

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

December 11, 2020

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.

VACCINE APPROVAL

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

According to the CDC, it is anticipated that the first supply of a vaccine will become available by the end of 2020. Although a vaccine may be authorized or approved, there will not be enough doses available for all adults. As supplies increase, it is anticipated that all adults should be able to get vaccinated sometime in 2021. A COVID-19 vaccine may not be available for young children, however, until more studies are completed.

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.

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 everyone on a Continuing Care Retirement Community campus, including those in Independent Living, eligible for the Pharmacy Partnership program?

Independent Living was not included in the list the ACIP reviewed during its December 1 meeting and, therefore, IL is not directly included in the 1a group of individuals in long term care group. IL is not included even when it is part of a larger CCRC.

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)

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.

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.

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)

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.

Is CDC putting out a toolkit for providers?

Yes. CDC expects to release a toolkit for long-term care providers on or around December 16. The toolkit will grow as more information becomes available. It will include posters and materials to encourage and educate staff to accept the vaccine. A toolkit for health care providers went live on December 10. While the LTC toolkit won't be the same, it will be similar. Providers may wish to review it.

(updated 12/10/2020)

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

There have not been changes to the testing requirements. CDC will release guidance on antigen testing in relation to vaccinations on or around December 12.

(updated 12/10/2020)

If a nursing home resident has flu or influenza like symptoms after receiving the vaccine, even though the symptoms might be side effects, do they still have to be tested?

Yes. Guidance about this will be coming out along with the ACIP recommendations on the week of December 14.

(updated 12/10/2020)

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)

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. States and private facilities can choose to mandate.

Employers generally, and specifically health care providers, can 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.

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 do 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.

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

(updated 12/10/2020)

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 who 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.

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?

According to the CDC, there is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again (natural immunity). Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this phenomenon. Until a vaccine is available and ACIP makes recommendations to the CDC on how to best use COVID-19 vaccines, the CDC can't comment on whether people who had COVID-19 should get a COVID-19 vaccine.

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.

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.

(updated 12/10/2020)

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 available in multiple languages?

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

(updated 12/10/2020)

My pharmacy partner is requiring paper consent forms in triplicate. Can they do this? Can't it be electronic?

They can. It is recommended providers talk to pharmacy partners about this.

(updated 12/10/2020)

SIDE EFFECTS

How will provider staff recognize side effects?

The ACIP will discuss side effects of vaccines and staggering immunizations in longterm care and information will be 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 this fact-checking article.

COVID-19 RESOURCES

Approval, Prioritization, and Distribution of the Vaccines

<u>Center for Disease Control (CDC) Frequently Asked Questions About COVID-19</u> 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

CVS/Omnicare COVID-19 Vaccine Resources

CVS COVID-19 Vaccine Clinic Guide

CVS COVID-19 Vaccine Intake Consent Form

COVID-19 Vaccine Clinic Process Webinar Deck

Walgreens COVID-19 Vaccine Resources

Education on the COVID-19 Vaccines

COVID-19 Vaccine Education and Equity Project

CDC - Benefits of Getting a COVID-19 Vaccine

CDC: Answering Patient's Questions on Vaccines

Healthcare Professionals: Preparing for COVID-19 Vaccinations