



COVID-19 Frequently Asked Questions

FOR MEDICAL PROVIDERS



DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health

COVID-19 Frequently Asked Questions for Vaccine Providers

Table of Contents

Contents

<u>EUA Information</u>	5
<u>What is the difference between an EUA, an EUA Fact Sheet for Health care Providers, and an EUA Fact Sheet for Patients?</u>	5
<u>How is the Emergency Use Authorization (EUA) Fact Sheet for Recipients different from a vaccine information statement (VIS)?</u>	5
<u>Can the EUA Fact Sheet for Recipients or VIS be provided to vaccine recipients electronically or is a hard copy required?</u>	5
<u>Are there any documents (e.g., fact sheets) that explain EUAs to the general public?</u>	5
<u>Is there material to support COVID-19 vaccine confidence for providers to use when talking with patients?</u>	5
<u>Pandemic Influenza Preparedness/COVID-19 Vaccine</u>	6
<u>Will any new COVID-19 vaccine be covered by the National Vaccine Injury Compensation Program?</u>	6
<u>Will there be guidance for mass vaccination clinics?</u>	6
<u>What are the PPE requirements when administering vaccines during the COVID-19 pandemic?</u>	6
<u>Can COVID-19 and influenza vaccines be administered at the same time on the same day?</u>	6
<u>COVID-19 Vaccine Safety</u>	6
<u>Does CDC recommend an observation period after vaccination?</u>	6
<u>Will vaccine be available for children and adolescents in the initial phase?</u>	6
<u>Is data available on the efficacy of the COVID-19 candidate vaccines?</u>	7
<u>Is social distancing necessary when an individual receives their second dose of vaccine?</u>	7
<u>Vaccine Allocation and Supply</u>	7
<u>How will the vaccine be allocated?</u>	7
<u>When will Delaware get their vaccine allocations?</u>	7
<u>CDC expects there will be limited vaccine supply in the initial phase. What does “limited” mean?</u>	7
<u>In the phased approach to COVID-19 vaccination, what are the phases and who will get the vaccine first?</u>	7
<u>How long after the initial phase will additional vaccine be available?</u>	7
<u>Will the Department of Defense (DOD) receive its own vaccine allocation? Will DOD or state be responsible for vaccine distribution/coverage for federal employees?</u>	8
<u>Will federally qualified health centers (FQHCs) have access to COVID-19 vaccine when it’s available?</u>	8
<u>What supplies will be provided with COVID-19 vaccine?</u>	8
<u>Will the ancillary supplies in the shipments include sharps containers?</u>	8

COVID-19 Frequently Asked Questions for Vaccine Providers

Are more details (brand, type, etc.) available about the supplies to be provided with COVID-19 vaccine?	8
When COVID-19 vaccine is available to the general public, will the vaccine be kitted with supplies, similar to what is being done in the initial phase?	8
Will ultra-cold vaccine come with gloves for use in unpacking the vaccine?	8
Billing, Costs and Reimbursement	8
Can a client be turned away if they owe a previous balance to the provider?	8
Can providers bill for an office visit when administering COVID-19 vaccine?	9
Will providers be able to charge a COVID-19 vaccine administration fee?	9
Who will pay for COVID-19 vaccine? Can it be ordered privately?	9
Critical Populations	9
Which groups are defined as the priority workforce for early COVID-19 vaccination?	9
Who will define the subgroups of critical populations—jurisdictions or CDC?	9
Vaccine Ordering & Shipping	10
How will COVID-19 vaccine be ordered?	10
How is the vaccine received?	10
How many vaccine doses will each shipment contain in the initial phase?	10
How will ultra-cold vaccines be shipped?	10
Will private providers have access to COVID-19 vaccine?	10
Will providers receive the same vaccine for both doses? Should providers hold back stock for second doses to ensure they have a matching product?	10
Will providers be required to perform vaccine inventory reconciliations and, if so, how often?	10
Vaccine Storage and Handling	10
Will there be different storage and handling requirements for COVID-19 vaccine?	10
How much space will be needed to store COVID-19 vaccines in the refrigerator or freezer?	11
Should Providers invest in ultra-cold storage units at this time?	11
What are the on-site storage requirements and warm-up protocols for vaccine that must be stored at ultra-cold temperatures?	11
What percentage of the vaccine will require ultra-cold storage?	11
Will vaccine be shipped with a temperature monitoring device or phase change indicator?	11
Will guidance on how to handle vaccines that require an ultra-cold chain be available?	11
Should providers plan to use digital data loggers to monitor storage unit temperatures?	11
Will ultra-cold vaccine need to be stored on site or can it be transported on the day vaccine is being administered?	11
Provider Recruitment and Enrollment	12
Can providers enroll in the COVID-19 Vaccination Program directly with CDC or do they have to enroll through their	

COVID-19 Frequently Asked Questions for Vaccine Providers

immunization program?	12
What steps should be taken to enroll as a COVID-19 provider?	12
If I have several clinics under one medical provider, can I register them all at once?	12
Does my practice need to have access to DeIVax to be a COVID-19 provider?	12
Which staff members will need DeIVax user accounts to complete the enrollment process?	12
What type of information will need to be included during the enrollment process?	12
Pharmacies and Long-term Care Facilities	13
Does HHS or CDC have Memoranda of Agreement (MOAs) in place with large pharmacy networks? When and how will HHS or CDC share planning assumptions for the large pharmacy chains?	13
Will clinics that reside in the same building as a pharmacy but are staffed by nurses (i.e., minute clinics and little clinics) receive direct shipments of vaccine or will vaccine only be shipped for administration by a pharmacist?	13
For independent pharmacies, can the pharmacists sign the CDC COVID-19 provider agreement even though they do not have prescribing authority?	13
Is CDC considering using private contractors, such as pharmacy chains, as PODs in future phases?	13
During which phase will pharmacy chains begin receiving vaccines?	13
Administration & Second-dose Reminders	14
Will there be a consent form for vaccination?	14
How should providers ensure the same vaccine is administered for the first and second doses? How will the type of vaccine and intervals between doses be tracked?	14
Will vaccine recipients be required to show their COVID-19 vaccination record card in order to get their second dose?	14
Vaccine Finder	14
Will CDC or OWS have a public-facing vaccine locator at the national level?	14
Will VaccineFinder have real-time information? For example, can a provider change their status if they run out of vaccine and update it when they have vaccine in stock?	14
Will VaccineFinder be active in Phase 1 when vaccine availability is limited?	15
Is there a point of contact for vaccinefinder.org?	15
Reporting to the IIS	15
How should we report administered COVID-19 doses?	15
What data elements need to be reported to DeIVAX?	15

Record of Changes / Updates:

COVID-19 Frequently Asked Questions for Vaccine Providers

EUA Information

What is the difference between an EUA, an EUA Fact Sheet for Health care Providers, and an EUA Fact Sheet for Patients?

The legal authority of the FDA to authorize emergency use of an investigational medical product (e.g., vaccines prior to licensure or drugs prior to approval) or an unapproved use of an approved medical product to diagnose, treat, or prevent a serious or life-threatening disease is referred to as Emergency Use Authorization (EUA). The term “EUA” can refer to either the legal authority itself or to the regulatory status of a medical product, such as COVID-19 vaccine. For example, one could say “FDA issued an EUA” or “an EUA is in place.”

When FDA authorizes emergency use of a medical product such as an anticipated COVID-19 vaccine, an EUA Fact Sheet for Health Care Providers (in place of a package insert typical of a licensed vaccine) and an EUA Fact Sheet for Recipients (akin to product information for patients or a CDC-provided VIS for a licensed vaccine) must be provided to the health care providers prescribing and/or administering the authorized medical product. The health care providers, in turn, provide the EUA Fact Sheet for Recipients to vaccine recipients or their guardians.

How is the Emergency Use Authorization (EUA) Fact Sheet for Recipients different from a vaccine information statement (VIS)?

When FDA authorizes a vaccine for use under an EUA, providers and public health entities involved in vaccine administration are legally required to provide the FDA-authorized EUA Fact Sheet for Recipients to individuals receiving vaccine or their guardians, similar to VISes that are also required by law for certain licensed vaccines. The EUA Fact Sheet for Recipients, like the VIS, explains the benefits and risks associated with the vaccine. Unlike a VIS, the EUA fact sheet also provides vaccine product-specific information, including the vaccine’s authorized use, dose/dose-series, and known information or experience with the vaccine from clinical trials that support issuance of the EUA by FDA.

Can the EUA Fact Sheet for Recipients or VIS be provided to vaccine recipients electronically or is a hard copy required?

The EUA Fact Sheet for Health Care Providers and EUA Fact Sheet for Recipients can be offered in an accessible form (e.g., printable as a hard copy) or through mass media (including print, broadcast, radio, satellite, Internet, or other electronic means of dissemination), videos/DVDs, or direct communication from public health agencies.

Are there any documents (e.g., fact sheets) that explain EUAs to the general public?

CDC is working with Operation Warp Speed (OWS), FDA, and manufacturers to develop public messaging materials about EUAs that will help support vaccination programs.

Is there material to support COVID-19 vaccine confidence for providers to use when talking with patients?

Focus groups are being conducted and materials will be developed. More information will be shared as soon as it is available.

COVID-19 Frequently Asked Questions for Vaccine Providers

Pandemic Influenza Preparedness/COVID-19 Vaccine

Will any new COVID-19 vaccine be covered by the National Vaccine Injury Compensation Program?

No, COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program.

The CICP is administered by the Health Resources and Services Administration within the Department of Health and Human Services. Information about the CICP and filing a claim is available by calling 1-855- 266-2427 or visiting <http://www.hrsa.gov/cicp/>.

Will there be guidance for mass vaccination clinics?

Yes. CDC has updated guidance for satellite, temporary, and off-site clinics and it is available at <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html>. The guidance provides information on procedures for protecting vaccine recipients and staff during the COVID-19 pandemic. However, programs will need to keep in mind recommendations for social distancing and considerations for events and gatherings during the COVID-19 pandemic and ensure mitigation strategies are in place to the extent possible. In many instances, curbside or drive-through clinics may be the best options.

What are the PPE requirements when administering vaccines during the COVID-19 pandemic?

CDC has issued “Interim Guidance for Immunization Services During the COVID-19 Pandemic” to help immunization providers in a variety of clinical settings plan for safe vaccine administration during the COVID-19 pandemic (see <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>). For information on PPE for health care workers, see <https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>. Additional guidance will be provided as needed when COVID-19 vaccine is available.

Can COVID-19 and influenza vaccines be administered at the same time on the same day?

Once COVID-19 vaccine(s) are authorized or approved by FDA, CDC will provide administration guidance.

COVID-19 Vaccine Safety

Does CDC recommend an observation period after vaccination?

ACIP currently recommends that providers should consider observing vaccine recipients for 15 minutes after receipt of a vaccine.

Will vaccine be available for children and adolescents in the initial phase?

At first, COVID-19 vaccines may not be authorized, approved, or recommended for children. The groups recommended to receive the vaccines could change in the future.

COVID-19 Frequently Asked Questions for Vaccine Providers

Is data available on the efficacy of the COVID-19 candidate vaccines?

Efficacy data are being collected as part of the Phase 3 clinical trials in the U.S. and other countries.

Is social distancing necessary when an individual receives their second dose of vaccine?

CDC recommends following the “Vaccination Guidance During a Pandemic” for all routine vaccination as well as for planning for COVID-19 vaccination clinics (see <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>.)

Vaccine Allocation and Supply

How will the vaccine be allocated to states?

Allocations will be made based on multiple factors, including population density and:

- Critical populations recommended by the Advisory Committee on Immunization Practices (with input from the National Academies of Sciences, Engineering, and Medicine)
- Current local spread/prevalence of COVID-19
- COVID-19 vaccine production and availability

When will Delaware get their vaccine allocations?

OWS is making allocation decisions. More information will be shared as soon as it is available.

CDC expects there will be limited vaccine supply in the initial phase. What does “limited” mean?

CDC doesn’t know when a vaccine(s) will be available or how many doses may be available. The COVID-19 vaccine landscape is evolving and uncertain.

In the phased approach to COVID-19 vaccination, what are the phases and who will get the vaccine first?

Phase 1: This initial effort focuses on reaching critical populations based on those at higher risk of acquiring COVID-19 and those at higher risk of experiencing severe COVID-19 outcomes (morbidity and mortality).

Phase 2: Large number of vaccine doses are expected to be available. Focus on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the general population; expand provider network.

Phase 3: A sufficient supply of vaccine doses for the entire population (surplus of doses). Focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.

How long after the initial phase will additional vaccine be available?

COVID-19 Frequently Asked Questions for Vaccine Providers

We don't know yet which of the vaccines will be available or how quickly vaccine supply will be scaled up to meet demand after the initial allocation. More information will be provided as it becomes available.

Will the Department of Defense (DOD) receive its own vaccine allocation? Will DOD or state be responsible for vaccine distribution/coverage for federal employees?

Federal agencies (VA, DOD, DHS, BOP, IHS) are in the process of developing their COVID-19 vaccination plans and some decisions are still pending. The agencies have requested that their allocation provide for their workforce and patient population. More information will be shared as soon as it is available.

Will federally qualified health centers (FQHCs) have access to COVID-19 vaccine when it's available?

FQHCs are mostly independent facilities that meet specific criteria to receive a designation from the Health Resources and Services Administration (HRSA), enabling them to receive special reimbursement under Medicaid and Medicare. FQHCs can play an important role, especially because of the populations they serve. To enroll, contact the Delaware Immunization program at immunizedph@delaware.gov.

What supplies will be provided with COVID-19 vaccine?

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders. Each kit will contain supplies to administer 100 doses of vaccine, including 105 needles (various sizes for the population served by the ordering vaccination provider), 105 syringes, 210 alcohol prep pads, four surgical masks and two face shields (per kit) for vaccinators, and 100 COVID-19 vaccination record cards for vaccine recipients.

Will the ancillary supplies in the shipments include sharps containers?

No, the ancillary supplies will not include sharps containers.

Are more details (brand, type, etc.) available about the supplies to be provided with COVID-19 vaccine?

The CDC will provide the brand information when it is available.

When COVID-19 vaccine is available to the general public, will the vaccine be kitted with supplies, similar to what is being done in the initial phase?

Yes, ancillary kits will ship to coincide or arrive just before shipments of vaccine throughout the response.

Will ultra-cold vaccine come with gloves for use in unpacking the vaccine?

Gloves are not currently planned to be provided for unpacking ultra-cold vaccine; however, this is subject to change.

Billing, Costs, and Reimbursement

Can a client be turned away if they owe a previous balance to the provider?

COVID-19 vaccine is being provided at no cost to participating vaccine providers and should be provided regardless of ability to pay.

COVID-19 Frequently Asked Questions for Vaccine Providers

Can providers bill for an office visit when administering COVID-19 vaccine?

Yes, providers can bill for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient's plan.

Will providers be able to charge a COVID-19 vaccine administration fee?

Yes, vaccine providers will be able to charge an administration fee. However, participating vaccine providers must administer COVID-19 vaccine regardless of the vaccine recipient's coverage status or ability to pay COVID-19 vaccine administration fees, as stated in the CDC Provider Agreement. Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient. For uninsured patients, the vaccine provider can seek reimbursement for an administration fee from the HRSA Provider Relief Fund.

Who will pay for COVID-19 vaccine? Can it be ordered privately?

COVID-19 vaccine will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. More information will be shared as soon as it is available.

Critical Populations

Which groups are defined as the priority workforce for early COVID-19 vaccination?

The Advisory Committee on Immunization Practices (ACIP), with input from the National Academies of Sciences, Engineering, and Medicine (NASEM), is considering recommendations for who should receive early doses of COVID-19 vaccine when supply may be limited. With assistance and input from NASEM, ACIP will advise the CDC on which people should receive vaccine when supply is limited. ACIP has expressed support for health care personnel receiving vaccination in the earliest phase of the vaccine program. The Delaware Division of Public Health and Medical Ethics Advisory Group will review these recommendations based on the available science and Delaware-specific data and trends. As more vaccine quickly becomes available, the goal is to provide easy access to vaccination for everyone who wants to be vaccinated. More information will be shared as soon as it is available.

Who will define the subgroups of critical populations—jurisdictions or CDC?

A jurisdiction's vaccine allocation for Phase 1 may be insufficient to vaccinate all people in the initial populations of focus. For planning purposes, CDC has divided the critical populations into Phase 1A, which includes health care workers who might be directly or indirectly exposed to patients or infectious materials, and Phase 1B, which includes people who play a key role in maintaining essential functions of society and will differ among jurisdictions, as well as people at increased risk of COVID-19 and people 65 years and older. Depending on vaccine supply, jurisdictions may need to plan for subsets within these groups. Jurisdictions should consult the Cybersecurity and Infrastructure Security Agency (CISA) guidance to see how these populations are broken down: <https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19>. ACIP will also provide guidance on prioritization of critical population subgroups for vaccination. While CDC recommends that tribal nations follow ACIP recommendations for vaccine prioritization, tribal nations have the authority to do their own prioritization of vaccine recipients, and jurisdictions must recognize this tribal sovereignty.

COVID-19 Frequently Asked Questions for Vaccine Providers

Vaccine Ordering & Shipping

How will COVID-19 vaccine be ordered?

Vaccination providers will follow their jurisdiction's vaccine ordering procedures. Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS) by jurisdiction immunization programs for vaccination providers they enroll.

How is the vaccine received?

The vaccine will be shipped directly to the shipping address designated in the enrollment form. If this address changes, contact the Delaware Immunization Program immediately. You may contact the program at immunizedph@delaware.gov or 1-800-282-8672.

How many vaccine doses will each shipment contain in the initial phase?

Vaccine shipment amounts will vary based on the vaccine. The minimum order size and increment for centrally distributed vaccines will be 100 doses per order; though early in the response, some ultra-cold (-60 degrees C to -80 degrees C) vaccine, if authorized for use or approved, may be shipped directly from the manufacturer in larger quantities. More information on these shipments will be shared as it becomes available.

How will ultra-cold vaccines be shipped?

Ultra-cold vaccines will ship to the vaccination provider location directly from the manufacturer in a pack-out that contains dry ice.

Will private providers have access to COVID-19 vaccine?

Public and private practices that enrolled as COVID-19 Vaccination Providers will have access to vaccine, based on the supply of vaccine and their patient profile.

Will providers receive the same vaccine for both doses? Should providers hold back stock for second doses to ensure they have a matching product?

Providers should only order from one manufacturer for each dose. The federal government has again said supply to ensure second dose completion will be available. (This strategy may change as vaccine becomes more widely available.) Providers should not hold vaccine for a second dose and instead vaccinate as many individuals in the current phase as possible.

Will providers be required to perform vaccine inventory reconciliations and, if so, how often?

Providers will be required to report vaccine inventory to VaccineFinder. Phase 1A providers will be required to submit inventory information daily.

Vaccine Storage and Handling

Will there be different storage and handling requirements for COVID-19 vaccine?

Yes, at least one vaccine candidate requires ultra-cold storage conditions. CDC is working on ways to support

COVID-19 Frequently Asked Questions for Vaccine Providers

ultra-cold chain vaccine storage and handling needs. We will provide more information and guidance as they become available.

How much space will be needed to store COVID-19 vaccines in the refrigerator or freezer?

Vaccine storage and handling guidance will vary by vaccine manufacturer. More information will be shared as soon as it is available.

Should Providers invest in ultra-cold storage units at this time?

Providers are not required to purchase ultra-cold storage equipment at this time. Ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice. Storage and handling instructions for ultra-cold vaccine will address repacking these coolers with dry ice for extended storage.

What are the on-site storage requirements and warm-up protocols for vaccine that must be stored at ultra- cold temperatures?

The vaccine is anticipated to ship directly to vaccination provider sites on a real-time, day-to-day basis. Currently, one vaccine candidate requires storage at -60 degrees C to -80 degrees C or at 2 to 8 degrees C for up to five days (i.e., 120 hours). Once reconstituted, the vaccine can be at room temperature for up to six hours. However, stability testing is still ongoing and storage temperatures may change. We understand and appreciate the operational complexities ultra-cold storage poses at the vaccination provider site. Some COVID-19 vaccine products will require a very different storage and handling approach than a normal cold- state vaccine.

What percentage of the vaccine will require ultra-cold storage?

We do not currently have this information. However, at least one vaccine candidate requires ultra-cold storage.

Will vaccine be shipped with a temperature monitoring device or phase change indicator?

Yes.

Will guidance on how to handle vaccines that require an ultra-cold chain be available?

Yes. The CDC will provide specific education and training materials to facilitate storage and handling of ultra-cold vaccine based on guidance from the vaccine's manufacturer.

Should providers plan to use digital data loggers to monitor storage unit temperatures?

It will be important to monitor storage unit temperatures to ensure vaccines are stored at appropriate temperatures at all times. Because of the differing storage requirements of the various COVID-19 vaccine candidates, we continue to assess the best options for monitoring vaccine temperatures. More information will be provided as it becomes available.

Will ultra-cold vaccine need to be stored on site or can it be transported on the day vaccine is being administered?

The transport of ultracold vaccine is not recommended. The Delaware Immunization Program will approve transfers on a case-by case basis. However, the vaccine can be kept for five days (120 hours) between 2 to 8 degrees C. Therefore, the amount needed to conduct off-site clinics may be removed, stored, and transported following guidance for vaccines stored between 2 degrees C to 8 degrees C. CDC's Vaccine Storage and Handling Toolkit is being updated to provide detailed guidance and key consideration for COVID-19 vaccine.

COVID-19 Frequently Asked Questions for Vaccine Providers

Provider Recruitment and Enrollment

Can providers enroll in the COVID-19 Vaccination Program directly with CDC or do they have to enroll through their immunization program?

To receive and administer COVID-19 vaccine, Delaware vaccination providers must enroll in the COVID-19 Vaccination Program through the Delaware Immunization Program. CDC is exploring coordination with some multijurisdictional entities (e.g., certain federal entities and national chain pharmacies) to receive vaccine outside of this process.

What steps should be taken to enroll as a COVID-19 provider?

If you are interested in enrolling as a COVID-19 provider, complete the survey within this link <https://www.surveymonkey.com/r/YGD8DDT>. Once your response is reviewed, the program will send an email containing a link to COVID-19 enrollment documents within the State Immunization Information System (IIS), known as DelVAX.

If I have several clinics under one medical provider, can I register them all at once?

No. Each clinic must sign a provider agreement separately.

Does my practice need to have access to DelVax to be a COVID-19 provider?

Yes. All provider practices will be required to register their practice in DelVAX. To register your practice, complete the Practice Registration/DelVAX Facility Code Request form at <https://www.dhss.delaware.gov/dhss/dph/dpc/files/delvaxfacilitycodereq.pdf>. Once completed, fax the form to 302-744-5363, or email it to immunizedph@delaware.gov.

Which staff members will need DelVax user accounts to complete the enrollment process?

To complete the COVID-19 vaccine enrollment process, the following staff members must have their own DelVAX user account:

1. Primary vaccine Coordinator
2. Back-Up vaccine Coordinator
3. Chief Medical officer (or Equivalent)
4. Chief Executive Officer (or Fiduciary)

To request a DelVax user account, visit <https://delvax.dhss.delaware.gov/delvax/UserRegistration/NewRegistration>.

What type of information will need to be included during the enrollment process?

You will need the following information for the enrollment so have it handy:

- Approximate number of children 18 years and younger at your location.
- Approximate number of adults 19-64 years of age at your location.
- Approximate number of adults 65 years of age and older at your location.

COVID-19 Frequently Asked Questions for Vaccine Providers

- Approximate number of unique patients seen per week on average.
- Approximate number of influenza vaccine doses administered during the peak week of the 2019-20 influenza season.
- How many full-time equivalent providers at your clinic can administer immunizations?
- What is the maximum number of immunizations your clinic can administer in a single day?
- How many days per week does your clinic offer immunizations?

Pharmacies and Long-term Care Facilities

Does HHS or CDC have Memoranda of Agreement (MOAs) in place with large pharmacy networks? When and how will HHS or CDC share planning assumptions for the large pharmacy chains?

CDC is working with OWS and national chain pharmacy organizations on COVID-19 vaccine distribution and administration planning. CDC will share details of the plans and information on coordination with jurisdictions as soon as it is available.

Will clinics that reside in the same building as a pharmacy but are staffed by nurses (i.e., minute clinics and little clinics) receive direct shipments of vaccine or will vaccine only be shipped for administration by a pharmacist?

CDC is working closely with jurisdictions and partners, including pharmacy chains, and details about how vaccines will be administered at pharmacy locations are still being finalized.

For independent pharmacies, can the pharmacists sign the CDC COVID-19 provider agreement even though they do not have prescribing authority?

Yes, pharmacists may sign the provider agreement. Per the PREP Act, state-licensed pharmacists have authority to order and administer COVID-19 vaccinations that have been authorized or licensed by FDA.

<https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>.

Is CDC considering using private contractors, such as pharmacy chains, as PODs in future phases?

In Phase 2, once we have adequate supply of COVID-19 vaccine(s) to support broader vaccination efforts, select pharmacy partners will receive a direct allocation of COVID-19 vaccine in order to increase the public's access to vaccines. Through the Federal Pharmacy Partnership Strategy for COVID-19 Vaccination Program, select pharmacy partners will receive a direct allocation of COVID-19 vaccine. Vaccine will be administered at partners' retail locations at no cost to recipients. This will be done through a provider agreement between the federal government and the pharmacy partner. CDC will share information on pharmacy partners as soon as it is available.

During which phase will pharmacy chains begin receiving vaccines?

HHS is partnering with CVS and Walgreens to offer on-site COVID-19 vaccination services for nursing homes and

COVID-19 Frequently Asked Questions for Vaccine Providers

assisted living facilities residents once they are recommended to receive vaccine. There may be other pharmacy partners that will be added to this program. Any updates will be shared with as soon as it is available.

In Phase 2, once there is adequate supply of COVID-19 vaccine(s) to support broader vaccination efforts, additional pharmacy partners will receive a direct allocation of COVID-19 vaccine in order to increase the public's access to vaccines. The program will be open to all jurisdictions willing to participate. Participating pharmacy partners will be required to share information on vaccine supply and doses administered to states and CDC. CDC will share information on pharmacy partners as soon as it is available.

Administration and Second-Dose Reminders

Will there be a consent form for vaccination?

No, informed consent is not a requirement. An Emergency Use Authorization (EUA) vaccine recipient fact sheet will be available online, and providers are required to provide those to vaccine recipients **prior** to vaccine administration.

How should providers ensure the same vaccine is administered for the first and second doses? How will the type of vaccine and intervals between doses be tracked?

COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. In addition to recording information in the IIS (DeIVAX), vaccination providers are required to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each vaccine recipient who receives vaccine to ensure a basic vaccination record is provided.

The Immunization Program will provide reminder/recall outreach for each administered dose of vaccines that comes with the phone number of the patient. Two messages will be sent out to the patient's phone number of record to remind the patient of the second dose of vaccine.

Will vaccine recipients be required to show their COVID-19 vaccination record card in order to get their second dose?

No. However, all vaccine recipients should be encouraged to keep their card and show it at their follow-up vaccination appointment. Retaining the COVID-19 vaccination record card is important to ensure that the first and second doses match when internet connectivity problems prevent access to the vaccine recipient's record at the time of vaccination.

Vaccine Finder

Will CDC or OWS have a public-facing vaccine locator at the national level?

As COVID-19 vaccine becomes widely available, providers will self-report to the website www.vaccinefinder.org.

Will VaccineFinder have real-time information? For example, can a provider change their

COVID-19 Frequently Asked Questions for Vaccine Providers

status if they run out of vaccine and update it when they have vaccine in stock?

Yes, VaccineFinder relies on providers to keep their location details up to date. The system will reflect the information and supply details entered by providers for their location (with an approximately 15-to-30-minute delay to reflect changes on the external website).

Will VaccineFinder be active in Phase 1 when vaccine availability is limited?

This is under discussion. However, because VaccineFinder is for use by the general public to locate vaccination services, VaccineFinder may not be active for public search of COVID-19 vaccine until vaccine is more widely available.

Is there a point of contact for vaccinefinder.org?

The point of contact for VaccineFinder is locatinghealth@healthmap.org.

Reporting to the IIS

How should we report administered COVID-19 doses?

All administered COVID-19 doses must be reported to the state IIS (DeIVAX) via Health Level 7 (HL7) Protocol Messaging from a provider's Electronic Medical Record (EMR) or by direct data entry within 24 hours of administration.

What data elements need to be reported to DeIVAX?

The following data elements are necessary for entry into DeIVAX:

1. Recipient Name
2. Recipient Date of Birth
3. Recipient Sex
4. Recipient ethnicity (Hispanic Yes or No)
5. Recipient Race
6. Recipient Address
7. Recipient Telephone Number
8. Recipient County
9. Recipient Phase Criteria (TBD)
10. Administrated at location: facility name/ID
11. Administered at location: type
12. Administration address (including county)
13. Administration date
14. CVX Code (Product)
15. Dose number
16. IIS Recipient ID
17. IIS vaccination event ID
18. Lot Number: Unit of Use and/or Unit of Sale
19. MVX (Manufacturer)
20. Sending organization
21. Vaccine administering provider suffix
22. Vaccine administering site (on the body)
23. Vaccine expiration date

COVID-19 Frequently Asked Questions for Vaccine Providers

24. Vaccine route of administration
25. Vaccination series complete
26. Vaccination Refusal (Y/N)