signed consent is not mandated by the federal government for vaccines approved under an EUA, but many vaccine providers including the LTC pharmacy clinic may require signed consent. This is an import issue and obtaining signed consent, if required, will take some time. We urge facilities to discuss this with their pharmacy partners.

Q. Can a resident refuse the vaccine?

A. Yes, vaccines authorized under an EUA cannot be mandated by the federal government. Residents or their representatives have the right to refuse the vaccine.

Q. Does signed consent have to be a physical signature, or can it be digital signature? Can email communication count as signed consent or does it require signature or digital signature on the form?

A. CVS and Walgreens will each accept their own form only but will allow email authorization from the responsible party in lieu of signature on the form. You can also check with them on other methods of confirmation from the responsible party that they will accept.

Q. Does the signatory for residents unable to consent have to be one of the three legally recognized decision makers (the resident representative, designated durable power of health care attorney or legal guardian) or can any family member or close personnel friend sign it?

A. This will be up to the pharmacy clinic team since signed consent is not federally mandated. However, when obtaining consent you will need to do so with the resident unless they are unable to consent, then you will need to approach the durable power of health care attorney or legal guardian for the resident or if neither available, the resident representative.

Q. If the patient is unable to give consent for receiving the vaccine and consent must be obtained from a family member or resident representative, are there any suggestions on how to handle that?

A. We recommend you follow the normal procedure in your state for how you obtain informed consent for any other treatments or procedures for your residents.

Q. Who can sign when the resident has dementia and has not designated a durable power or health care decision maker and there is no legal guardian?

A. We recommend you follow the process you normally do for obtaining consent for any treatment or procedure with these individuals. You can also consider reaching out to the state Ombudsman for input and assistance as state laws vary on who and how you can obtain consent for individuals without a resident representative or durable power of health care attorney.

Q. What happens if there is no family member available/alive?

A. We recommend you follow the process you normally do for obtaining consent for any treatment or procedure with these individuals. You can also consider reaching out to the state Ombudsman for input and assistance as state laws vary on who and how you can obtain consent for individuals without a resident representative or durable power of health care attorney.

EMPLOYER MANDATE OF VACCINE

Q: Will the federal government mandate the vaccine?

A: Since this vaccine will be authorized under an emergency use authorization (EUA) it cannot be mandated by the federal government, but the EUA does not expressly prohibit an employer, state or locality from requiring vaccination.

Q: Can the vaccine be required as a condition of employment?

A: In general, under federal law an employer can require vaccination as a condition of employment where it is job-related necessity (meaning the employee's ability to perform their job will be impaired or there is significant risk of substantial harm to the health or safety of the individual or others). Given the nature of the business, employees providing healthcare services often (but not always) fall into that category. That said, the EEOC has yet to provide guidance specifically as to COVID-19.

There are, however, exceptions for medical or religious concerns under federal law. When considering whether the employee would be required to have the vaccine as a condition of employment, the employer would need to consider (i) the employee's ability to safely perform the essential functions of the job, (ii) the imminence of the risk, (iii) the severity of the harm to the health or safety of the individual or others, and (iv) the availability of reasonable accommodations to reduce the risk absent undue hardship. Depending on these circumstances, an employer may be required to accommodate an employee with a medical or religious concern by providing alternative safety equipment or PPE, teleworking, or reassignment, among other alternatives.

Beyond federal considerations, the ability of an employer to require a vaccine can vary from state to state and could be impacted by local laws or regulations as well. Prior to implementing any mandatory vaccination program, employers should discuss the particulars of such plan with their employment attorney to be sure to comply with applicable requirements.

Q: Can the condition of employment be added for existing employees?

A: Yes, subject to the medical and religious concerns mentioned above, but employers will want to make sure they check local and state laws and any employment contracts that may be in place. Employers should discuss this with their employment attorney as issues may arise for employees that refuse the vaccination, even if a condition of employment.

Q: Are there workers compensations issues with requiring a vaccine as a condition of employment?

A: Yes, if a vaccination is listed as a condition of employment, and the employee has an adverse reaction due to the vaccine, there could be potential for a worker's compensation claim.

Q: Will my employees still need to use PPE after being vaccinated?

A: Yes, OSHA requirements for PPE use will continue to be in place after an employee is vaccinated. Current information suggests that the vaccine takes four (4) weeks after the last dose to generate antibodies, but even in people who are vaccinated some may still have the ability to get sick and current information is unclear whether vaccinated individuals will still be able to spread the virus or not. Employers should continue to monitor developments in this information as it becomes available in the near future.

Q: Do I have to provide paid leave for employees with adverse reactions from the vaccine?

A: While there is no current federal requirement for an employer to provide paid leave for an adverse reaction from the vaccine, an employer may be obligated to provide leave consistent with the Family and Medical Leave Act or ADA. Additionally, paid leave may be required under applicable state or local laws or the employer's own policies and therefore employers should consult with their employment attorney to the extent the need for leave arises.

Q: Do I have to pay my employees for their time to get vaccinated?

A: Where the employer maintains a vaccination program, the time an employee spends getting vaccinated is compensable regardless of whether the program is mandatory or voluntary. Additionally, the employer must cover the cost of the vaccination.

If an employer does not administer a vaccine program and does not mandate the vaccine as a condition of employment, the employer would not be required to pay for the employee's time.

Where the state or locality is requiring the vaccine, the employer would not be required to pay for the employee's time to get the vaccine, subject to the state or locality requiring that of employers. **Hope Landing will pay employees for their time to get vaccinated.**

Q: What responsibilities does the employer have under OSHA to offer the vaccine?

A: To date, OSHA has not issued any specific standard that would obligate an employer to require employees to provide the vaccine. While the General Duty Clause under the OSH Act obligates employers to provide a workplace "free from recognized hazards that are causing or are likely to cause death or serious physical harm to . . . employees," without further guidance

from OSHA, the CDC, or other state and local public health officials on the vaccine, this catch-all provision likely does not itself require employers to provide vaccinations as part of their infection control procedures. OSHA previously advised that employers may require flu vaccinations. That guidance, however, also advised that “an employee who refuses [the influenza] vaccination because of a reasonable belief that he or she has a medical condition that creates a real danger of serious illness or death (such as serious reaction to the vaccine) may be protected. For more information on OSHA Standard Interpretation, OSHA's position on mandatory flu shots for employees (Nov. 9, 2009): <https://www.osha.gov/laws-regs/standardinterpretations/2009-11-09>.