

Protecting and Improving the Health of Iowans

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Local Public Health Agency COVID-19 Vaccine Frequently Asked Questions Updated October 2, 2020

Changes from the previous version are highlighted in yellow.

COVID-19 Vaccine Administration

1. Is it possible for a county to decline offering the COVID-19 vaccine?

LPHAs will be responsible for coordinating and communicating with local health care entities and allocating doses of COVID-19 to health care providers in the county. LPHAs are not required to administer COVID-19 vaccine. LPHAs can choose to allocate all doses of vaccine to health care providers and entities in the county who have completed a COVID-19 Vaccination Provider Agreement. COVID-19 vaccine will be shipped directly to these providers.

Even if a LPHA does not choose to receive and administrer COVID-19 vaccine, the COVID-19 Vaccination Provider Agreement must be completed by the LPHA to allow the agency to allocate doses of vaccines to other health care providers in the county.

2. Will COVID-19 vaccine be mandatory for essential healthcare workers?

No. There will not be a state mandate to receive COVID-19 vaccine. Similar to influenza requirements, health systems and clinics may choose to set policies requiring COVID-19 vaccine for organization own staff.

COVID-19 Vaccine Provider Enrollment

1. Will providers need to enroll in IRIS to receive and administer COVID-19 vaccine? Yes. To receive and administer COVID-19 vaccine, all providers will need to be enrolled in IRIS and are required to sign a COVID-19 Vaccination Provider Agreement.

2. Does the LPHA need to complete the COVID-19 Vaccination Provider Agreement even if they do not plan to receive COVID-19 vaccine?

Yes. The COVID-19 Vaccination Provider Agreement must be completed to allow the LPHA to allocate doses of COVID-19 vaccines to other health care providers in the county.

3. Will health care providers be able to charge for the COVID-19 vaccine?

No. Providers cannot charge for COVID-19 vaccines provided by the federal government. It is unknown at this time if an administration fee will be able to be charged. IDPH will share more information about reimbursement claims for administration fees as it becomes available from insurers and federal and state partners.

4. How will the COVID-19 Vaccination Provider Agreement be made available to health care providers?

The CDC COVID-19 Provider Agreement was sent via HAN and email message to all LPH and IRIS providers on September 30. LPH is encouraged to share with local partners as well.

5. Can schools become COVID-19 vaccine providers?

Yes. A school can be listed as a local partner in the county vaccination plan. School teachers may be listed as priority groups. However, information regarding COVID-19 vaccine age indications are not available at this time. It is anticipated the initial COVID-19 vaccine will come to market for adults only. Additional studies on other populations will be needed prior to expanding the vaccine age indications.

6. Does the COVID-19 Vaccination Provider Agreement provide any liability protection for the provider?

The CDC COVID-19 Vaccination Provider Agreement specifies the requirements to receive, store and administer COVID-19 vaccines.

The administration of COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program. The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the covered countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of covered countermeasures identified in a PREP Act declaration. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any

device used in the administration of any such product, and all components and constituent materials of any such product.

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 are available at the toll-free number 1–855–266–2427 or http://www.hrsa.gov/cicp/.

7. Does LPH need to manage the REDCap surveys for all the potential providers in the county?

No. IDPH will manage the data collected through the REDCap survey. IDPH is responsible for sending COVID-19 Vaccination Provider information to CDC multiple times each week. IDPH will provide a list of enrolled COVID-19 vaccine providers to counties via the HAN for the duration of the event.

8. Does a provider have to be enrolled in IRIS to be able to receive COVID-19 vaccine allocations?

Yes. Health care providers are required to enroll in IRIS and complete a COVID-19 Vaccination Provider Agreement if the provider will be receiving and administering COVID-19 vaccine.

9. Does a provider already enrolled in IRIS need to complete the COVID-19 Vaccination Provider Agreement?

Yes. All providers planning to receive and administer COVID-19 vaccines must complete a COVID-19 Vaccination Provider Agreement.

10. Does a Long Term Care facility need to become an IRIS provider to vaccinate their residents and staff?

If the county vaccination plan has LTC administering COVID-19 vaccine to their residents and staff, yes they need to enroll as a provider. If the county plan includes LPHA staff administering vaccine to LTC residents and staff on site, then no, the LTC does not need to enroll as a COVID-19 vaccine provider.

11. Can health care providers already enrolled in IRIS add additional users for the organization?

Yes. An admin user in each organization can add additional users. Contact the IRIS helpdesk for additional assistance.

Ancillary Supply and Staffing

- Are Public Health Emergency Response (PHER) funds allowed to purchase supplies such as sharps containers, gloves, bandages or to pay for personnel costs?
 PHER and Hospital Response Funds may be used if any are remaining and available.
- 2. Will there be additional funding to cover vaccine administration activities such as staff time and supplies?

Immunization Service contract funds can be used to purchase supplies, however, it will not be sufficient to meet overall funding needs. Vaccine administration supplies will be provided with the exception of sharps containers, gloves and bandages. Immunization Service funds can not be utilized for contact tracing.

COVID-19 Allocation and Distribution

1. Will IDPH handle vaccine allocations for state institutions located in counties such as, mental health institutes, juvenile facilities, resource centers, civil commitment units or correctional facilities?

IDPH anticipates <u>all</u> COVID-19 vaccine distribution will be coordinated by the county LPHA with a few exceptions (see Q2 below). IDPH is awaiting guidance from the federal government to determine if <u>correctional facilities</u> will receive direct shipments of vaccines that by-passes the state allocation process. However, the county LPHA should plan to allocate vaccines to <u>all</u> of these agency types at this time. Information will be shared as it becomes available.

2. Some chain pharmacies have indicated they will receive COVID-19 vaccine directly from the federal government. Does the LPHA need to allocate COVID-19 vaccines to these locations?

IDPH does anticipate the federal government will ship vaccines to some of the national chain pharmacies. The allocation of these doses is not likely to occur in Phase 1. Additional information will be shared as it becomes available.

3. Can COVID-19 vaccine be redistributed among providers within the same health system?

As much as possible, COVID-19 vaccine should be shipped to the health care provider location where it will be administered to limit the possibility of storage and handling issues. However, due to minimum order quantities, transferring the COVID-19 vaccine will be an

acceptable practice. IDPH will be providing guidance about the process to transfer COVID-19 vaccine, approval process and the need to transfer vaccine doses in IRIS.

- 4. Will counties with more providers be allocated more COVID-19 vaccine?

 COVID-19 vaccine will be allocated based on priority groups, not the number of providers per county. It may be advantageous to have more providers to vaccinate the entire county population.
- 5. Is IDPH looking at additional tech platforms to manage the mass vaccination campaign?

No. IRIS will be utilized to allocate, distribute and document the administration of COVID-19 vaccines.

6. A medical provider has an office in our county, but the main office is located either out of county or out of state. Does the LPHAs work with the local clinic to provide COVID-19 vaccines or does the clinic work with their main office to order COVID-19 vaccines?

LPHAs/counties will allocate doses of COVID-19 vaccine only to providers within their respective counties. Each provider location will be required to sign a COVID-19 Vaccination Provider Agreement to receive and administer vaccine.

7. If the minimum allocation for COVID-19 vaccine is 1,000 doses, would smaller counties be able to order the vaccine if they took a regional approach?

This would need to be agreed upon at a regional level. IDPH would also have to take this into consideration when shipping COVID-19 vaccines. It is anticipated one county will need to be the lead agency and the vaccine will need to be transferred to the agency responsible for the administration and documentation of vaccine doses administered.

8. Will LPHAs be required to take a regional approach? This may not be feasible for agencies with only 1-2 public health staff.

LPHAs are not required to take a regional approach to COVID-19 vaccine planning. LPHAs will have the ability to allocate doses within their counties. LPHAs can choose to allocate all the doses to themselves or to have it shipped directly to providers in the county who are COVID-19 vaccine providers.

9. Will counties be designated to receive only certain types of COVID-19 vaccines? It is unknown which COVID-19 vaccine will be available first. Agencies will not be restricted to one vaccine and should be prepared to receive the vaccine included in the planning scenarios. It is anticipated COVID-19 vaccine will be available in multiple presentations as the

vaccine supply increases into 2021. Vaccine distribution considerations should include vaccine storage requirements and the ability to timely administer COVID-19 vaccine.

10. Can LPH choose to order/stock certain COVID-19 vaccines?

No. Allocations to counties will be based upon available COVID-19 vaccines. LPHAs will be able to determine where doses of vaccine are allocated in their counties.

11. If Local Public Health Agencies are allocated doses, how will they be notified when an allocation is made to their agency?

LPHAs will receive a HAN notification a COVID-19 vaccine allocation has been made to the county/LPHA in IRIS. The message will also indicate when the allocation needs to be submitted to the Immunization Program through IRIS. LPHAs will be able to see in IRIS all providers in their county who have signed a COVID-19 provider agreement. LPHAs can allocate all doses of COVID-19 vaccine to LPHA or allocate doses to partners based on the county vaccination plan.

12. Will COVID-19 vaccine be directly shipped to LTC facilities?

It is unknown what agencies will be receiving direct shipments of vaccines from a federal level. LPHAs should consider plans to allocate COVID-19 vaccine to LTC facilities or conduct closed PODs to vaccinate LTC residents and staff based on the county vaccination plan. More information will be shared as it becomes available.

13. Will packaging materials be provided to LPHAs to use for redistribution to providers in our county?

No, the Iowa Department of Public Health will not provide packing materials or pay for the redistribution of COVID-19 vaccines. Whenever possible, COVID-19 vaccines should be shipped to the location where it will be administered to minimize potential vaccine storage and handling issues.

14. Do LTC and ALF have to become IRIS providers if they work through LPHAs?

No. If the LPHA will be using a closed POD to vaccinate these facilities and the doses are documented in IRIS from the LPHA's inventory, it is not necessary for the facility to become a COVID-19 provider and enroll in IRIS. If the LPHA desires to ship COVID-19 vaccine to a facility to vaccinate their own staff and residents, the facility should become a COVID-19 vaccine provider and enroll in IRIS.

15. Will COVID-19 vaccines be directly shipped to LPHAs and the LPHAs deliver vaccines to providers?

No. LPHAs will allocate doses in IRIS to health care providers in their county who have signed a COVID-19 Vaccination Program Provider Agreement and who are part of the county

vaccination plan. Once the order is submitted in IRIS, the provider office will receive a direct shipment of the vaccine. LPHAs will not be responsible for re-packaging and distributing COVID-19 vaccines.

16. Will pharmacies receive direct shipments of COVID-19 vaccines?

CDC has indicated they are working with national pharmacies chains to receive direct shipments of COVID-19 vaccines. It is unknown at this time which pharmacy chains will be selected. It is also unknown when direct shipments to pharmacies will begin. Further information will be provided as soon as it is received.

17. What information sources will be utilized to determine the number of people in each priority group?

This will depend upon the tier groups selected by the ACIP. IDPH has provided a listing of priority group resources to LPHAs for planning purposes. Additional guidance will be forthcoming as soon as decisions have been made regarding the tier groups.

- 18. Who determines which populations makeup society's critical infrastructure?

 Federal guidance exists on critical infrastructure groups. ACIP will provide further guidance on populations within these groups. This will depend upon the tier groups selected by the ACIP. More information will be shared as it becomes available.
- 19. When will priority groups be released? This information is critical for local planning. The ACIP will make the final determination on priority groups. Groups prioritized for initial COVID-19 vaccination have not yet been confirmed but are expected to be critical infrastructure, health care workers and high risk individuals.

Priority Groups

1. Can an LPHA vaccinate health care providers in a priority group who live in lowa but work outside of the state or vaccinate out of state health care providers who work in lowa?

It is anticipated individuals in specified priority groups may be vaccinated regardless of the state of residence. Iowa's surrounding states should be taking the same measure to assure individuals in priority groups are vaccinated regardless of these variables.

2. Can IDPH provide guidance on how to assist local partners (hospitals, LTC, etc.) in prioritizing their workforce for vaccination?

Groups prioritized for initial COVID-19 vaccination have not yet been confirmed but are expected to be critical infrastructure, health care workers and high risk individuals. The ACIP

will make final recommendations on priority groups. LPHAs should work with local partners to determine the number of individuals in these populations and develop vaccination plans.

COVID-19 Storage and Handling

1. How long will it take to thaw ultra-frozen stored vaccines from frozen to refrigerated?

This information has not been released from the vaccine manufacturer. IDPH will share more information as it becomes available.

2. Should providers purchase additional cold chain storage devices?

It is not recommended that local public health or health care providers purchase freezers to store ultra-frozen vaccines. Local public health and Health care providers should consider the need to obtain additional temperature monitoring devices (data loggers) capable of measuring ultra-frozen vaccine temperature ranges. CDC will provide guidance regarding data logger specifications to monitor ultra-frozen vaccines.

Local public health and health care providers should consider requirements for vaccine storage and handling of COVID-19 vaccines to include locations to secure dry ice and facilities capable of storing ultra cold vaccines (-70°C). These facilities may include universities with research labs and large health systems who conduct clinical trials. An addendum to the CDC Storage and Handling Toolkit that specifically addresses COVID-19 vaccines is currently being developed in addition to other training materials.

3. The Planning Assumptions refer to the ultra-frozen vaccine shipping container needing to be "recharged". Please clarify what this means.

The ultra-frozen vaccine will arrive in a shipping container able to maintain the -70°C ± 10°C storage requirement. The shipping container will need to be replenished (recharged) with dry ice within 24 hours of receipt if agencies plan to use the container to store vaccine. The container will need to be recharged with dry ice every five days.

4. What are the calibration temps for ultra cold data loggers?

Information from CDC indicates the ultra cold vaccine will need to be maintained at temperatures between -60 and -80 °C. IDPH does not currently have data logger specifications for ultra cold vaccines. IDPH will share more information as it becomes available.

5. Will there be training/guidance provided for dry ice handling?

Handling instructions will be provided for dry ice to maintain vaccines at ultra-frozen storage requirements.

6. Should LPHAs coordinate dry ice MOUs with local vendors?

Not at this time. IDPH will share more information as it becomes available.

7. Can you let us know which agencies will receive ultra-frozen vaccines as this will take additional planning time.

For planning purposes, all agencies should plan to receive ultra-frozen vaccine and the need to obtain dry ice. IDPH will share more information as it becomes available.

COVID-19 Points of Dispensing

1. Is it necessary to conduct drive-thru vaccination clinics if a clinic can properly social distance indoors?

A COVID-19 vaccine clinic can be held in a building with proper social distancing and use of masks. Drive through clinics are not required to administer COVID-19 vaccine.

- 2. When a Long Term Care facility enrolls in IRIS, is a closed POD MOU required?

 No. Enrollment in IRIS does not require the LPHA to have a closed POD MOU. If the LPHA will be using a closed POD to vaccinate staff/residents at the LTC and the doses are documented in IRIS from the LPHAs inventory, it is not necessary for the facility to become a COVID-19 provider and enroll in IRIS. If the LPHA desires to ship COVID-19 vaccine to a facility who will in turn vaccinate their own staff and residents, the facility should become a COVID-19 vaccine provider and enroll in IRIS.
- 3. If agencies have closed POD MOUs in place, will this ensure priority is given to these agencies?

No. COVID-19 vaccine will be allocated based on priority groups, not the number of POD MOUs in place. However, it will be advantageous to have POD MOUs in place for planning purposes.

4. Is a template MOU for closed PODS available? This would help ensure consistency with businesses that span several counties.

A sample POD MOU is available on the HAN. LPHAs should consult with legal counsel to incorporate the appropriate language for each public health agency.

5. Could the POD workbook be included in EMResource?

Not at this time. Given the timeframe required to complete and return the workbook, it will not be included in EM Resource in sufficient time. Adding the workbook to EM Resource will be explored in the future.

6. Will closed PODs be listed on vaccinefinder.org?

No. Closed pods will not be listed on Vaccine Finder.

7. Is it necessary to create a POD Worksheet for every enrolled IRIS provider in our county?

No. It is not necessary to have a POD worksheet for every IRIS-enrolled provider in your county.

8. Does IDPH have guidance on closed PODs?

IDPH provided guidance on vaccine clinic planning and PODs during the September 9, 2020 LPHA Webinar. Information is posted to the HAN.

9. WIII LPHAs be able to have open PODS for COVID-19 vaccination? Are there additional considerations since this will be a new vaccine?

CDC has developed guidance for giving vaccines at <u>large-scale influenza clinics</u>. All COVID-19 vaccines will have to demonstrate safety and efficacy through Phase 3 clinical studies before being approved by the FDA. The current ACIP recommendation is providers should consider observing patients for 15 minutes after receipt of any vaccine.

10. Is the state planning to use existing Testlowa.com testing sites as mass vaccination sites for COVID-19?

No. The state is not planning to use these sites for the administration of COVID-19 vaccines.

COVID-19 Vaccine

1. We have already heard concerns from clients and patients about the safety of a new vaccine. How do we address this?

This is a very important point. The CDC and IDPH will be addressing vaccine confidence throughout the COVID-19 vaccination campaign. CDC is in the process of developing materials to address concerns about COVID-19 vaccines. We will share more information as it becomes available.

2. Are vaccine information statements available now?

Fact sheets will be developed for each vaccine that comes to market. This information is not available at this time. Information regarding each vaccine will come from the clinical trials.

3. Can vaccine information be provided in multiple languages so we can help build trust for the vaccine among the diverse populations in our communities?

CDC and other public health partners are working on a communication campaign which will include multiple languages and formats. IDPH will share more information as it becomes available.

4. Do we know when the first doses of vaccine will be available?

Not at this time. It is anticipated very small amounts of vaccine will be made available late fall 2020 with supplies increasing in early 2021.

5. Are there any contraindications with providing COVID-19 vaccine while someone is being treated with antivirals for influenza?

IDPH does not have any information on contraindications at this time. This information will be shared as COVID-19 vaccines complete clinical trials and are either approved by the FDA or are distributed under an Emergency Use Authorization (EUA).

6. Normally the minimum interval between live virus vaccines is four weeks. Will this apply to COVID-19 vaccines as well?

IDPH does not have this level of information for the vaccines being developed. It is unknown if the vaccines are a live virus vaccine and what the minimum interval will be between doses of COVID-19 vaccine or other routinely recommended vaccines. IDPH will share more information as it becomes available.

7. Is the COVID-19 vaccine a live vaccine?

There are currently multiple vaccine candidates in various stages of clinical trials. The first two vaccines anticipated to be available are not live vaccines. We will share more information as it becomes available.

IDPH Contacts

1. Will IDPH provide a COVID-19 contact list for CADE, the Immunization Program and BETS?

Questions relating to POD planning should be directed to Matt Shroyer at Matthew.Shroyer@idph.iowa.gov. Questions regarding COVID-19 vaccines, allocation and distribution of COVID-19 vaccines and IRIS enrollment can be directed to the Immunization Program at 1-800-831-6293 or COVID19Vaccine@idph.iowa.gov. Questions regarding COVID-19 cases, contact tracing, or any issues related to case investigations should be directed to your regional epidemiologist.

Influenza Vaccine

1. Will additional doses of influenza vaccine be available to order from the Immunization Program?

If the agency is a VFC provider, please contact the VFC Program at 1-800-831-6293 to discuss the request for additional influenza vaccine.

2. Is there any guidance for conducting seasonal flu vaccination clinics in schools and other situations where social distancing is difficult and sustained community spread of COVID-19?

CDC has issued revised Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations (Guidance for Planning Vaccination Clinics). The purpose of this guidance is to assist with planning and implementation of satellite, temporary, or off-site vaccination clinics by public and private vaccination organizations.

The Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations also provides information on additional considerations required during the COVID-19 pandemic, including physical distancing, personal protective equipment (PPE), and enhanced sanitation efforts. Additionally, curbside and drive-through clinics may provide the best option for staff and patient safety during the COVID-19 pandemic.