

Vaccine Planning Work Group

In order to keep an accurate roll call, we ask that everyone joining this meeting rename themselves to include the following information:

- First Name
- Last Name
- Organization

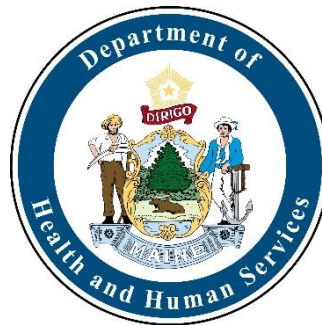
Please type all questions into the chat box.

Presentations slides will be sent to meeting attendees by COB today. If you did not receive an invitation to this meeting directly from the Maine Immunization Program, please email Jessica.Shiminski@Maine.Gov to be added to the distribution list.

We appreciate the time and effort taken by everyone joining to help the Maine CDC with COVID-19 vaccine planning.

Vaccine Planning Work Group

Tonya Philbrick
Maine Immunization Program
October 8, 2020



Disclaimer

All information in this presentation is subject to change.
Information shared in these slides are assumptions
as of 10/7/2020.

This presentation is being recorded.
If there are any objections, please disconnect now.

Agenda

- Webpage
- FAQ's
- Priority Group 1A
- Organization Planning and Technical Assistance
- COVID-19 Email Box

Webpage

Live By October 26th

- Provider Agreement
 - Including Instructions
- Provider Training
- Storage and Handling Tools and Guidance
- Communications
 - Including FAQ's
- Vaccine Safety
- Previous Presentations

Frequently Asked Questions

Will VFC providers need to have a COVID-19 agreement signed as well as their VFC agreement or will the VFC agreement supersede a pandemic agreement?

Any provider receiving and administering COVID-19 vaccine will need to sign the COVID-19 agreement.

Will private providers have access to COVID-19 vaccine?

Public and private providers enrolled in the COVID-19 Vaccination Program will have access to vaccine, based on supply, state and local need, and enrollment procedures.

Frequently Asked Questions

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.

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

CDC will share more information about reimbursement claims for administration fees as it becomes available.

Frequently Asked Questions

Will CDC provide a consent form for vaccination?

No, informed consent is not a federal requirement.

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. <http://www.hrsa.gov/cicp/>.

Frequently Asked Questions

Will mass vaccination clinics in large venues be considered as an appropriate strategy for COVID-19 vaccinations?

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>.

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

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. “Vaccination Guidance During a Pandemic” <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>

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

For information on PPE for healthcare workers, see <https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>

Frequently Asked Questions

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.

Does CDC recommend an observation period after vaccination?

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

Are 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.

Frequently Asked Questions

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

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.

Once vaccine arrives, should doses be held in reserve for the second dose? (e.g., 200 doses are delivered, 100 are held in reserve for second doses)

No. Vaccines should be administered to critical populations as soon as they arrive in the state. The Maine Immunization Program and federal CDC will be tracking vaccine allocation to ensure that the second dose vaccine is distributed to facilities based on the first dose presentation.

Frequently Asked Questions

What assistance will jurisdictions receive to 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, EHR, and/or Vaccine Administration Management System (VAMS), vaccination providers are required to complete these cards with accurate vaccine information.

Will IHS receive its own vaccine allocation for distribution to tribes in areas it serves?

Tribal Nations are being offered a choice for how they wish to receive vaccine. They can choose between receiving vaccine through the state allocation or through the IHS allocation.

Frequently Asked Questions

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:

- 105 needles
- 105 syringes
- 210 alcohol prep pads
- 4 surgical masks
- 2 face shields for vaccinators
- 100 COVID-19 vaccination record cards

Ancillary supply kits will NOT include sharps containers or gloves to handle dry ice

What happens to the ancillary supplies if there becomes a national shortage of (needles, masks, etc.)?

COVID-19 vaccine providers should anticipate all ancillary supplies listed above be shipped with each COVID-19 vaccine order, regardless of a shortage for private purchase for these same supplies.

Frequently Asked Questions

How will COVID-19 vaccine be ordered?

Vaccination providers will order COVID-19 through the Maine Immunization Information System, ImmPact. Vaccination providers must have an approved CDC COVID-19 Vaccine Provider Agreement.

Will vaccine orders go to McKesson and be sent directly to providers?

CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.

Frequently Asked Questions

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.

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

Currently, one vaccine candidate requires storage at -60°C to -80°C or at $2-8^{\circ}\text{C}$ for up to 5 days (i.e., 120 hours). Once reconstituted, the vaccine can be at room temperature for up to six hours.

Frequently Asked Questions

Does CDC know 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 CDC provide guidance on how to handle vaccines that require an ultra-cold chain?

Yes, a product-specific EUA fact sheet for COVID-19 vaccination providers will be made available on the web to download that will include information on the specific vaccine product, instructions for its use, and storage and handling requirements. CDC will provide additional education and training materials.

Frequently Asked Questions

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

Yes, at least one vaccine requires ultra-cold storage conditions.

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

Providers are not advised to purchase ultra-cold storage equipment at this time. Ultracold vaccines will ship to the vaccination provider location directly from the manufacturer in a pack-out that contains dry ice. Storage and handling instructions for ultra-cold vaccine will address repacking these coolers for extended storage.

Frequently Asked Questions

Is there a tip sheet 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.

Concerns have been expressed regarding the COVID-19 vaccine 24-hour administration documentation requirement in ImmPact. Will it be possible to extend this timeline to allow for the necessary manual process to take place?

Federal CDC has required that all COVID-19 vaccine administration be documented within 24 hours of administration of vaccine.

Will Maine CDC have a website where organizations can list the COVID-19 vaccination clinics they are conducting for the general public?

The Maine Immunization Program has a website page dedicated to informing the public of vaccine clinics: catch-up, influenza, and COVID-19.

<https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/vaccine-clinic.shtml>

Additionally, we urge influenza and COVID-19 providers to use VaccineFinder.

Frequently Asked Questions

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

- Phase 1: Potentially limited supply of COVID-19 vaccine doses available. Focus initial efforts on reaching the critical populations. Ensure vaccination locations selected can reach populations, manage cold chain requirements, and meet reporting requirements for vaccine supply and uptake.
 - Due to limited supply Phase one will be broken down into Phase 1 A and Phase 1 B.
- Phase 2: Large number of vaccine doses 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: Sufficient supply of vaccine doses for 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.

Planning

Have you started planning for how you would vaccinate Priority Group 1a?

Does your plan cover the key elements for COVID Planning?

Do you need technical assistance?

Priority Group 1A

Assumed Targeted Population	Key Partners	Role of Partners
High-risk workers in health care facilities	Maine Hospital Association	To assist in communicating to Hospitals throughout Maine to ensure vaccination efforts are in place for the priority population.
First responders	Emergency Medical Services	To assist in vaccinating the priority population.
	Public Health Nursing	To assist in vaccinating the priority population.
	Tribal Health Centers	To assist in vaccinating the priority population.

Elements for COVID Planning

Phased Approach to COVID-19 Vaccination

Outline how your Organization will respond to COVID-19 vaccination efforts during the three phases of vaccine administration:

- Phase 1: Potentially Limited Doses Available
- Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand
- Phase 3: Likely Sufficient Supply, Slowing Demand

Elements for COVID Planning

COVID-19 Organizational Structure

- Outline your Organizational structure.
- Describe your Organizations planning team
 - Include individuals with a wide array of expertise
 - Include key partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.

Elements for COVID Planning

Critical Populations

- Have you identified priority individuals within your Organizations workforce.
- Describe how your Organization will establish points of contact (POCs) and communication methods for employees or patients, or communities (as appropriate) within the critical population groups.

Elements for COVID Planning

COVID-19 Vaccine Administration Capacity

- Determine your Organizations vaccine administration capacity.
- Be sure to consider staffing availability and the need for social distancing.

Elements for COVID Planning

COVID-19 Vaccine Inventory Management

- Describe your Organizations plans for ordering vaccine to ensure that vaccination administration is conducted in accordance with priority groups.
- Describe who will have responsibility within your Organization to order COVID-19 vaccine.
- Describe how your Organization will coordinate any vaccine transfers.
- Describe how you will monitor COVID-19 vaccine wastage and inventory levels.

Elements for COVID Planning

COVID-19 Vaccine Storage and Handling

Describe how your Organization plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultracold chain requirements, at all levels:

- Clinic locations
- Satellite, temporary, or off-site settings
- Situations that require vaccine transfers
- Return of vaccine to Central location at the end of the day

Elements for COVID Planning

COVID-19 Vaccine Administration Documentation and Reporting

- Are you ready and able (e.g., staff is trained, internet connection and equipment are adequate) to report the required COVID-19 vaccine administration data elements to the IIS or other external system every 24 hours.
- Describe the steps you will take to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.
- Describe how each dose of COVID-19 vaccine administered will be fully documented and reported every 24.

Elements for COVID Planning

COVID-19 Vaccination Second-Dose Reminders

Describe all methods your Organization will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.

Examples:

- Reminder Post Cards
- Scheduling for a follow up appointment
- Text messaging

Elements for COVID Planning

Regulatory Considerations for COVID-19 Vaccination

- Describe how you will ensure vaccinators are aware of, know where to locate, and understand the information in any Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients or vaccine information statements (VISs), as applicable.
- Describe how you will ensure vaccinators provide Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs), as applicable, to each vaccine recipient prior to vaccine administration.

Elements for COVID Planning

COVID-19 Vaccine Safety Monitoring

Describe how your Organization will make sure that staff and patients understand how to report a vaccine adverse event.

COVID-19 Vaccination Program Monitoring

Describe how your Organizations will monitor COVID-19 vaccination response efforts.

COVID Planning

- We are asking that each Organization plan on how they will ensure that their Priority 1a employees will be vaccinated.
- Develop, review, test, inform and continue to update.
- The Maine Immunization Program.
 - Email C19Vaccine.MECDC@maine.gov

New Contact Information

C19Vaccine.MECDC@maine.gov

This new inbox is for questions regarding vaccine planning for COVID-19:

- Provider Enrollment Requirements
- CDC COVID-19 Vaccine Provider Agreement
- Any follow-up questions to these weekly Vaccine Planning Work Group Meetings

Questions?

Tonya Philbrick
Director
Maine Immunization Program

