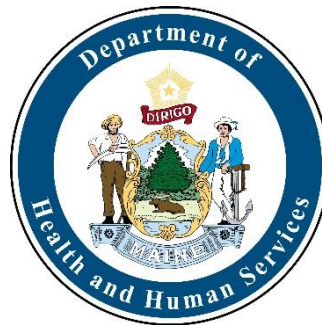


Vaccine Planning Work Group

Tonya Philbrick
Maine Immunization Program
September 17, 2020



Disclaimer

All information in this presentation is subject to change.
Information shared in these slides are assumptions
as of 9/16/2020.

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

Agenda

- Change in format of calls
 - Roll Call
- Influenza
- Vaccine Life Cycle
- Planning Assumptions
- Vaccine Ordering
- Priority Groups
- Vaccine Implementation
- VAERS
- COVID-19 Provider Considerations

VaccineFinder

What is VaccineFinder?

The VaccineFinder website helps people find providers who offer seasonal influenza vaccination and routine adult and child vaccination (www.vaccinefinder.org). VaccineFinder relies on partnerships with vaccination providers to report accurate and up-to-date information about vaccination services. The HealthMap Computational Epidemiology Lab maintains VaccineFinder in partnership with CDC.

Overview and Benefits

- VaccineFinder's goal is to make it simple for people to find a nearby location to receive a vaccination. Users specify a location and the vaccine(s) they need
- VaccineFinder displays mapped results of sites and their projected vaccine availability
- Key benefits help save time and resources during a seasonal outbreak or pandemic
- Easy to use website that directs patients to nearby locations with vaccines on hand
- Flexible reporting options allow providers to update vaccine supply (manual and automated methods available)

VaccineFinder

What Providers Need to Know

VaccineFinder is the only existing service that provides a comprehensive listing of current locations offering various vaccines in a community, and includes providers in all 50 states, DC, and Puerto Rico. All information on VaccineFinder is updated by participating vaccine providers.

- Providers enroll and report supply estimates for the vaccines they carry at each participating location. Reporting options include: (1) manually via a secure online portal (web form or data upload); or (2) an automated secure data transfer to report vaccine availability.
- During the 2020-2021 influenza season, providers are encouraged to update influenza vaccine availability frequently to ensure accurate information is available for the public. Sites with updates older than 14 days will not display on VaccineFinder.
- VaccineFinder will also help direct people to find COVID-19 vaccine once it is widely available to the public.

To participate in VaccineFinder, register your site at <https://locating.health/register>.

If your site dispenses influenza antiviral drugs, help people find you to fill their prescription for the medications they need.

Learn more at <https://medfinder.org>.

VaccineFinder

VaccineFinder Home **Find Vaccines** FAQ [VISIT MEDFINDER →](#)

We found 6 locations

Showing results for **Flu Shot (Adult)**, **Flu Shot (Child)** and **Tdap** near **2801 Mission Street, SF CA 94110** within 10 miles

Vaccine availability is subject to change. We recommend calling ahead to confirm availability.

EDIT SEARCH

SORT BY
Relevance

Rank	Location	Address	Distance	Contact
1.	Walgreens	880 Harbour Way South #e - Richmond, CA 94804	0.1 miles	(844) 782-2739
2.	Traveler Medical Group	880 Harbour Way South #e - Richmond, CA 94804	.18 miles	(844) 782-2739
3.	CVS	880 Harbour Way South #e - Richmond, CA 94804	0.1 miles	(844) 782-2739
4.	CVS Pharmacy in Target	880 Harbour Way South #e - Richmond, CA 94804	.5 miles	(844) 782-2739
5.	Partners Urgent Care	880 Harbour Way South #e - Richmond, CA 94804	1.4 miles	(844) 782-2739
6.	Passport Health	880 Harbour Way South #e - Richmond, CA 94804	1.4 miles	(844) 782-2739

CVS
2801 Mission Street, San Francisco, CA 94016
(415) 123-2345

2 of the 3 vaccines you searched for are currently provided:

- Flu Shot (Adult) ● ○ Low Supply
- Flu Shot (Child) ● ○ Medium Supply

Last updated: Thurs March 21, 2019 at 10:05 AM
[View Additional Details](#)

VaccineFinder connects people with available adult and child vaccines

Vaccine Life Cycle

Phase 1-Safety

Phase 2-Effectiveness

Phase 3-Safety and Effectiveness

FDA Review

ACIP Recommendations

Phase 4-Safety Monitoring for Serious, Unexpected Adverse Events

The Vaccine Life Cycle

safety at every phase

GUIDE

ACIP

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

BLA

BIOLOGICS LICENSE APPLICATION

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

FDA

FOOD AND DRUG ADMINISTRATION

IND

INVESTIGATIONAL NEW DRUG APPLICATION

VACCINE

DEVELOPMENT

safety is a priority during vaccine development + approval

safety continues with CDC + FDA safety monitoring

PHASE 1
safety

PHASE 2
effectiveness

PHASE 3
safety + effectiveness

CLINICAL STUDIES / TRIALS

FDA REVIEW

ACIP REVIEW

POST-APPROVAL MONITORING + RESEARCH

PHASE 4

safety monitoring for serious, unexpected adverse events

BASIC RESEARCH

DISCOVERY

PRE-CLINICAL STUDIES

IND SUBMITTED

BLA SUBMITTED

FDA APPROVAL OF 1 NEW VACCINE

ACIP RECOMMENDATION



LEARN MORE

FDA VACCINE DEVELOPMENT + APPROVAL PROCESS <http://go.usa.gov/xvVNd>

CDC VACCINE SAFETY MONITORING + RESEARCH <http://go.usa.gov/xvVNe>

COVID-19 Vaccine Planning Considerations

- Limited amount of vaccine to begin with, supplies will increase in 2021
- One vs. two dose series
- Products not interchangeable
- Potential varying efficiency and adverse event profile in different populations (e.g., minority groups, elderly, etc.)
- Varying cold-chain requirements
- Use in children and pregnant women
- Need for physically distanced vaccination practices
- Communication and education
- Some groups at risk for COVID-19 may distrust public health

COVID-19 Vaccine Planning Process

COVID-19 vaccine planning will look different from prior pandemic vaccine processes:

- Variation and complexity of vaccines in clinical development
- Federal and state end-to-end visibility on vaccine supply and uptake
- Commercial partnerships will augment public health implementation (e.g., pharmacies)
- Federal engagement with state planning process

Vaccine Ordering and Distribution

- COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will share more information about reimbursement claims for administration fees as it becomes available.
- Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators. o Each kit will include supplies needed to administer 100 doses of vaccine.
- CDC Will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.
- Jurisdiction-enrolled vaccination providers will follow the jurisdiction's vaccine ordering procedures.
- COVID-19 vaccination providers will be required to report ongoing COVID-19 vaccine inventory.
- Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS) by jurisdiction immunization programs for vaccination providers they enroll.
- Vaccine (and adjuvant, if required) will be shipped to provider sites within 24 hours of order approval by the immunization program, if supply is available. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but shipment will be timed to arrive with or before the vaccine.

Vaccine Ordering and Distribution, cont.

Minimum order size for CDC centrally distributed vaccines will be 100 doses per order for most vaccines. Minimum order size for direct-ship vaccines may be much larger. CDC will provide more detail as it becomes available.

Vaccine will be sent directly to vaccination provider locations for administration or designated depots for secondary distribution to administration sites.

Jurisdictions are not advised to purchase ultra-cold storage equipment at this time; ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice, can store vaccine for an extended period of time, and can be repacked for longer use. CDC will provide additional detail as it becomes available.

Ancillary Supply Kit Contents

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. Each kit will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit

For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will also be included. Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

Prioritization of Vaccine Administration

- The Advisory Committee on Immunization Practices (ACIP) and the National Academies of Sciences, Engineering, and Medicine (NASEM) are considering who should be recommended to receive the early, limited doses of COVID-19 vaccine.
- With assistance and input from NASEM, ACIP will advise the U.S. CDC on which groups are recommended to receive vaccine when supply is limited.
- As more vaccine becomes available, the goal is for everyone to be able to easily obtain a COVID-19 vaccine.

Phases

Phase 1

Phase 1a “Jumpstart Phase”:

- High-risk workers in health care facilities
- First responders

Phase 1b:

- People of all ages with comorbid and underlying conditions that put them at significantly higher risk
- Older adults living in congregate or overcrowded settings

Phase 2

- Critical risk workers—workers who are both in industries essential to the functioning of society and at substantially high risk of exposure
- Teachers and school staff
- People of all ages with comorbid and underlying conditions that put them at moderately higher risk
- All older adults not included in Phase 1
- People in homeless shelters or group homes for individuals with physical or mental disabilities or in recovery
- People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings

Phase 3

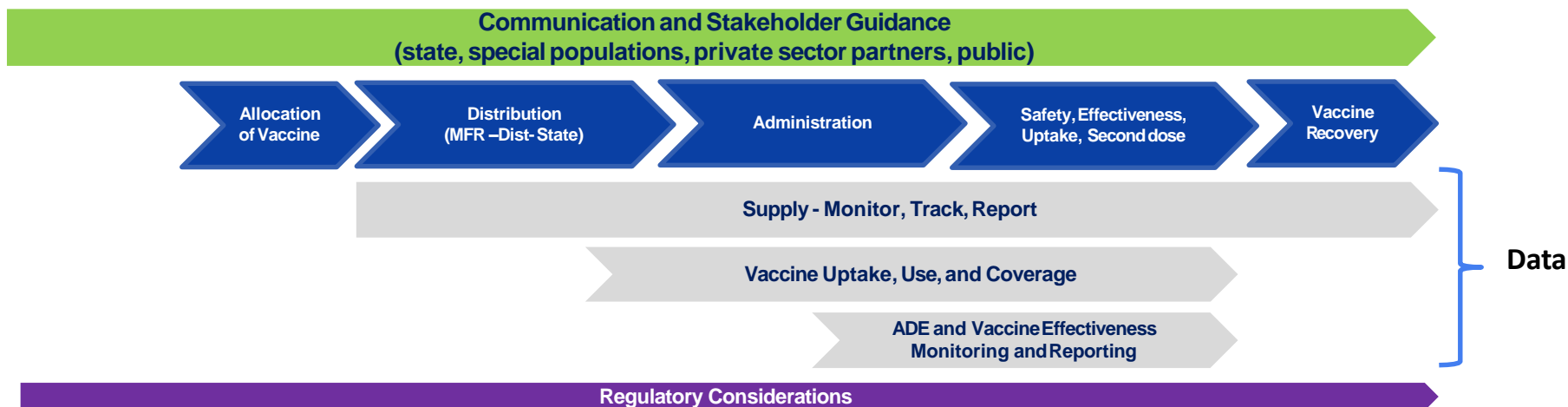
- Young adults
- Children
- Workers in industries essential to the functioning of society and at increased risk of exposure not included in Phase 1 or 2

Phase 4

- Everyone residing in the United States who did not receive the vaccine in previous phases

<http://nap.edu/25914>, [Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine](#), 9/2/2020

Critical Components of Vaccine Implementation



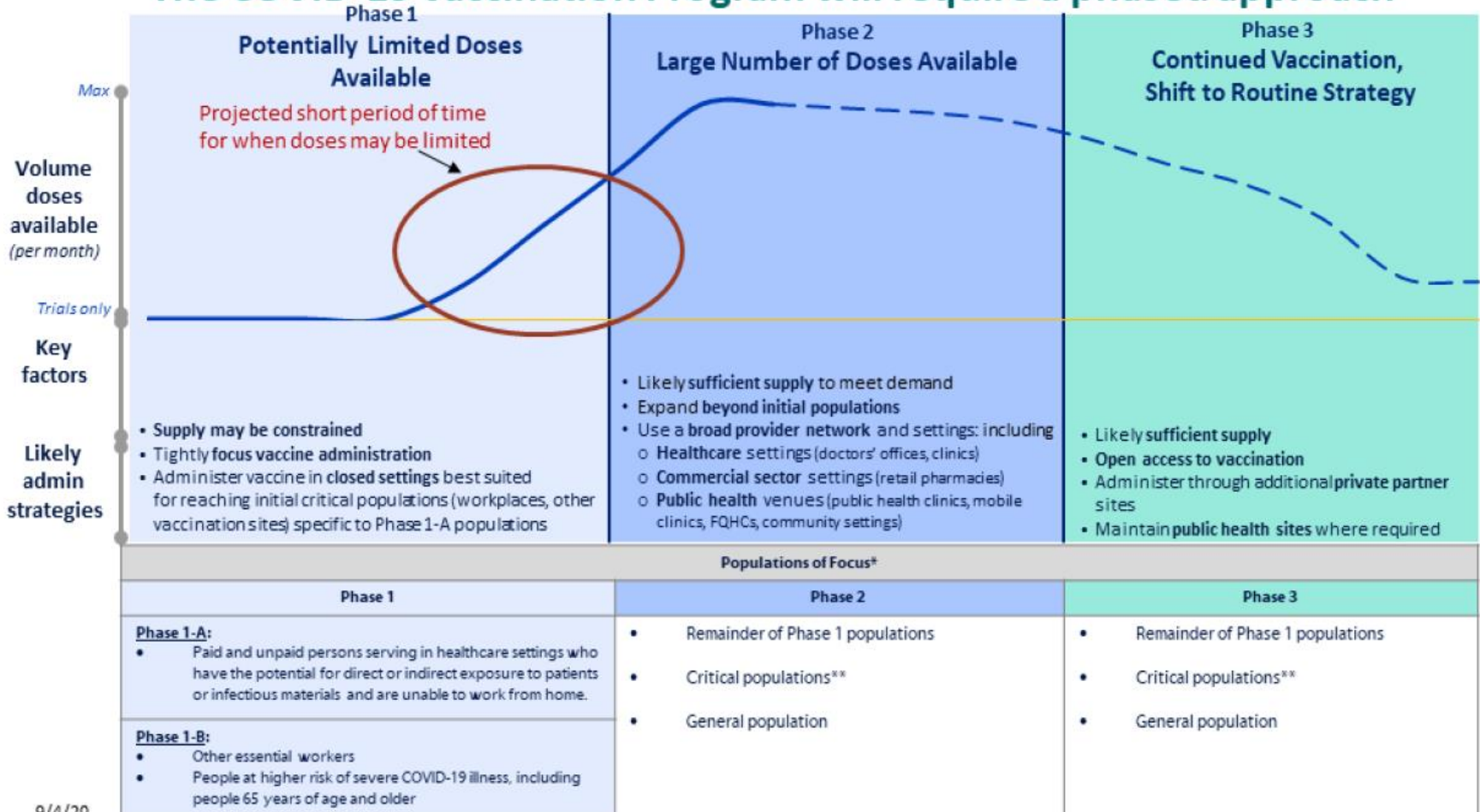
Public health impact relies on rapid, efficient, and widespread uptake of vaccinations, with focus on high-risk groups

Draft Concept of Operations for Select Critical Populations

Populations are not comprehensive; additional populations to be added

Population	Vaccination Sites
Critical Infrastructure/Essential Workers	
Health care personnel	Occupational health setting, pharmacies, other settings
Other essential workers	Occupational health setting, pharmacies, other settings
People at Increased Risk of Severe Illness	
Elderly (65 years and older)	Doctors' offices, pharmacies, other settings
Long-term care facility residents (nursing home/assisted living facility residents)	Facility health services, pharmacy partners, mobile vaccination units
People with underlying medical conditions	Doctors' offices, pharmacies, other settings
People at Increased Risk for COVID-19	
People from racial and ethnic minorities	Doctors' offices, PODs, other settings
People from tribal populations	IHS facilities, tribal health units, other settings
People who are incarcerated/detained	Correctional facility health services, pharmacies, mobile clinics
People experiencing homelessness	PODs, mobile vaccination units, health clinics serving population
People attending university or college	Student health clinics, PODs, other settings
People with Limited Access to Vaccinations	
People living in rural jurisdictions	FQHCs, mobile clinics, other settings
People with disabilities	Home health organizations, mobile clinics, other settings
People who are under- or uninsured	PODs, mobile vaccination units, other settings

The COVID-19 Vaccination Program will require a phased approach



9/4/20

Phase 1: Limited Amount of Vaccine

In the initial phase, or Phase 1, of the COVID-19 Vaccination Program, initial doses of vaccine will likely be distributed in a limited manner, with the goal of maximizing vaccine acceptance and public health protection while minimizing waste and inefficiency. The key considerations in planning for the phase are:

- COVID-19 vaccine supply may be limited.
- COVID-19 vaccine administration efforts must concentrate on the initial populations of focus to achieve vaccination coverage in those groups.
- Inventory, distribution, and any repositioning of vaccine will be closely monitored through reporting to ensure end-to-end visibility of vaccine doses.

Vaccine Adverse Event Reporting

COVID-19 Vaccine Safety

- Clinically important adverse events following any vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

<https://vaers.hhs.gov/>

- Adverse events will also be monitored through electronic health record and claims-based systems (e.g., Vaccine Safety Datalink).

<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>

- Additional vaccine safety monitoring may be required under the EUA.

Considerations Providing COVID-19 Vaccine

It is important to consider infection control measures that are currently necessary when selecting COVID-19 vaccination clinic setting:

- Providing specific appointment times or other strategies to manage patient flow and avoid crowding and long lines
- Ensuring sufficient staff and resources to help move patients through the clinic flow as quickly as possible
- Limiting the overall number of clinic attendees at any given time, particularly for people at higher risk for severe illness from COVID-19
- Setting up a unidirectional site flow with signs, ropes, or other measures to direct site traffic and ensure physical distancing between patients
- When feasible, arranging a separate vaccination area or separate hours for people at increased risk for severe illness from COVID-19, such as older adults and people with underlying medical conditions
- Making available a point of contact for any reasonable accommodation needs for people with disabilities
- Ensuring vaccination locations are accessible to individuals with disabilities consistent with disability rights statutes such as the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973
- Selecting a space large enough to ensure a minimum distance of 6 feet between patients in line or in waiting areas for vaccination, between vaccination stations, and in postvaccination monitoring areas.

Note: ACIP recommends that providers consider observing patients for 15 minutes after vaccination to decrease the risk for injury should they faint. For mobile or drive-through vaccination clinics, it is important to assess parking to accommodate vaccine recipients as they wait after vaccination.

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.

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Provider Enrollment

1. Administer COVID-19 vaccine in accordance with ACIP recommendations. (*Note: ACIP will review data on the safety and efficacy of each available COVID-19 vaccine and vote on recommendations for use.*)
2. Within hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. (*See Appendix D. CDC IIS Data Requirements for COVID-19 Vaccine Monitoring*). The provider must maintain the vaccine administration records for at least 3 years following vaccination, or longer if required by state, local, or territorial law. These records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3. Not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies provided by the federal government.

Provider Enrollment

4. Administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay.
5. Provide an Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as applicable, to each vaccine recipient/parent/legal representative prior to vaccination.
6. Comply with CDC requirements for vaccine management, including storage and handling, temperature monitoring at all times, complying with jurisdiction's instructions for dealing with temperature excursions, and monitoring expiration dates. Providers must keep all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by law.
7. Report COVID-19 vaccines and adjuvants that were unused, spoiled, expired, or wasted as required by the jurisdiction's immunization program.

Provider Enrollment

8. Comply with federal instruction regarding disposal of unused COVID-19 vaccine and adjuvant.
9. Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
10. Provide a completed COVID-19 vaccination record card to every vaccine recipient/parent/legal representative.
11. Comply with the U.S. Food and Drug Administration's requirements, including EUA-related requirements, if applicable. Providers must also administer COVID-19 vaccine in compliance with all applicable state and territorial vaccine laws.

Failure of any enrolled COVID-19 vaccination provider organization or vaccination location under its authority to meet the conditions of the agreement may impact whether COVID-19 vaccine product orders are fulfilled and may result in legal action by the federal government.

Next Weeks Topics

Overview of COVID-19 Provider Agreement Forms

- COVID-19 Vaccination Program Provider Agreement
- Profile Form
- COVID-19 Vaccine Redistribution Agreement

Data Reporting and Transport

- Requirements for COVID-19 Vaccine Administration

Questions?

Tonya Philbrick
Director
Maine Immunization Program

