COVID-19 Vaccine Planning
Frequently Asked Questions – October 7, 2020

Please note: Keep in mind that there will likely be more than one COVID-19 vaccine and that supplies, recommendations, and guidance will develop over a period of at least 12 months. This is a fluid situation and there is inherent uncertainty about some of the information in this FAQs document. The Maine Immunization Program will routinely incorporate new questions and update answers to previous questions as new information becomes available.

1) **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.

2) **How can providers enroll to administer COVID-19 vaccine?**
   To receive and administer COVID-19 vaccine, vaccination providers must enroll in the COVID-19 Vaccination Program through their jurisdiction's immunization program. Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement. **(**Note: Federal clinicians working in federal facilities may have professional licensure from a different jurisdiction.) Enrolled COVID-19 vaccination providers must also fully complete the CDC COVID-19 Vaccination Provider Profile form for each location where COVID-19 vaccine will be administered. Some national pharmacy chains and federal entities will be instructed to enroll directly with CDC.

3) **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.

4) **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.

5) **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 in the state of Maine, vaccination providers must enroll in the COVID-19 Vaccination Program though the Maine Immunization Program. CDC is exploring coordination with some multijurisdictional entities (e.g., certain federal entities, HIS, and national chain pharmacies) to receive vaccine outside of this process.

6) **Will private providers have access to COVID-19 vaccine? (Updated 10/2/2020)**
   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.

7) **Will CDC provide a consent form for vaccination?**
No, informed consent is not a federal 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. Immunization programs will be required to ensure providers are aware of the fact sheet requirements.

8) **Will vaccine be available for children and adolescents in the initial phase?**
At first, COVID-19 vaccines may not be recommended for children. The groups recommended to receive the vaccines could change in the future.

9) **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 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. The CICP can also provide 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 medication, any other drug, any biologic, any diagnostic, any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, the transmission of SARS-CoV–2 or a virus mutating from SARS-CoV-2, or any device used in the administration of 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 is available by calling 1-855-266-2427 or visiting http://www.hrsa.gov/cicp/.

10) **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. The guidance provides information on procedures for protecting patients 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.

11) **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 healthcare 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.

12) **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.

13) **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.

14) **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.

15) **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).

16) **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. States should engage with the Tribal Nations located in their area to discuss their preferred option. States should include documentation of Tribal preference in the plans they submit to CDC.

17) **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.
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.

The Maine CDC will provide clear guidance on the critical populations of Phase 1. More information will be shared as it becomes available.

18) **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.

19) **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.

20) **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 in VTrckS. 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 for vaccinators, and 100 COVID-19 vaccination record cards for vaccine recipients.

21) **Will the ancillary supplies in the shipments include sharps containers?**
No, the ancillary supplies will not include sharps containers.

22) **Are more details (brand, type, etc.) available about the supplies to be provided with COVID-19 vaccine?**
CDC will provide the brand information when it is available.

23) **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.

24) **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, complete an educational training, and have at least two staff with active ImmPact User Agreements (a primary and secondary vaccine coordinator).

25) **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 as approved by jurisdiction immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.

26) **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 (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives vaccine to ensure a basic vaccination record is provided.
Several of the vaccines in clinical trials will require 2 doses, separated by 21 or 28 days. Immunization information systems (IISs) will be critical for reporting and tracking intervals.

Jurisdictions should also be planning for redundant methods of providing second-dose reminders to vaccine recipients.
Vaccination providers should be highly encouraged to complete the vaccination cards and give them to each patient who receives vaccine to ensure a basic vaccination record is provided and to keep the card in case the IIS or other system is not available when they return for their second dose.

27) **Are there planning considerations for distributing ultra-cold vaccines to high-temperature areas?**
Ultracold vaccines will ship to the vaccination provider location directly from the manufacturer in a pack-out that contains dry ice. CDC will confirm with the manufacturer about the ambient temperature conditions under which the packout was qualified to determine if there are specific considerations for jurisdictions. The thermal shipper is the way to get vaccine to clinics/sites with temperature extremes.

28) **Will there be different storage and handling requirements for COVID-19 vaccine?**
Yes, at least one vaccine requires ultra-cold storage conditions. CDC is working on ways to support ultra-cold chain vaccine storage and handling needs. We will provide more information and guidance as they become available.

29) **Should jurisdictions invest in ultra-cold storage units at this time?**
Jurisdictions are not advised 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 for extended storage.

30) **What are the on-site storage requirements and warm-up protocols for vaccine that must be stored at ultra-cold temperatures?**
CDC anticipates jurisdictions will receive direct shipment to the vaccination provider site on a real-time, day-to-day basis. Currently, one vaccine candidate requires storage at -60°C to -80°C or at 2–8°C for up to 5 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.

31) **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.

32) **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.

33) **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.

34) **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. The Maine Immunization Program is required to send this data to the federal CDC biweekly. This data will be used to determine state uptake on vaccine and the need for further allocations.

35) **Will Maine CDC have a site 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. COVID-19 providers are encouraged to notify the Maine Immunization Program of clinics at their facility to include on this webpage (closed or open). Additionally, we urge influenza and COVID-19 providers to use VaccineFinder.

36) **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.