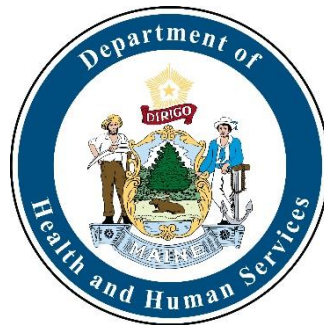


# Vaccine Planning Work Group

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Maine Immunization Program  
September 23, 2020



# Disclaimer

All information in this presentation is subject to change.  
Information shared in these slides are assumptions  
as of 9/23/2020.

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

# Agenda

- COVID-19 Provider Agreement
- Provider Training
- Testing Plans
- Technology

# Provider Enrollment

- To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in the federal COVID-19 Vaccination Program coordinated through the Maine 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.

# Provider Enrollment

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*.

## Two Sections

- A. Organization Identification
- B. Provider Profile Information

# COVID-19 Provider Agreement

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

ORGANIZATION IDENTIFICATION		
Organization's legal name:		
Number of affiliated vaccination locations covered by this agreement: _____		
Organization telephone number:	Email ( <i>must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program</i> ):	
Organization address:		
RESPONSIBLE OFFICERS		
For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements.		
Chief Medical Officer (or Equivalent) Information		
Last name	First name	Middle initial
Title	Licensure (state and number)	
Telephone number:	Email:	
Address:		
Chief Executive Officer (or Chief Fiduciary) Information		
Last name	First name	Middle initial
Telephone number:	Email:	
Address:		

# COVID-19 Provider Agreement, cont.

<b>AGREEMENT REQUIREMENTS</b>	
<p>I understand this is an agreement between Organization and CDC. This program is a part of collaboration under the relevant state, local, or territorial immunization's cooperative agreement with CDC.</p> <p>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:</p>	
<b>1.</b>	<p>Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).<sup>1</sup></p>
<b>2.</b>	<p>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.<sup>2</sup></p> <p>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.<sup>2</sup></p> <p>Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.</p>
<b>3.</b>	<p>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.</p>
<b>4.</b>	<p>Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees.</p>

# COVID-19 Provider Agreement, cont.

5.	Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
6.	Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines. <sup>3</sup>
7.	Organization must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following: a) Organization must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit <sup>4</sup> , which will be updated to include specific information related to COVID-19 Vaccine; b) Organization must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit <sup>4</sup> ; c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;

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

<sup>1</sup> <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>

<sup>2</sup> <https://www.cdc.gov/vaccines/programs/iis/index.html>

<sup>3</sup> <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>

<sup>4</sup> <https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html>



# COVID-19 Provider Agreement, cont.

	d) Organization must monitor and comply with COVID-19 Vaccine expiration dates; and e) Organization must preserve all records related to COVID-19 Vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
<b>8.</b>	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.
<b>9.</b>	Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses. <sup>5</sup>
<b>10.</b>	Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS). <sup>6</sup>
<b>11.</b>	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.
<b>12.</b>	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.
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.	

# COVID-19 Provider Agreement, cont.

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 and Medicaid, or submitted to any HHS-sponsored COVID-19 relief program, including the Health Resources & Services Administration COVID-19 Uninsured Program. Reimbursement for administering COVID-19 Vaccine is not available under any federal healthcare 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 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.<sup>7</sup>

# COVID-19 Provider Agreement, cont.

Chief Medical Officer (or Equivalent)		
Last name	First name	Middle initial
Signature:		Date:
Chief Executive Officer (or Chief Fiduciary)		
Last name	First name	Middle initial
Signature:		Date:
<p><i>For official use only:</i>            VTckS ID for this Organization, if applicable: _____            Vaccines for Children (VFC) PIN, if applicable: _____ Other PIN (e.g., state, 317): _____            IIS ID, if applicable: _____            Unique COVID-19 Organization ID (Section A)*: _____</p> <p><i>*The jurisdiction's immunization program is required to create a unique COVID-19 ID for the organization named in Section A that includes the awardee jurisdiction abbreviation (e.g., an organization located in Georgia could be assigned "GA123456A"). This ID is needed for CDC to match Organizations (Section A) with one or more Locations (Section B). These unique identifiers are required even if there is only one location associated with an organization.</i></p>		

# COVID-19 Provider Agreement, cont.

## 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 vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

<b>ORGANIZATION IDENTIFICATION FOR INDIVIDUAL LOCATIONS</b>			
Organization location name:		Will another Organization location order COVID-19 vaccine for this site?	
		<input type="checkbox"/> Yes; provide Organization name: _____	
		<input type="checkbox"/> No	
<b>CONTACT INFORMATION FOR LOCATION'S PRIMARY COVID-19 VACCINE COORDINATOR</b>			
Last name:	First name:	Middle initial:	
Telephone:	Email:		
<b>CONTACT INFORMATION FOR LOCATION'S BACK-UP COVID-19 VACCINE COORDINATOR</b>			
Last name:	First name:	Middle initial:	
Telephone:	Email:		
<b>ORGANIZATION LOCATION ADDRESS FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS</b>			
Street address 1:		Street address 2:	
City:	County:	State:	ZIP:
Telephone:		Fax:	

# COVID-19 Provider Agreement, cont.

## 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:*

VTrcks ID for this location, if applicable: \_\_\_\_\_

Vaccines for Children (VFC) PIN, if applicable: \_\_\_\_\_

IIS ID, if applicable: \_\_\_\_\_

Unique COVID-19 Organization 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 will 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 Provider Agreement, cont.

## CDC COVID-19 Vaccination Program Provider Profile Information

COVID-19 VACCINATION PROVIDER TYPE FOR THIS LOCATION (SELECT ONE)	
<input type="checkbox"/> Commercial vaccination service provider <input type="checkbox"/> Corrections/detention health services <input type="checkbox"/> Health center – community (non-Federally Qualified Health Center/non-Rural Health Clinic) <input type="checkbox"/> Health center – migrant or refugee <input type="checkbox"/> Health center – occupational <input type="checkbox"/> Health center – STD/HIV clinic <input type="checkbox"/> Health center – student <input type="checkbox"/> Home health care provider <input type="checkbox"/> Hospital <input type="checkbox"/> Indian Health Service <input type="checkbox"/> Tribal health <input type="checkbox"/> Medical practice – family medicine <input type="checkbox"/> Medical practice – pediatrics <input type="checkbox"/> Medical practice – internal medicine <input type="checkbox"/> Medical practice – OB/GYN <input type="checkbox"/> Medical practice – other specialty	<input type="checkbox"/> Pharmacy – chain <input type="checkbox"/> Pharmacy – independent <input type="checkbox"/> Public health provider – public health clinic <input type="checkbox"/> Public health provider – Federally Qualified Health Center <input type="checkbox"/> Public health provider – Rural Health Clinic <input type="checkbox"/> Long-term care – nursing home, skilled nursing facility, federally certified <input type="checkbox"/> Long-term care – nursing home, skilled nursing facility, non-federally certified <input type="checkbox"/> Long-term care – assisted living <input type="checkbox"/> Long-term care – intellectual or developmental disability <input type="checkbox"/> Long-term care – combination (e.g., assisted living and nursing home in same facility) <input type="checkbox"/> Urgent care <input type="checkbox"/> Other (Specify: _____)
SETTING(S) WHERE THIS LOCATION WILL ADMINISTER COVID-19 VACCINE (SELECT ALL THAT APPLY)	
<input type="checkbox"/> Childcare or daycare facility <input type="checkbox"/> College, technical school, or university <input type="checkbox"/> Community center <input type="checkbox"/> Correctional/detention facility <input type="checkbox"/> Health care provider office, health center, medical practice, or outpatient clinic <input type="checkbox"/> Hospital (i.e., inpatient facility) <input type="checkbox"/> In-home <input type="checkbox"/> Long-term care facility (e.g., nursing home, assisted living, independent living, skilled nursing)	<input type="checkbox"/> Pharmacy <input type="checkbox"/> Public health clinic (e.g., local health department) <input type="checkbox"/> School (K – grade 12) <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary or off-site vaccination clinic – point of dispensing (POD) <input type="checkbox"/> Temporary location – mobile clinic <input type="checkbox"/> Urgent care facility <input type="checkbox"/> Workplace <input type="checkbox"/> Other (Specify: _____)

# COVID-19 Provider Agreement, cont.

## APPROXIMATE NUMBER OF PATIENTS/CLIENTS ROUTINELY SERVED BY THIS LOCATION

Number of children 18 years of age and younger: \_\_\_\_\_ (Enter "0" if the location does not serve this age group.)

Unknown

Number of adults 19 – 64 years of age: \_\_\_\_\_ (Enter "0" if the location does not serve this age group.)

Unknown

Number of adults 65 years of age and older: \_\_\_\_\_ (Enter "0" if the location does not serve this age group.)

Unknown

Number of unique patients/clients seen per week, on average: \_\_\_\_\_

Unknown

Not applicable (e.g., for commercial vaccination service providers)

## INFLUENZA VACCINATION CAPACITY FOR THIS LOCATION

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)

Unknown

# COVID-19 Provider Agreement, cont.

## CDC COVID-19 Vaccination Program Provider Profile Information

### 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 under-insured or uninsured
- People with disabilities
- People with underlying [medical conditions](#)\* that are risk factors for severe COVID-19 illness
- Other people at higher-risk for COVID-19 (Specify: \_\_\_\_\_)



# COVID-19 Provider Agreement, cont.

DOES YOUR ORGANIZATION CURRENTLY REPORT VACCINE ADMINISTRATION DATA TO THE STATE, LOCAL, OR TERRITORIAL IMMUNIZATION INFORMATION SYSTEM (IIS)?		
<input type="checkbox"/> Yes [List IIS Identifier: _____] <input type="checkbox"/> No <input type="checkbox"/> Not applicable		
If "No," please explain planned method for reporting vaccine administration data to the jurisdiction's IIS or other designated system as required:		
If "Not applicable," please explain:		
ESTIMATED NUMBER OF 10-DOSE MULTIDOSE VIALS (MDVs) YOUR LOCATION IS ABLE TO STORE DURING PEAK VACCINATION PERIODS (E.G., DURING BACK-TO-SCHOOL OR INFLUENZA VACCINE SEASON) AT THE FOLLOWING TEMPERATURES:		
Refrigerated (2°C to 8°C):	<input type="checkbox"/> No capacity	<input type="checkbox"/> Approximately _____ additional 10-dose MDVs
Frozen (-15° to -25°C):	<input type="checkbox"/> No capacity	<input type="checkbox"/> Approximately _____ additional 10-dose MDVs
Ultra-frozen (-60° to -80°C):	<input type="checkbox"/> No capacity	<input type="checkbox"/> Approximately _____ additional 10-dose MDVs
STORAGE UNIT DETAILS FOR THIS LOCATION		
List brand/model/type of storage units to be used for storing COVID-19 vaccine at this location: 1. <i>Example: CDC &amp; Co/Red series two-door/refrigerator</i> 2. 3. 4. 5.	I attest that each unit listed will maintain the appropriate temperature range indicated above: <i>(please sign and date)</i>  <hr/> Medical/pharmacy director or location's vaccine coordinator signature  <hr/> Date	



# Provider Training

COVID-19 vaccination providers must understand the following:

- ACIP COVID-19 vaccine recommendations, when available
- How to order and receive COVID-19 vaccine
- COVID-19 vaccine storage and handling (including transport requirements)
- How to administer vaccine, including reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
- How to document and report vaccine administration via the jurisdiction's IIS or other external system

# Provider Training, cont.

- How to manage vaccine inventory, including accessing and managing product expiration dates
- How to report vaccine inventory
- How to manage temperature excursions
- How to document and report vaccine wastage/spoilage
- Procedures for reporting moderate and severe adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets or VISs to vaccine recipients
- How to submit facility information for COVID-19 vaccination clinics to CDC's VaccineFinder (particularly for pharmacies or other high-volume vaccination providers/settings)

# Testing Plans

Improvement planning is the identification of strengths, areas for improvement, and corrective actions that results from workshops, exercises, or real-world events.

Conduct exercises, including workshops or tabletop, functional, or full-scale exercises.

Gaps in program planning are often identified when plans are tested, whether through a real event, such as a hepatitis A outbreak, or a full-scale vaccination exercise.

# Reporting Requirements

Jurisdictional IIS COVID-19 Data Elements	Mass Vaccination or Standard	Data Element Description
Administered at location	Standard	The facility name/identifier of the facility that administered the immunization. This information may not be available for a historical dose.
Administered at location: type	Standard	Report the characteristic of the provider site that reported the immunization to the IIS (i.e. the sending organization)
Administration address: city	Standard	The city component of the administered at location's address (exception for mobile clinics)
Administration address: county	Standard	The county component of where the vaccine is being administered (i.e. the administered at location). Exception for mobile clinics.
Administration address: state	Standard	The state component of where the vaccine is being administered (i.e. the administered at location). Exception for mobile clinics.
Administration address: street	Standard	The street component of where the vaccine is being administered (i.e. the administered at location). Exception for mobile clinics.
Administration address: zip code	Standard	The zip code component of where the vaccine is being administered (i.e. the administered at location). Exception for mobile clinics.
Administration date	Standard	The date the vaccination event occurred. Note: Based on local need, this may include immunoglobulin or other medical substances.
CVX (Product)	Standard	The vaccine type that may be administered, historical, or refused, and is messaged using the NDC or CVX code sets. Note: based on local need, this may include immunoglobulin or other medical substances.
Dose Number	Standard	Report dosage/dose number being administered, if the vaccine requires more than one (e.g., dose #1, dose #2)
IIS Recipient ID	Standard	Report the same unique patient identifier reported in the Demographic Record. This can be the ID used by your IIS to uniquely identify the individual. Or, it can be a randomly assigned unique identifier.

# Reporting Requirements

Jurisdictional IIS COVID-19 Data Elements	Mass Vaccination or Standard	Data Element Description
IIS Vaccination Event ID	Standard	The vaccination event's unique identifier assigned by the submitting system. Note: this is referred to as the "Filler Order Number," in the HL7 Implementation Guide.
Lot Number: Unit of Sale	Standard	The lot number of the vaccine administered: Unit of Sale (UoS). Note: Based on local need, this may include immunoglobulin or other medical substances
Lot Number: Unit of Use	Standard	The lot number of the vaccine administered: Unit of Use (UoU). Note: Based on local need, this may include immunoglobulin or other medical substances
MXV	Standard	The manufacturer of the vaccine administered
Recipient address: county	Standard	The county component of the recipient's address
Recipient address: city	Standard	The city component of the recipient's address
Recipient address: state	Standard	The street component of the recipient's address
Recipient address: street	Standard	The state component of the recipient's address
Recipient address: zip code	Standard	The zip code of the recipient's address
Recipient date of birth	Standard	Recipient's date of birth
Recipient name	Standard	Recipient's first, middle, last name
Recipient sex	Standard	Report the sex of recipient

# Reporting Requirements

Jurisdictional IIS COVID-19 Data Elements	Mass Vaccination or Standard	Data Element Description
<b>Sending Organization</b>	Standard	The identifier of the organization that connects to the IIS and submits the record. May be referenced as IIS-AO ID.
<b>Vaccine administering provider suffix</b>	Standard	The professional designation of the person administering the vaccination. (e.g., MD, LPN, RN). May also be referenced as vaccination administering provider type.
<b>Vaccination Complete</b>	Mass Vaccination	Report the completion status of the vaccination
<b>Vaccine administering site</b>	Standard	Record the site of vaccine administration associated with the vaccine reported in the CVX code variable.
<b>Vaccine expiration date</b>	Standard	The expiration date of the vaccine administered. Note: Based on local need, this may include immunoglobulin or other medical substances.
<b>Vaccine route of administration</b>	Standard	The route of vaccine administration (e.g., oral, subcutaneous) - this should be captured in the IIS if the IIS is used as the primary vaccination event record (e.g., mass vaccination clinic)

## IIS Data Elements: Optional

Required Data Element	Standard or Mass Vaccination
<i>Data elements optional for IIS to report (e.g., state mass vaccination tool collects this information)</i>	<i>Mass Vaccination = may require mass vaccination module or enhancement Standard = IIS Core Data Element commonly collected during routine vaccination</i>
Comorbidity status (Y/N)	Mass Vaccination
Recipient ethnicity	Standard
Recipient race	Standard
Recipient missed vaccination appointment (Y/N)	Mass Vaccination
Serology results (Presence of Positive Result, Y/N)	Mass Vaccination
Vaccination Refusal (Y/N)	Standard



# Questions?

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