Maine EMS Vaccination Plan for Public Safety Professionals

December 12, 2020

Maine Bureau of Emergency Medical Services (Maine EMS)

Maine Department of Public Safety (Maine DPS)

Government of the State of Maine





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Change Log

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Abbreviation List

Abbreviation	Meaning
ACIP	Advisory Committee on Immunization Practices
AEMT	Advanced Emergency Medical Technician
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CDC	Center(s) for Disease Control and Prevention (U.S. is plural/Maine singular)
CICP	Countermeasures Injury Compensation Program
CMS	U.S. Centers for Medicare & Medicaid Services
DHHS	Department of Health and Human Services
DPS	Department of Public Safety, Maine
EMA	Emergency Management Agency
EMD	Emergency Medical Dispatchers
EMR	Emergency Medical Responder
EMS	Emergency Medical Services
EMT	Emergency Medical Technician
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
MAC	Medicare Administrative Contractor
Maine EMS	Maine Bureau of Emergency Medical Services
ME	Maine
MEFIRS	Maine EMS and Fire Incident Reporting System
MEMSEd	Maine EMS Education System
MIP	Maine Immunization Program
NPI	National Provider Identification Number
PHEP	Public Health Emergency Preparedness (Maine CDC Program)
PREP Act	Public Readiness and Emergency Preparedness Act
TIN	Tax Identification Number
U.S.	United States
VAERS	Vaccine Adverse Event Reporting System
VIS	Vaccine Information Statement

Purpose of the Plan

The purpose of this plan is to define the pathway by which all public safety professionals within the State of Maine are to be afforded the opportunity to receive the SARS-CoV-2 vaccine to prevent COVID-19 disease. This plan is intended to work in tandem with the plans promulgated by the Maine Governor's Office, Maine Department of Health and Human Services (Maine DHHS), Maine Center for Disease Control and Prevention (Maine CDC), and the Maine Immunization Program (MIP). The most recent draft of the <u>Maine CDC COVID-19 Interim Draft</u> <u>Vaccination Plan</u> (V 1.0, October 16, 2020) for the State of Maine indicates that first responders will be eligible to receive the COVID-19 vaccine as part of the first phase of distribution when supplies are expected to be scarce.¹ This plan is designed to outline a pathway by which all public safety professionals within the State of Maine may receive a vaccine as quickly as possible when doses come available. It is important to note that this plan is not intended to override, supersede, or supplant the Vaccination Plan developed by Maine CDC. This plan is solely intended to operationalize the Maine CDC plan to safely deliver COVID-19 vaccinations to public safety professionals throughout the State of Maine.

Information Disclaimer

It is important to note that this plan is not static, but instead is subject to change as more information is discovered regarding the epidemiology of the virus, vaccine efficacy, and at-risk populations. This plan will also change as more vaccine variations come available on the market and there is increased access to available vaccine doses. Individuals utilizing this plan should be sure to monitor the <u>Maine EMS website</u> (www.maine.gov/ems) to ensure that they have the most up-to-date version of the plan as information within the document is subject to change. Maine EMS and the Maine CDC commit to keeping this plan up to date as timely as possible; however, there may be times where there are delays in producing a new version. In addition, Maine EMS hosts biweekly COVID-19 Update Briefings via Zoom. The schedule for these meetings can be found on the calendar tool of the <u>Maine EMS website</u>.

Background

In anticipation of the COVID-19 vaccination, the National Academies of Sciences, Engineering, and Medicine compiled a consensus study report outlining potential vaccine allocations

¹ Maine CDC. (Oct. 16, 2020). *COVID-19 Interim Draft Vaccination Plan: Maine*, V1.0. Access on November 10, 2020 from https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/documents/covid-19-vaccination-plan-maine-interim-draft.pdf

entitled, a Framework for Equitable Allocation of COVID-19 Vaccine.² This report is to be used by organizations like the U.S. FDA, U.S. CDC, Maine DHHS, and Maine CDC to devise the best allocation strategy to safely deliver the vaccine throughout the United States while accounting for risks, maximizing benefits, equality, health equities, fairness, transparency, and scientific evidence. The study places first responders in the first phase of the vaccine distribution plan (pg. 116). The U.S. CDC also has an Advisory Committee on Immunization Practices (ACIP) that is charged with developing recommendations for use of vaccines in the United States on civilian populations. This committee is comprised of leading medical and public health experts who offer guidance on the safe use of these measures. The ACIP plays an important role in the allocation of COVID-19 vaccination as they direct the United States strategy based on input from other documents such as the Framework for Equitable Allocation of COVID-19 Vaccine. The ACIP has identified three guiding principles by which it is using to determine the allocation strategy based on the very limited supply of vaccine: science, implementation, and ethics. As a result of their work they have broken Phase 1 into three parts based on the very limited supplies available throughout the United States. In their first phase, Phase 1A, they have designated healthcare personnel, including emergency medical services clinicians, and longterm care facility residents as the individuals who will be receiving the initial doses. This weighs the overall risk to these populations in terms of contracting the virus as well as morbidity and mortality data(i.e., mortality rates in long-term care facilities is significantly higher than any other population).³ The ACIP has further designated that essential workers (including



firefighters, law enforcement, and emergency medical dispatchers (EMDs)) will be prioritized in Phase 1B. These subphases within Phase 1 will be occurring simultaneously where Phase 1B will begin in the middle of 1A as soon as vaccine supplies are available to support the additional individuals (see Figure 1). All persons working in these fields are eligible to receive

Figure 1: ACIP COVID-19 Vaccine Work Group Recommendation for Phase 1 (Source: See Footnote 3)

the vaccine within the initial phase regardless of whether they function in paid or volunteer

² National Academies of Sciences, Engineering, and Medicine. (2020). *Framework for Equitable Allocation of COVID-19 Vaccine.* Washington, D.C.: The National Academies Press. Accessed on November 10, 2020 from https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novelcoronavirus#sectionPublications

³ Dooling, K. 2020. Phased Allocation of COVID-19 Vaccines – December 1st, 2020 ACIP Meeting. (2020). [Slide Deck]. Accessed on December 12, 2020 from https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/COVID-02-Dooling.pdf

roles. "First responders who are at higher risk of exposure and those who are at higher risk for severe illness and/or death because of comorbid conditions and age should be among the first receiving the vaccine in this group" (pg. 117).⁴

As of November 10, 2020, the best estimates of public safety professionals in the State of Maine are as follows:

TYPE OF PUBLIC SAFETY PROFESSIONAL ⁵	COUNT
EMERGENCY MEDICAL SERVICES (EMS) ⁶	4,991
EMERGENCY MEDICAL RESPONDER (EMR)	91
EMERGENCY MEDICAL TECHNICIAN (EMT)	2,577
ADVANCED EMERGNECY MEDICAL TECHNICIAN (AEMT)	875
PARAMEDIC	1,448
EMERGENCY MEDICAL DISPATCHERS ⁴	405
FIREFIGHTERS (ROUGH ESTIMATES) ⁷	7,700
PAID	~5,800
VOLUNTEER	~1,900
LAW ENFORCEMENT ⁸ (AS OF 2018)	2,921
SWORN OFFICERS	2,346
CIVILIAN PERSONNEL	575
TOTAL	16,017

Strategy

In order to protect continuity of operations of essential services within the community, it will be necessary to rapidly deploy the COVID-19 vaccine to members of the public safety community as quickly as possible. Maine EMS will identify the two to three largest EMS agencies within each county based on their number of affiliated staff within the Maine EMS eLicensing system. The office will coordinate with these agencies to determine their level of interest in participating in this pilot program to vaccinate public safety professionals throughout the county where their primary base of operations is located. They will have access to the plan to better understand the intentions of the office as well as the Maine Department of Health and Human Resources. Maine EMS will coordinate with them to ensure that they have

⁴ See Footnote 2

⁵ Due to the nature of the public safety workforce, there are duplicate counts. For example, many firefighters also hold an EMS certification. There isn't enough information to tease this information apart at this time and so this table highlights the maximum number of individuals in each of these categories from the most recent data source. ⁶ Maine EMS. eLicensing System Report – All Maine Active Personnel. Accessed on November 10, 2020.

⁷ Maine Fire Service Institute Fire Department Census (March 2014)

⁸ Maine Department of Public Safety. (2018). Police Employment Data. Accessed on November 10, 2020 from https://www.maine.gov/dps/msp/sites/maine.gov.dps.msp/files/inline-files/085%20Employ.pdf

sufficient billing infrastructure in place to process billing of vaccine administration fees and other necessary aspects including a service level medical director which will be discussed later. In the event that organizations are not interested in participating in the process, Maine EMS will proceed to the next largest EMS agency within that county to understand their interest in participating in the program. Once Maine EMS has secured their commitment, the office will assist the agency in working through the logistics described in this plan.

Maine EMS envisions that there are two pathways by which EMS organizations will work to deliver the vaccinations to public safety professionals: hospital-based system that is managed by the health system and independently as a designated COVID-19 vaccine provider. It is important to note that in the initial phases of this administration plan, these agencies will be serving as pilot organizations to assist with the office navigating the logistics of transitioning a select group of EMS clinicians into a role of vaccinators. It is likely that going forward, subsequent administration campaigns in later stages of Maine CDC's plan may require varying strategies that will be developed overtime.

Hospital Partnerships

There are multiple EMS agencies that are directly affiliated with healthcare systems throughout the State of Maine as well as others that maintain close ties but aren't a subsidiary of the health system. As healthcare systems throughout the state receive allocations of the vaccine, they will likely need to pull in resources from their partner EMS agencies to support vaccination efforts within their system. In this scenario, EMS clinicians will be able to work within their scope to provide vaccination support to the existing hospital infrastructure. Individuals administering vaccinations on behalf of healthcare systems will need to directly enter records within the health system's electronic health record or other systems designed for collecting vaccination information. EMS clinicians in this model will serve exclusively to fill the role of administering the vaccination unless otherwise directed by the health system as part of their vaccination management plan. If EMS agencies intend on billing directly for vaccine administration costs (discussed below), they will need to complete the application process to become a COVID-19 Vaccine Provider with Maine CDC and Maine EMS and document within the Maine EMS & Fire Incident Reporting System (MEFIRS). It should be noted that during Phase 1 of the Maine CDC COVID-19 Vaccination Plan EMS agencies partnering with health systems must agree to participate in vaccinating public safety professionals within the designated county.

Designated COVID-19 Vaccine Provider

Agencies that intend on offering vaccinations directly to the public safety community and ultimately the public outside of an existing vaccination program recognized by the MIP will need to become a designated COVID-19 Vaccine Provider with the U.S. Centers for Disease Control and Prevention as well as the Maine CDC. The <u>application</u> process to become

recognized in the State of Maine is accessible on the <u>Maine CDC MIP website</u> (see <u>Appendix A</u> for sample). These organizations will be independently authorized to deliver COVID-19 vaccine throughout the State of Maine in alignment with the immunization plan that is promulgated by the Maine CDC that is specific to the needs of the state. Organizations that are authorized by U.S. CDC, Maine CDC, and Maine EMS will be eligible to receive direct shipments of COVID-19 vaccine. Shipments will be determined based on number of individuals that need to be vaccinated in each county and the daily throughput capacity of the organization to administer vaccinations. Based on the various formulations of the vaccine that are likely to be available for administration, there will be various shipment sizes. Some vaccines will be shipped in bulk due to the need for ultra-cold (-60 to -80°C) chain storage. EMS agencies will likely be ineligible to receive these vaccination shipments directly because of their lack in capacity to maintain ultra-cold temperatures; however, other vaccine products may be shipped directly if they do not require special equipment or services (i.e., ultra-cold storage).

There will be capacity through the Maine CDC's plan of vaccine distribution throughout the state for organizations to acquire this vaccine through vaccine transfers that will be described later in this document. The Pfizer vaccine will be able to be stored temporarily for up to five days in refrigerators until use. This will help to minimize inequities regarding the distribution of the vaccination because the vaccine depots are pre-positioned throughout the state. Additionally, EMS organizations that are approved as providers will be able to request aliquots of vaccine from the Maine CDC's Public Health Emergency Preparedness warehouse supply in consultation with the MIP.

Statewide Capacity

In the State of Maine there are 4,900 licensed EMS clinicians that will be authorized to deliver vaccines after completing the appropriate training required by Maine EMS. This number includes 1,448 paramedics and 875 AEMTs who already have intramuscular injections as part of their standard scope of practice within the State of Maine. On December 2, 2020, the Maine Board of EMS voted unanimously of the members present to expand the scope of practice of EMTs to include the administration of vaccine.⁹ This move was based on established practices where EMTs are already authorized to administer intramuscular epinephrine. The 2,577 EMTs will be able to assist with vaccine administration under the supervision of a higher-level clinician (i.e., AEMT, paramedic, RN, MD, DO, etc.) and following the completion of the standardized training course called Ready, Check, Vaccinate. It is important to note that EMTs will *not* be able to administer the vaccination without at least one paramedic or higher-level healthcare clinician on site at the location where the vaccination is being delivered. In this

⁹ See Minutes from December 2, 2020 Maine EMS Board Meeting

situation, there must be at least an AEMT, paramedic, nurse, physician assistant, advanced practice nurse/nurse practitioner, or physician physically present at the location for them to be able to administer the vaccine so that the higher-level clinician can assist in managing any complications that may arise.

EMS organizations already have pre-existing relationships with other public safety partners within the community that they serve and so utilizing those existing connections will help to facilitate identification of groups that need to be vaccinated. It will be important for organizations within each county to identify all the active members of their respective public safety entity (i.e., fire, police, dispatchers, EMS) so they can be vaccinated. While the estimates reflected in the background section of this document represent the high-end, it is likely that many of the fire personnel listed also hold an EMS license as well. This reduces the burden on the identified EMS organizations in that there are fewer people that will likely need the vaccination.

COUNTY	EMS AGENCY
ANDROSCOGGIN	Auburn Fire Department
	United Ambulance Service
AROOSTOOK	Ashland Ambulance Service
	Caribou Fire/Ambulance
	Presque Isle Fire Department
CUMBERLAND	Gorham Fire Department
	MEDCU – Portland Fire Department
	Scarborough Fire Department
FRANKLIN	Carrabassett Valley Fire/Rescue
	NorthStar
HANCOCK	Bar Harbor Fire Department
	Peninsula Ambulance Corps
KENNEBEC	Augusta Fire Department
	Delta Ambulance
KNOX	Rockland Fire and EMS
	Union Fire-Rescue
LINCOLN	Boothbay Region Ambulance
	Waldoboro EMS
OXFORD	Med-Care Ambulance Service
	PACE Paramedic Service
PENOBSCOT	Bangor Fire Department
	East Millinocket Fire Department
	Northern Light Medical Transport
PISCATAQUIS	Charles A Dean Ambulance Service
	Northern Light May Hospital

Services Identified by County

SAGADAHOC	Topsham Fire – EMS Woolwich Fire Dept.
SOMERSET	Redington Fairview EMS Sebasticook Valley Hospital Ambulance
WALDO	Belfast Ambulance and Rescue Service Unity Volunteer Ambulance Corps
WASHINGTON	Calais Fire/EMS Moosabec Ambulance WCEMSA dba Downeast EMS
YORK	Kennebunk Fire Rescue Old Orchard Beach EMS Sanford Fire Department

Service Requirements

For EMS organizations to be able to participate in this vaccination program, they will need to identify resources within in their organization to help support the ongoing campaign. Specifically, the service will need to identify the following aspects of their program in order to be considered as part of this pilot and likely as part of subsequent vaccination efforts.

Physician Medical Director

Physician medical directors are a required component of the COVID-19 Vaccine Provider Application process. All organizations that wish to participate in this program will need to have a medical director that will provide general medical oversight to the program. This individual will also serve as the Chief Medical Officer on the paperwork that is required by the U.S. and Maine CDC to become a vaccine provider. They must be in good standing in the State of Maine with their respective licensure board (i.e., Board of Licensure in Medicine and Board of Osteopathic Licensure). This individual will be responsible for general oversight of the program within EMS agencies and quality assurance efforts. They will also serve as a resource to the agency and vaccination administration team if they are to encounter any emergencies or irregularities during vaccine administration. The medical director will be required to sign the provider application with the U.S. and Maine CDC.

Dedicated Vaccination Team

The agencies selected to participate in this pilot program will ideally commit to establishing a dedicated vaccination team of staff members who will be solely dedicated to vaccination efforts of the public safety community within their county. This will be stand-alone, and they may not function as part of the 911 or interfacility transport system during periods when they are conducting vaccination campaigns. For instance, they cannot host a vaccine clinic while on a 911 shift where they may have leave mid-campaign to run an emergency call for service. The

team will likely need to be comprised of at least three to six qualified personnel as well as adequate support resources to ensure that they can efficiently and effectively conduct vaccine clinics throughout the county. EMS organizations that choose to participate will be required to identify the individuals that they intend on serving on the vaccination team. It will be important to identify alternative members in case individuals on the team are unavailable (e.g., vacation, out sick, personal leave, etc.). The agency will not be limited to only using these specific individuals as part of their vaccination campaigns; however, these should be the primary EMS clinicians who will be responsible. It is important to note that all individuals who are administering the vaccine will need to complete the appropriate training on the Maine EMS Education (MEMSEd) learning management system. As soon as more information is available about the vaccine, this training will become available to all licensees.

While this is the recommended strategy from Maine EMS, we will also be open to considering other pathways to operationalize administration of this vaccine locally. We understand the complex burden that staffing may pose for many agencies. Maine EMS will work with each identified agency to ensure that they have a significant plan in place to provide staffing, as needed for vaccinations to occur within the county.

Medical Waste Capacity

While most agencies already have existing agreements and capacity to manage medical waste, it will be important for the EMS agencies that choose to participate in this program to clearly identify their capacity to support the increase in medical waste that will come as a result of vaccine administration (i.e., sharps). Some organizations have agreements with health systems or hospitals that allow them to leave behind sharps containers, but those same agreements may not include significant increases in waste that may come as a result of these campaigns. Agencies should prepare to have multiple sharps containers available at each vaccination clinic.

Personal Protective Equipment

The U.S. CDC has indicated that shipments of the vaccine will include some pieces of personal protective equipment (PPE); however, it may or may not include all necessary PPE. They have indicated that the ancillary supply kits will include four surgical masks and two face shields for vaccinators.¹⁰ Based on the U.S. CDC's guidance regarding personal protective equipment, Maine EMS is recommending that vaccinators wear at least a surgical mask or higher for respiratory protection, eye protection in the form of a face shield or wrap-around glasses, and

 ¹⁰ U.S. CDC. (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations – October 29,
 2020. Accessed on December 12, 2020 from https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19 Vaccination-Program-Interim_Playbook.pdf

gloves.¹¹ Clinicians may use goggles in place of the face shield or wrap-around glasses. If any of the equipment becomes visibly soiled or grossly contaminated it should be discarded and new PPE should be donned. U.S. CDC indicates that gloves are optional for administration of intramuscular vaccinations; however, Maine EMS is concerned that this is contrary to established practices of the profession and may constitute a safety hazard for vaccinators.¹² As such, Maine EMS is requiring the use of gloves for COVID-19 vaccine administration. Gloves should be changed between each patient and vaccinators should practice hand hygiene (i.e., hand sanitizer).¹³

Agencies should be prepared to provide persons receiving the vaccine a face covering or face mask in the event they report to the site without a mask. In alignment with Executive Order No. 19 FY 20/21 from Governor Janet Mills issued on December 11, 2020, agencies must require that persons entering their building or other public spaces where the vaccine is being administered wear at least a face covering at all times. If someone is unable to wear a face covering or mask, then the agency should make every attempt to make a reasonable accommodations to ensure that they are able to receive the vaccine (i.e., administer the vaccine in their car) without potentially putting others at higher risk of exposure.¹⁴

Vaccine Storage Capacity

Maine EMS agencies that participate in this program will need to acquire, if necessary, and designate a refrigerator that will specifically house the vaccines when they are on site and be able to maintain temperatures of 2-8°C (35.6-46.4°F). If an EMS agency has an existing refrigerator then they must completely remove all other food products and dedicate it exclusively to the storage of vaccinations and/or medications. If the service must purchase a refrigerator, most commercially available refrigerators will work including undercounter refrigerators. Refrigerators that contain a freezer section within the refrigerator section (e.g., many dorm style fridges) will not be accepted as they do not maintain consistent temperatures throughout the space. Maine EMS is working to partner with community organizations to assist with offsetting the costs associated with acquisition. If agencies need assistance with purchasing a refrigerator, they should reach out to the Maine EMS office so that we can help

¹¹ National Center for Immunization and Respiratory Diseases. (2020). Vaccine Administration: COVID-19 Personal Protective Equipment. Accessed on December 12, 2020 from

https://www.cdc.gov/vaccines/hcp/admin/downloads/COVID-19-vaccine-administration-PPE-508.pdf ¹² See Footnote 11

¹³ U.S. CDC. (2020). General Practices for the Safe Delivery of Vaccination Services. Accessed on December 7, 2020 from https://www.cdc.gov/vaccines/pandemic-guidance/index.html

¹⁴ Office of the Governor, Maine (2020). An Order Simplifying and Strengthening Enforcement of Face Covering Requirements. Accessed on December 12, 2020 from

https://www.maine.gov/governor/mills/sites/maine.gov.governor.mills/files/inline-

files/An%20Order%20Simplifying%20and%20Strengthening%20Enforcement%20of%20Face%20Covering%20Requirements.pdf

facilitate connections to resources and organizations that may be able to help. Any questions regarding the suitability of a refrigerator should be directed to the MIP by emailing <u>immunizeme.dhhs@maine.gov</u> or calling (207) 287-3746.

After securing a suitable refrigerator, add water bottles labeled (DO NOT DRINK) on the bottom and top shelves as well as in the door. These bottles will help to maintain temperatures within the unit if there is a power failure. Food products must not be stored in this space. The organization will need to provide digital photographs of the refrigerator to the Maine CDC as part of the application process. The device should be placed in a secure location to protect the security of the vaccines but accessible to assigned personnel so that they can monitor temperatures daily. Maine CDC's MIP has agreed to distribute electronic digital data loggers that will serve as temperature monitoring devices. MIP will send these via mail to the service once it has been approved. The devices will all be pre-calibrated and ready to use. Services will be required to ensure that the vaccines are maintained at the appropriate temperature to prevent excursion (temperature variations) and the viability of the doses. U.S. CDC requires daily temperature monitoring and reporting via their online system. Training will be provided by MIP on how to document and report these temperatures.

Documentation Tools

Maine EMS is requiring that EMS agencies participating in this program utilize iPads to document vaccine administration within the MEFIRS system. iPads have the unique capability of scanning driver's licenses within the documentation system. This will improve the throughput speeds of vaccine administration and more importantly consistency in demographic information. By scanning the driver's license, it automatically imports the basic demographic information (name, date of birth, address, etc.) which helps to avoid transcription errors that may occur if they are entered manually. This will aid Maine EMS and the MIP when connecting the patient care reports from the first dose of the vaccine series to the second dose. While many, if not most, EMS agencies already use iPads for documentation purposes of traditional 911 calls, if an organization doesn't have access to these devices they should reach out to Maine EMS for assistance. Maine EMS is working to partner with community organizations who may be willing to assist with procurement of iPads to help improve the efficiency of the vaccine administration process.

Logistics

Maine EMS continues to work closely with the Maine CDC and other agencies regarding the logistics processes that will be associated with the safe and reliable delivery of the COVID-19 vaccine to agencies that have agreed to participate. MIP indicates that first responders will likely be receiving exclusively the Moderna vaccine pending its approval or issuance of an

Emergency Use Authorization (EUA). This vaccine does not require ultra-cold storage and so will be easier to manage logistically. That said, Maine EMS continues to build contingency plans for how the Pfizer vaccine may be used if the Moderna vaccine is delayed or not authorized. The Pfizer vaccine would likely be shipped from the state's stockpile as a just-in-time shipment because it must be maintained at ultra-cold temperatures until no more than five days prior to administration. Maine CDC and their Public Health Emergency Preparedness Program to solidify the logistics associated with these shipments. They will likely be shipped in specialized containers that contain dry ice. It is important the receiving agencies handle the dry ice with care as direct contact with bare skin can cause localized frostbite and tissue damage.

For planning purposes, agencies should operate under the assumption that they likely will be working exclusively with the Moderna vaccine until other vaccines come on the market. In the initial weeks of vaccine deployment, the Moderna vaccine will be received and reshipped from Maine CDC's public health warehouse. Moving forward after that point, the Moderna vaccine will likely be shipped directly to participating EMS agencies in 100 dose increments. The agency will be responsible for maintaining appropriate temperatures for this vaccine and will be required to use all 100 doses within the storage window that is detailed by the manufacturer. It should be noted that there have been fluctuations in the preliminary reports coming from sources knowledgeable of the Moderna vaccine that its shelf-life in standard refrigeration may be anywhere from seven to thirty days. Storage practices will be solidified prior to distribution of the vaccine and will be communicated by the MIP, Maine EMS, and the vaccine manufacturer. It is imperative that agencies participating in this program, utilize the vaccine as quickly as possible to avoid any possible wastage. There is a potential that the shelf-life for the vaccine may be adjusted in the future as more information comes available about the viability of the vaccine for longer periods of time. The initial requirements will likely be conservative to maintain consistency but as more data comes to light then it may be adjusted.

Administration Plans

Each of the EMS agencies within each county will need to coordinate to figure out the best pathway to ensure safe and equitable delivery of the COVID-19 vaccine to all public safety professionals throughout their county. Maine EMS appreciates the complexities of each locality and will advise on these plans to the best of our ability; however, we cannot offer a standardized plan for the entire state on delivery because each county is so unique. Maine EMS strongly encourages the inclusion of local and county emergency management agencies as resources to assist with planning and coordination throughout the county.

Each organization will need to develop a vaccine delivery/administration plan that is compatible with their organization and the resources that they have available for vaccination. There are a variety of options that agencies could use to achieve this goal including, but not limited to:

- Drive-through clinics where individuals drive through the bay and receive their vaccination and speak on the phone to someone entering their information into the documentation system
- Standard clinic settings with scheduled appointments where persons can come in and receive the vaccination at a specific date and time (remote or at the agency's primary base location)
- Walk-in clinics may be established where they communicate to the public safety community that they will be administering the vaccine between specific hours on a certain day (Note: it will be imperative that if agencies choose this method they are able to implement social distancing strategies to ensure that there are not lines, crowding, or situations where the virus may be spread if persons are asymptomatic, positive cases)
- Strike teams may be set up that go and deliver the vaccine to a specific group of people in a targeted manner

This list is certainly not exhaustive; however, it details some potential options that agencies may use to deliver vaccine. Agencies must coordinate their vaccination campaigns with the other authorized vaccine programs within their county to ensure that they are delivering the vaccine equitably and efficiently. Maine EMS and the MIP commit to serving as technical assistance at any point in this planning and implementation process and we are aware that there may be situations that present themselves requiring that these strategies to be modified quickly and without traditional notice.

MIP is actively working to procure a scheduling tool that will assist agencies that wish to set up traditional clinics. This tool will enable persons to register and sign up for a specific time for when they can receive their vaccination. Once this product becomes available, Maine EMS will release information to all agencies involved on how to begin setting up and using the tool to assist them with vaccine delivery.

It will be important for the authorized agencies for each county to obtain rosters from all public safety organizations operating within their county. This may be more easily accomplished by partnering with the county EMA as they often have pre-established relationships with these organizations. It is important that agencies be as thorough as possible when identifying law enforcement, EMS, fire, and emergency dispatch organizations. For example, one might not think of the U.S. Marshal's Office; however, there are at least two locations within the State of Maine that should be accounted for during planning. Maine EMS and the Department of Public Safety (DPS) commit to assisting as much as possible in the aggregation of these lists for each county, but most local agencies have greater situational awareness of the resources that are in their communities.

As part of the planning process, agencies must also account for the fact that they must observe the recipient for at least fifteen (15) minutes following administration of the vaccine. Persons can potentially return to their cars and sit there and wait to complete their waiting period; however, this is designed to ensure that in the unlikely event that there is a severe adverse reaction those persons have access to care. In order to minimize the time that is required for persons to be on site, one solution may be to have persons be vaccinated first and then complete the documentation after. This would economize on the time required as part of the waiting period and will potentially minimize the total time that persons would spend on site. It is critical that if this model is followed that the administered clinician obtain informed consent prior to administration of the vaccine.

Maine EMS anticipates that the bottleneck in this process will likely be associated with documentation process. The Maine EMS office has worked diligently to try and streamline the vaccination record that will be used to document administration. That said, the initial dose will likely approximately six to seven minutes for clinicians or other authorized persons to document the record. When the individual receives their second dose in the series, the process will likely be significantly quicker with estimated documentation times of two to three minutes. If agencies can commit three to five people to vaccination efforts, Maine EMS recommends that the ratio be weighted where there are more persons completing documentation than there are vaccinating. Maine EMS is operating under the assumption that one person can vaccinate approximately four to five people per hour if they are administering the vaccine and documenting themselves. If using a team approach, Maine EMS estimates that the throughput per hour could be upwards of 15 to 20 people per hour depending on the number of staff and model.

Maine EMS is requiring that EMS agencies participating in this program detail their vaccine administration plan and how their site will work and handle patients in writing. It will be crucial for agencies to review this plan internally and to ensure that their vaccinators and other persons involved are intimately familiar with how the plan is organized and the patient flow. The Maine EMS will be available for technical assistance for any agency wishing to discuss their vaccine administration plan and wanting feedback and/or input.

Supplies and Equipment

It will be important that participating agencies consider what supplies and equipment will be necessary for the administration of this vaccine including, but not limited to, PPE; ancillary supplies, and safety equipment. Maine EMS has created a list of supplies and equipment below that is based off the guidance that was provided by the U.S. CDC. These lists are likely not exhaustive but should assist agencies in the planning process. A checklist with these items can be found in <u>Appendix B</u>.

Personal Protective Equipment

The required PPE can be found on page 16 of this document. It includes at least surgical masks, eye protection (face shield, wrap-around eyewear, or goggles), and gloves. As was discussed in the preceding section, four surgical masks and two face shields will be provided as part of the ancillary supply kits associated with every 100 doses of Moderna vaccine that are received. Agencies will be responsible for ensuring that all persons participating in the administration team be properly outfitted in appropriate PPE. Agencies may opt to increase the level of protection to aerosol precautions; however, in doing so they should take into consideration their available PPE supplies. Agencies must attempt to secure supplies through their existing supply chains before reaching out to the county EMA or the Maine CDC for assistance with PPE supplies. If those supply chains are overwhelmed or are unable to source appropriate equipment, requests can be made from the stockpile. It should be noted that there is a limited supply of PPE within the state stockpile and so requests for PPE related to vaccine administration may be scrutinized to a greater degree to ensure that the agency did everything in their power to meet the need locally.

Intramuscular Vaccine Administration Equipment

The U.S. CDC has indicated that the ancillary supply kits that accompany every 100 doses of the Moderna vaccine will include the following equipment:

- Needles, 105 per kit (various sizes 22 to 25-guage, 1-1.5")
- Syringes, 105 per kit (ranging from 1-3 mL)
- Alcohol prep pads, 210 per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit
- Vaccine needle guide detailing the appropriate length gauge for injections based on route, age (for children, when authorized), gender, and weight (for adults)¹⁵

It should be noted that at this time, Maine EMS nor the MIP knows what brand or style of needles will be provided as part of the kits. It will be important that training officers and other members of the participating agency's leadership team ensure that there is just-in-time training on use of the needles and their associated safety features (i.e., safety needles with flip covers). We know that many agencies exclusively use safety needles for intramuscular injections; however, these needles may or may not be the same.

¹⁵ U.S. CDC. (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations – October 29, 2020. Accessed on December 12, 2020 from https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

Safety Equipment/Emergency Medical Supplies

It is important that persons on site be prepared to respond to an emergency should it arise as they should with the administration of any medication including other vaccines. Maine EMS is requiring that agencies participating in this program have access to the following items, at a minimum, to enable a response in the event there is a significant adverse reaction:¹⁶

- All equipment associated with the provision of Gold 1: Allergy/Anaphylaxis Protocol based on the level of clinician available at the site (i.e., EPINEPHrine, diphenhydramine, IV supplies, fluids, etc.)¹⁷
- Cell phone or radio to activate local 911, transport unit, and/or higher-level of care
- Blood pressure cuff
- Pen light
- Oxygen
- Stethoscope
- Pulse oximetry
- Tourniquet
- Basic first aid supplies

Miscellaneous Additional Equipment

Sites will need to make sure that they have the following items to help with the administration of the vaccine:

- Alcohol-based hand sanitizer (at least 60% alcohol)
- EPA-registered antimicrobial products to sanitize spaces and surfaces
- Sharps containers
- Trash cans for non-regulated medical waste (e.g., bandage wrappers, etc.) and bags
- Vaccine information statements (VISs) and emergency use authorization (EUA) documentation for each person that is receiving the vaccine. (Note: if administering the vaccine to the general public later, agencies will be required to be able to provide these documents in the primary language of the recipient)
- Signage for patient flow and directions for persons participating in the clinic to encourage physical distancing and ideally one-way flow through the clinic
- Adhesive bandages (e.g., Band-Aids)

¹⁶ U.S. CDC. (2020). You Call the Shots: Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist. Accessed on December 12, 2020 from https://www.cdc.gov/vaccines/hcp/admin/downloads/2020-vaccine-clinicsupply-checklist-508.pdf

¹⁷ Maine EMS. (2019). Maine EMS Prehospital Treatment Protocols: Gold 1 – Allergy/Anaphylaxis. Accessed on December 12, 2020 from https://www.maine.gov/ems/sites/maine.gov.ems/files/inline-files/2019%20Protocols%2009%2019.pdf

- Face coverings for those who arrive without them
- Thermometers for checking temperatures prior to entering the space (this is not required and may be impractical with limited staffing; however, it's best practice)

Documentation and Reporting

Maine EMS agencies operating under this plan will be required to utilize MEFIRS to document vaccination records unless they are working directly with a healthcare facility and documenting directly into their electronic health record or other similar portal adopted by that health system. Maine EMS is creating a custom patient record that will include all the specific elements required within the Maine Immunization Information System (ImmPact). This system is intended to be a repository for accurate and up-to-date immunization records for all persons born, residing, or receiving vaccine in the State of Maine. Services will be required to enter into a standard User Agreement with MIP. Maine EMS is creating a custom upload that will be able to be imported into the ImmPact system to document administration of the vaccine. All EMS clinicians will be required to complete vaccine documentation records within 12 hours following the administration of the vaccine. These should ideally be completed in real-time during vaccine administration but must be finalized within this window. The record must be submitted to Maine CDC within 24 hours following the administration of the vaccine to maintain compliance with standards set forth by the U.S. CDC. Maine EMS is working collaboratively with the MIP to automate the submission process so that this is done automatically without any additional actions on the part of the clinician or the agency.

Most vaccines that are anticipated to come to market soon are comprised of a two-dose series. It is imperative to ensure that that all patient demographic information is complete and accurate so that it can be appropriately reported within the ImmPact system. In order to do so, Maine EMS requires that EMS clinicians administering the COVID-19 vaccine scan each patient's driver's license for consistent demographic information. If for some reason the individual does not have a driver's license on their person or they have not been issued a driver's license or identification card, it is imperative that the clinician document the individual's demographic information as thoroughly and completely as possible. Information on their driver's license or identification card can be used to populate the system by using an Apple iPad product. Ensuring consistency in the patient demographic information will allow for easier matching of records from each administration of the vaccine. If someone has moved or legally changed their name and the information is different than what is on their driver's license, edit the fields after scanning and update it with the most current information. If it is the second dose of vaccine, ensure that individual has not moved since their first dose, enter in the same information that was used for the first dose. In addition to the electronic patient care reporting system,

vaccinators will also be required to complete the vaccination record cards that are going to be included in the ancillary supplies associated with shipments of vaccines.

Vaccine Adverse Event Reporting System (VAERS)

An adverse event following immunization is an adverse health problem or condition that happens after vaccination (i.e., a temporally associated event). It might be truly caused by the vaccine or it might be purely coincidental and not related to vaccination. CDC continuously monitors the safety of vaccines given to children and adults in the United States. VAERS, co-administered by CDC and FDA, is the national frontline monitoring system for vaccine safety.

VAERS is a national early warning system to detect possible safety problems with vaccines. Anyone – an EMS clinician, doctor, nurse, pharmacist, or any member of the general public – can submit a report to VAERS.

The main goal of VAERS are to:

- Detect new, unusual or rare adverse events that happen after vaccination
- Monitor for increases in known side effects
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Assess the safety of newly licensed vaccines
- Detect unexpected or unusual patterns in adverse event reports

Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the event.

Events can be reported by going to the <u>VAERS Reporting Portal</u> (https://vaers.hhs.gov/).

Training

There is a substantial training component required to safely and effectively participate in this vaccination effort.

All Persons Involved in Vaccination Campaign

All persons involved in the vaccination campaign will be required to online complete training that is offered by Maine EMS regarding the vaccination itself and considerations when administering the vaccine. This training will include information about the vaccine, guidance on administration techniques, and other attributes of the vaccine administration process. This course is still being constructed and will be released as soon as the EUA information is released for the Moderna vaccine. This course will be available on MEMSEd for licensed EMS clinicians and will also be made publicly available for other public safety professionals who would like to learn more about the vaccine.

EMTs involved in the process will also need to take an additional specialized training that refreshes them how to draw up a medication and perform an intramuscular injection. EMTs must have documented proof that they have completed the Maine EMS Ready, Check, and Vaccinate Training Program (under development) on MEMSEd in order to participate. Individuals who complete the training will need to demonstrate competency by performing the skill in front of a qualified evaluator by identifying the appropriate site for vaccine administration, the deltoid muscle. Qualified evaluators may be AEMTs, paramedics, physicians, physician extenders, or nurses.

Vaccine Coordinators

Every service must identify a primary and secondary vaccine coordinator. These individuals will be responsible for receiving specialized training from Maine CDC's MIP program regarding storage and handling, administration, documentation, and an overview of the vaccines themselves. Vaccine coordinators will be responsible for maintaining an active ImmPact User Agreement that allows them access into the ImmPact system.

ImmPact Training

ImmPact training will include topics such as temperature logging, reconciliation of vaccination supplies, and ordering. This training will be required for both the primary and secondary vaccine coordinator for each agency that chooses to participate in this initial phase. It is estimated that this training will take approximately one (1) hour. The training will be administered virtually by the Maine CDC's MIP program staff and will be specifically tailored for EMS organizations in the State of Maine. In order to receive vaccines organizations must have at least one individual who has completed the training.

Storage and Handling

Maine CDC's MIP program will also host a storage and handling course that will be specifically tailored to EMS organizations. It will focus on techniques to manage the vaccine as well as action steps that must be taken in the event of temperature excursion or temperature that are outside the specified range. This training is estimated to take approximately one (1) hour and will be conducted virtually. Maine EMS will assist in coordinating dates when this training will be offered.

Specific Vaccine Training

MIP will provide specific vaccine training for each vaccine type as it enters the market. More information will be made available to the coordinators regarding this training as soon as the

data is released to the MIP. The MIP office will reach out to vaccine coordinators directly to arrange this virtual training. This training will include information regarding reconstitution, if applicable, and vaccine administration guidance as well.

Billing and Reimbursement

The operational costs of EMS organizations providing vaccinations for the public safety community and ultimately the general public will likely be vast. We have explored payment and reimbursement opportunities to recuperate the costs associated with vaccine administration.

Medicare

U.S. Centers for Medicare and Medicaid Services has released <u>guidance</u> regarding administration of COVID-19 vaccines and how to conduct billing. EMS organizations that are enrolled in Medicare but are not generally permitted to bill for the administration of COVID-19 vaccines are able to enroll as a mass immunizer. Services in the State of Maine will need to contact National Government Services (NGS) in as the Medicare Administrative Contractor (MAC) via phone in order to enroll. They can be contacted between the hours of 08:00 and 16:00 Central Time via (888) 802-3898. You will need the following information during the call:

- Legal Business Name;
- National Provider Identification Number (NPI);
- Tax Identification Number (TIN);
- State License Number, if applicable;
- Location Information; and
- Contact Information (including, but not limited to, telephone number and email).

When speaking with the MAC, they will screen your organization over the phone and establish temporary Medicare billing privileges. Official notification and authorization will be sent within 24 hours to the contact information on file.

This step may be completed by your billing agency on your behalf as they likely integrate with National Government Services through the PC-ACE system or another software platform for Medicare claims. You will submit roster billing claims through their online portal.

Medicare is paying the following rates for mass vaccinators and other individuals administering the vaccine:

VACCINE TYPEPAYMENT RATE18SINGLE DOSE VACCINE\$28.39TWO-DOSE SERIES VACCINE (TOTAL)†\$45.33INITIAL DOSE\$16.94FINAL DOSE\$28.39

Table 2 Vaccine Administration Payment Rates from Medicare

⁺Note: In the case of two-dose series vaccines, the initial and final dose will be billed separately but totaling \$45.33 at the completion of the series.

For private payers and for Medicaid, we are working on building out capacity for roster billing with these organizations as well. We anticipate private insurers will honor these same rates as Medicare.¹⁹ It will be vital that those conducting the vaccines capture all necessary billing information in order to facilitate the billing processes.

Medicaid

Maine DHHS and Maine EMS are working through the process by which EMS agencies will be able to submit rosters to MaineCare for roster billing. More information will be made available as soon as the pathway has been defined by the MaineCare team at Maine DHHS.

Privately Insured

Maine EMS is working closely with the Maine Bureau of Insurance to work through the details of roster billing with private insurers in the State of Maine. Maine EMS will provide the details by which EMS organizations can submit rosters to private insurers as soon as it becomes available. Maine EMS is building a custom export from the MEFIRS system that can be sent directly to each insurer for reimbursement. Details regarding this process for each payer will be made available as soon as it is finalized.

Uninsured

If an EMS organization administers the vaccine to a person who is uninsured, there is a pathway for reimbursement through the Coronavirus Aid, Relief, and Economic Security (CARES) Act via the U.S. Health Resources and Services Administration. Using the following <u>link</u>, services can sign up to be able to submit claims for uninsured persons for vaccine administration costs. Services must attest that to their knowledge the individual is uninsured and not eligible for Medicare or Medicaid benefits at the time.²⁰

 ¹⁸ Centers for Medicare & Medicaid Services. Medicare COVID-19 Vaccine Shot Payment. (Nov. 12, 2020). Accessed on Nov. 19, 2020 from https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment
 ¹⁹ 85 FR 71175

²⁰ U.S. Health and Human Services. COVID-19 Claims Reimbursement. (2020). Accessed on Nov. 20, 2020 from https://coviduninsuredclaim.linkhealth.com/get-started.html

Liability and Indemnification

It is important for EMS organizations to evaluate their liability coverage when electing to begin vaccination campaigns. It will be important to consult with the organization's legal counsel and/or insurance carrier, if applicable, to ensure that vaccine administration is covered under the policy. It is important to note that there are dollar amount limitations in the State of Maine for civil suits against government entities and potentially their contractors.

Please note that this information does not constitute legal advice, it is important to consult with your legal counsel to better understand the potential, or lack thereof, for liability.

COVID-19 vaccines, and subsequent adverse reactions, 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 U.S. 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/.

Participating clinicians should take note that none of these programs or rules provide any immunity or protections in the event of gross negligence by the clinician.

Appendices



Please complete Sections A and B of this form as follows:

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement (Section A). In addition, the CDC COVID-19 Vaccination Program Provider Profile Information (Section B) must be completed for each vaccination location (Location) covered under the Organization listed in Section A.

Section A. COVID-19 Vaccination Program Provider Requirements and Legal Agreement

Organization ide	entification				
Organization's legal nan	ne:				
Number of affiliated vac	cination locations cove	ered by this agre	eement:		
Organization telephone	:			▼	
Email:		(must be mo	onitored d win as dedi	cated contact method for t	he COVID-19 Vaccination Program)
Street address 1:		_		Street address 2:	
City:		Cou <u>nt</u> y:		- State:	ZIP:
D 111 (1)					
Responsible offi	cers				
For the purposes of this conditions specified in t	agreement, in addition	viduals i b	n, Responsible Officers name elow must provide their sign	ed below will also be acco natures after reviewing th	ountable for compliance with the
	(E t		cion must provide their sign	atures arter reviewing th	e agreement requirements.
Chief Medical Offic	cer (or Equiva	hation			
Last name:			First name:		Middle initial:
Title:			Licensure state:	Licensure number:	
Telephone:			Email:		
			20040		
Street address 1:				Street address 2:	
City:		County:		State:	ZIP:
Chief Executive Of	ficer (or Chief Fidu	uciary) Inform	nation		
Last name:			First name:		Middle initial:
Telephone:			Email:		
Street address 1:				Street address 2:	
City:		County:		- State:	ZIP:

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Agreement requirements

I understand this is an agreement between Organization and CDC. This program is part of a collaboration under the relevant state, local, or territorial immunization program's cooperative agreement with CDC.

To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:

- 1. Organization must administer COVID-19 vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).¹
- 2. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine Administration Data) for reporting can be found on CDC's website.² Organization must submit Vaccine Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.² Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such
- 3. Organization must not sell or seek reimbursement for COVID-19 vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.

records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.

Organization must administer COVID-19 vaccine regardless of the vaccine recipient's ability in pay of ID-19 vaccine administration fees or coverage status. Organization may seek appropriate reimbursement from a program or plan the pay of ID-19 vaccine administration fees for the vaccine recipient. Organization may not seek any reimbursement, including through balance billing of the vaccine recipient.
 Before administering COVID-19 vaccine, Organization must provide an approved regrency Use morization (EUA) fact sheet or vaccine

information statement (VIS), as required, to each vaccine recipient, the adult caregiver and part the recipient, or other legal representative.

- Organization's COVID-19 vaccination services must be conducted in comparison of the conducted o
- 7. Organization must comply with CDC requirements for COVID-19 in encourse ment. Those requirements include the following:
 - a) Organization must store and handle COVID-19 vaccine under, a submitted with the manufacture of the submitted with the submitted with the manufacture of the submitted with the submit
 - b) Organization must monitor vaccine storage up imperation that times using equipment and practices that comply with guidance in CDC's Vaccine Storage and Handling Toolkit⁺;
 - c) Organization must comply with each relevant jubic on simmunization program guidance for dealing with temperature excursions;

O 9 vaccine expiration dates; and

o COVID-19 vaccine management for a minimum of 3 years, or longer if required by state,

8. Organization must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.

9. Organization must comply with all federal instructions and timelines for disposing of COVID-19 Vaccine and adjuvant, including unused doses.⁵

10. Organization must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or http://vaers.hhs.gov/contact.html).

11. Organization must provide a completed COVID-19 vaccination record card to every COVID-19 vaccine recipient, the adult caregiver

accompanying the recipient, or other legal representative. Each COVID-19 vaccine shipment will include COVID-19 vaccination record cards.

12. a) Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 vaccine.

b) Organization must administer COVID-19 vaccine in compliance with all applicable state and territorial vaccination laws.

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

1 www.cdc.gov/vaccines/hcp/acip-recs/index.html

d) Organization must monitor and c
 e) Organization must preserve all r

local, or territorial law.

- ² www.cdc.gov/vaccines/programs/iis/index.html
- ³ www.cdc.gov/vaccines/pandemic-guidance/index.html
- 4 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

⁵ The disposal process for remaining unused COVID-19 vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.

⁶ See Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15, 198, 15, 202 (March 17, 2020).

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By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 vaccine understand and will comply with the agreement requirements listed above and that the information provided in sections A and B is true.

The above requirements are material conditions of payment for COVID-19 vaccine administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare, Medicaid, and the Health Resources and Services Administration COVID-19 Uninsured Program. Reimbursement for administering COVID-19 vaccine is not available under any federal healthcare benefit program if Organization fails to comply with these requirements with respect to the administered COVID-19 vaccine dose. Each time Organization submits a reimbursement claim for COVID-19 vaccine administration to any federal healthcare benefit program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose.

Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

By entering Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.⁶

Organization Medical Director (or equivaler	nt)	
Last server	Einst names	Middle in Middle
Last name:	First name:	Middle Initial:
Signature:	te:	
Chief Executive Officer (chief fiduciary role)		
Last name:	First me:	Middle initial:
Signature:	Date:	
For official use only:		
IIS ID, if applicable:		
Unique COVID-19 Organization ID (See Sn M		
*The jurisdiction's immunization program is required to the a unique abbreviation (e.g., an organization located in Germanuld be assigned by the second seco	ue COVID-19 ID for the organization named in Section A that includ ned "GA 123456A." This ID is needed for CDC to match Organization s only one location associated with an organization.	les the awardee jurisdiction s (Section A) with one or more

Section B. CDC COVID-19 Vaccination Program Provider Profile Information Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization

Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

Organization identification for individual locations					
Organization location name:		Will another Organization	Will another Organization location order COVID-19 vaccine for this site?		
		☐ If YES: provide Oraaniz	ation name:		
Contact information	for location's primary	COVID-19 vaccine coo	ordinator		
	for rocation o primary				
Last name:		First name:		Middle initial:	
Telephone:		Email:			
Contact information	for location's backup (COVID-19 vaccine cool	rdinato		
Last name:		First name:		Middle initial:	
Telephone		Emaile			
Organization locatio	n address for receipt o	of COVID-19 v ² es.	.(s		
Street address 1:			Street address 2:		
			_		
City:	County:		State:	ZIP:	
Telephone:					
Organization address	s of location wh	VID accine will be	administored		
(if different from receiv.	ing location)	AD-1 Vaccine will be	eaunnistereu		
Charles and the second			6		
Street address 1:			Street address 2:		
City:	C ity:		State:	ZIP:	
Telephone:		Fav			
Days and times vaccine coordinators are available for receipt of COVID-19 vaccine shipments					
Monday	Tuesday	Wednesday	Thursday	Friday	
AM:	AM:	AM:	AM:	AM:	
PM:	PM:	PM:	PM:	PM:	
For official use only:					
WTreks ID for this location if a	unlizable.	coines for Children (VEC) Dial if	applicables IIC ID	if applicable	
v ireks iD for this location, if a	ophcable: Va	comes for Children (VFC) PIN, If (appricable: IIS ID,	ir applicable:	
Unique COVID-19 Organizatio	on ID (from Section A):		Unique Location ID**:		

**The jurisdiction's immunization program is required to create an additional unique Location ID for each location completing Section B. The number should include the awardee jurisdiction abbreviation. For example, if an organization (Section A) in Georgia (e.g., GA123456A) has three locations (main location plus two additional) completing section B, they could be numbered as GA123456B1, GA123456B2, and GA123456B3).

COVID-19 vaccination provider type for this lo	ocation (select one)	
COVID-19 vaccination provider type for this le Commercial vaccination service provider Corrections/detention health services Health center – community (non-Federally Qualified Health non-Rural Health Clinic) Health center – occupational Health center – occupational Health center – STD/HIV clinic Health center – student Home health care provider Hospital Indian Health Service Tribal health Medical practice – family medicine	Decation (select one) Medical practice – other specialty Pharmacy – chain Center/ Pharmacy – independent Public health provider – public health clinic Public health provider – Federally Qualified Health Center Public health provider – Rural Health Clinic Long-term care – nursing home, skilled nursing facility, federally certified Long-term care – nursing home, skilled nursing facility, non-federally certified Long-term care – assisted living Long-term care – intellectual or developmental disability Long-term care – combination (e.g., assisted living and nursing home	
Medical practice – pediatrics	in same facility)	
Medical practice – internal medicine	Urgent care	
Medical practice – OB/GYN	Other (Specify:	
Setting(s) where this location will administer Child care or day care facility College, technical school, or university Community center Correctional/detention facility Health care provider office, health center, medical practice, or outpatient clinic Hospital (i.e., inpatient facility) In home Long-term care facility (e.g., nursing home, assisted living, independent living, skilled nursing)	COVID-19 vaccine (sek W xt araly) Pharmacy Public with clinic (e.g. cal health department) School wade 1 r r rem wary on white vaccination clinic – point of dispensing (POD) Contrary location – mobile clinic Contrary location – mobile clinic Contrary ace Dther (Specify:)	
Approximate number of patients/clie	in served by this location	
Number of children 18 years of age and younger:	enter "0" if the location does not serve this age group.)	
Number of adults 19 – 64 years of age:	(Enter "0" if the location does not serve this age group.)	
Number of adults 65 years of age and older.	(Enter "0" if the location does not serve this age group.)	
Number of unique patients/clients seen per week on average:		
□ Not applicable (e.g., for commercial vaccination service providers)		
Influenza vaccination capacity for this locatio	n	

Number of influenza vaccine doses administered during the peak week of the 2019–20 influenza season:

(Enter "0" if no influenza vaccine doses were administered by this location in 2019-20.)

Population(s) served by this location (select all that apply)	
 General pediatric population General adult population Adults 65 years of age and older Long-term care facility residents (nursing home, assisted living, or independent living facility) Health care workers Critical infrastructure/essential workers (e.g., education, law enforcement, food/agricultural workers, fire services) Military – active duty/reserves Military – veteran People experiencing homelessness 	 Pregnant women Racial and ethnic minority groups Tribal communities People who are incarcerated/detained People living in rural communities People who are underinsured or uninsured People with disabilities People with <u>underlying medical conditions</u>[*] that are risk factors for severe COVID-19 illness Other people at higher risk for COVID-19 (Specify:)
Does your organization currently report vaccine ad immunization information system (IIS)?	lministration data to the state, local, or territorial
If YES [List IIS Identifier:	
If NOT , please explain planned method for reporting vaccine administr	ation data to the jurisdict to so or the designated system as required:
If NOT APPLICABLE, please explain:	
Estimated number of 10-dose multidose vials (MD) vaccination periods (e.g., during back-to-school	's) , ocation is able to store during peak 'en. 'ason) at the following temperatures:
Refrigerated (2°C to 8°C): No capacity OR Approx	additional 10-dose MDVs
Frozen (-15°C to -25°C): No capacity OR	additional 10-dose MDVs
Ultra-frozen (-60°C to -80°C): 🗌 No capacity OR	additional 10-dose MDVs
Storage unit details for this Latin	
List brand/model/type of storage units ased storing COVID-19 vaccine at this location:	I attest that each unit listed will maintain the appropriate temperature range indicated above (<i>please sign and date</i>):
1.	
2.	Medical/pharmacy director or location's vaccine coordinator signature:
3.	-
4.	Date:
5.	

Providers practicing at this facility (additional spaces for providers at end of form)

Instructions: List below all licensed healthcare providers at this location who have prescribing authority or will have oversight of the handling or administration of COVID-19 vaccine (i.e., MD, DO, NP, PA, RPh). Only those with direct involvement with COVID-19 vaccine should be listed.



Appendix B

EMS Vaccination Clinic Checklist

This document is designed to assist EMS agencies in identify equipment that may necessary to conduct a satellite, temporary, or off-site vaccination clinic. This list may not be comprehensive. Quantities of supplies needed will vary significantly between they type of clinic and how many individuals the clinic anticipates vaccinating.

Vaccine

Ensure that you have sufficient quantities of vaccine for the number of people who are scheduled to be vaccinated or are anticipated to show up. Keep the vaccine stored within the refrigerator until ready for use, minimizing the time outside of the fridge to no more than 12 hours total. Once the vial has been punctured, it must be used within six (6) hours or discarded.

Administration Supplies (See Ancillary Supply Kits)	
 Syringes (1-3 mL) [Supplied] Various needle sizes [Supplied] Vaccine Administration Record Cards [Supplie 	Alcohol prep pads [Supplied] Adhesive bandages (e.g., Band-Aids) d]
Clinic Supplies Alcohol-based hand sanitizer (>=60% alcohol) EPA-registered cleaning supplies Sharps containers Vaccine Information Sheets (VISs) and EUA documentation for each person receiving the vaccine Gloves	 Trash cans and bags Signage (patient flow and physical distancing) Additional face coverings for patients Thermometer (optional) Eye protection for vaccinators [Some Supplied] Surgical masks for vaccinators [Supplied]
Safety Equipment/Emergency Medical Sup	olies - 🕡
 Cell phone/radio Blood pressure cuff All appropriate equipment associated with the provision of Maine EMS Protocols Gold 1: Allergy/Anaphlaxis (i.e., EPINEPHrine, diphenhydramine, IV supplies, fluids, etc.) 	 Oxygen Stethoscope Pulse oximetry Tourniquet Basic first aid supplies Pen light

Documentation Equipment

iPad(s)

Note: This list is not exhaustive and agencies may need more supplies depending on the nature of their clinic or vaccine being administered. It should be noted that recommendations regarding equipment may change as more information comes available and other vaccines come onto the market. This information is current as of Dec. 12, 2020.



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