Department of Public Health
CITY OF PHILADELPHIA

COVID-19 Vaccine Provider Enrollment

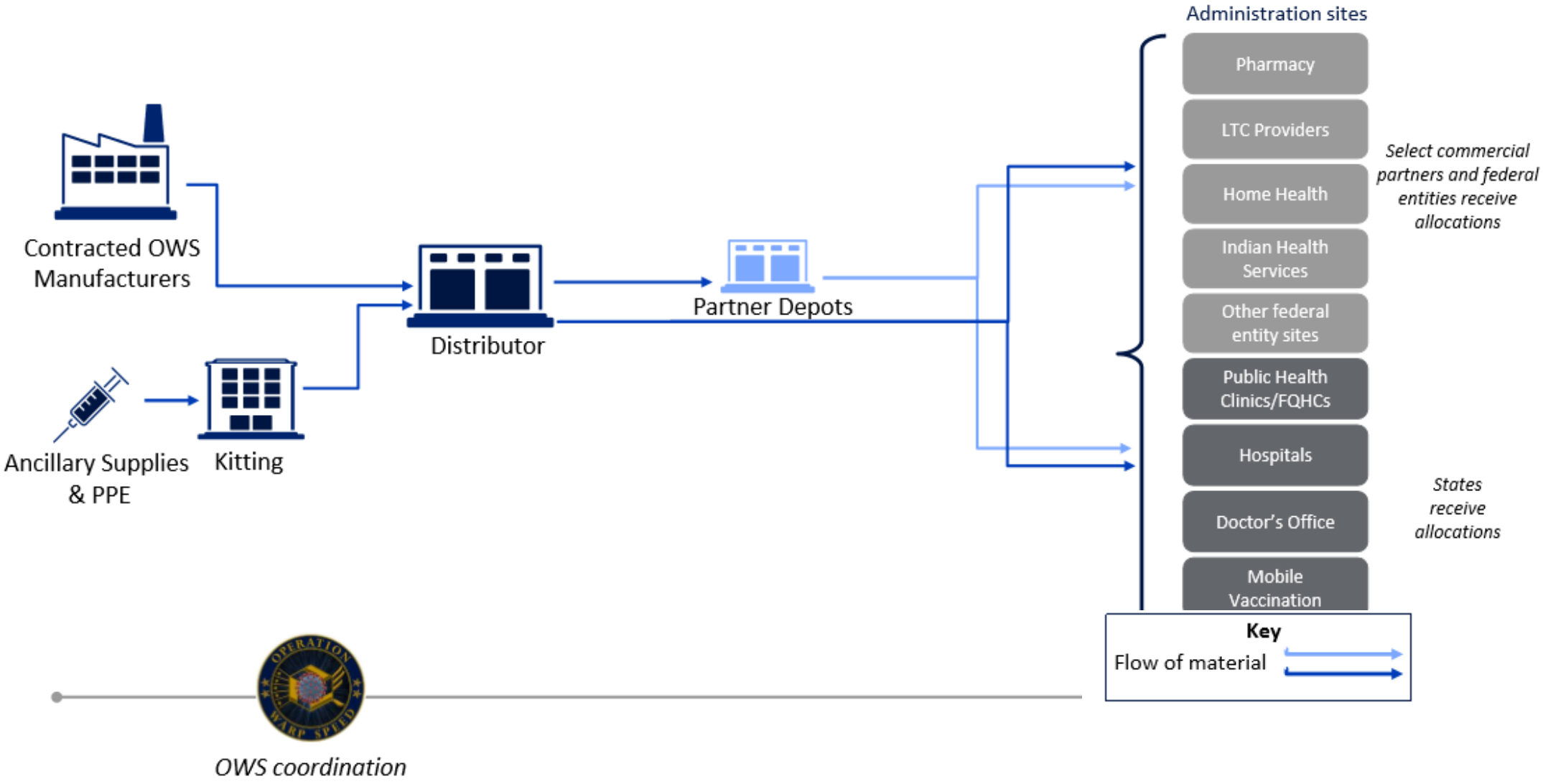
PDPH Immunization Program

COVID-19 vaccines to receive FDA Emergency Use Authorizations (EUAs)

- Two vaccines expected to receive Emergency Use Authorizations (EUAs) from the FDA:
  - **Pfizer/BioNTech (BNT162b2):** 2 doses given at least 21 days apart
  - **Moderna (mRNA-1273)**: 2 doses given at least 28 days apart
- Both vaccines were tested in tens of thousands of adults from diverse backgrounds, including older adults and communities of color.
- Clinical trial data show that both vaccines are safe and effective at preventing COVID-19.

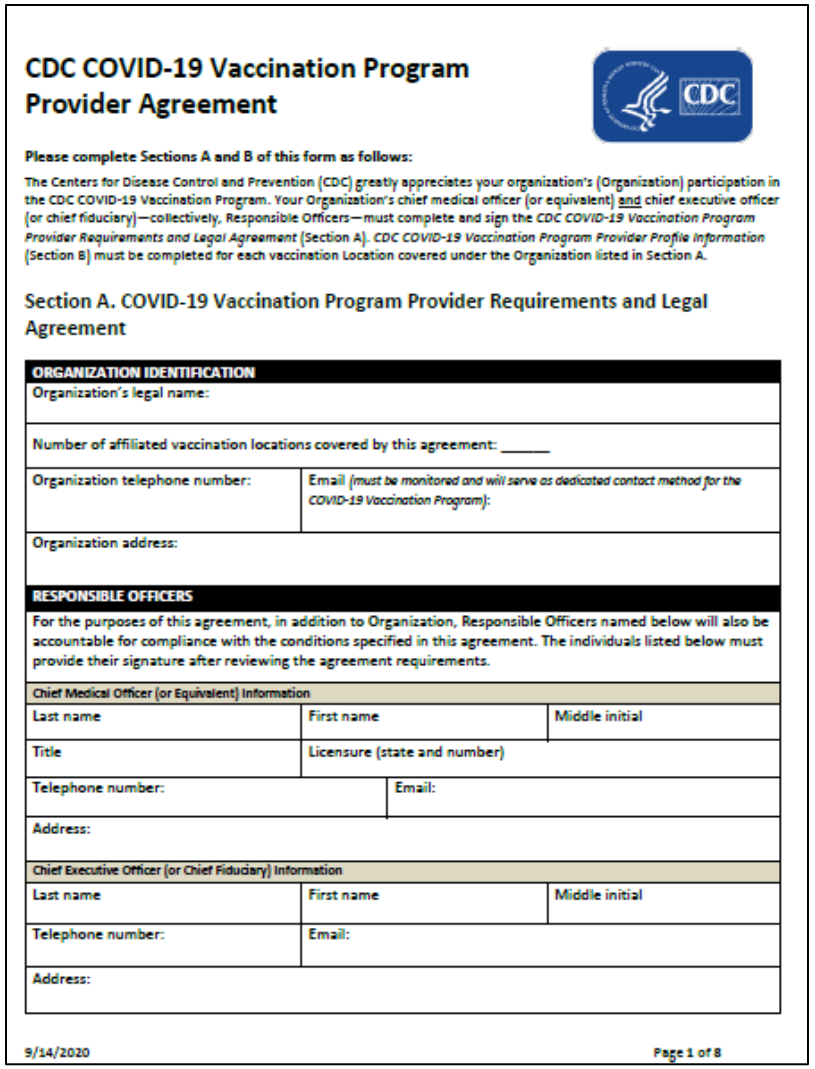
Sources: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine
https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy

Overview of Distribution and Administration



COVID-19 Vaccination Program Requirements

- CDC COVID-19 Vaccination Program Provider Agreement
- 8-page agreement reformatted as an electronic form for Philly
- Must be completed in addition to VFC/VFAAR enrollment
- Federal form – unable to modify for local use



CDC COVID-19 Vaccination Program Provider Agreement

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). *CDC COVID-19 Vaccination Program Provider Profile Information* (Section B) must be completed for each vaccination Location covered under the Organization listed in Section A.

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

ORGANIZATION IDENTIFICATION		
Organization's legal name:		
Number of affiliated vaccination locations covered by this agreement: _____		
Organization telephone number:	Email *(must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program)*:	
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:		

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COVID-19 Provider Enrollment

- CDC COVID-19 Vaccination Program Provider Agreement is electronically available for PDPH providers
- Instructions are on website
- Section A – Completed by CEO and CMO
- Section B – Completed by designated staff member
- Once all red fields are submitted, click “Submit”

Philadelphia
Immunization Program

City of Philadelphia
DEPARTMENT OF
PUBLIC HEALTH
Division of Disease Control

Resize font:

If you need assistance please email PDPH's Immunization Program

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (hereafter referred to as Organization) participation in the CDC COVID-19 Vaccination Program.

Your organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary) are the Responsible Officers for the CDC COVID-19 Vaccination Agreement.

As the Responsible Officers, the chief medical officer (or equivalent) and chief executive officer (or chief fiduciary), (hereafter referred to as the Responsible Officers) must complete and sign the *CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement* Section A).

The *CDC COVID-19 Vaccination Program Provider Profile Information* (Section B) must be completed for each vaccination location covered under the Organization listed in Section A.

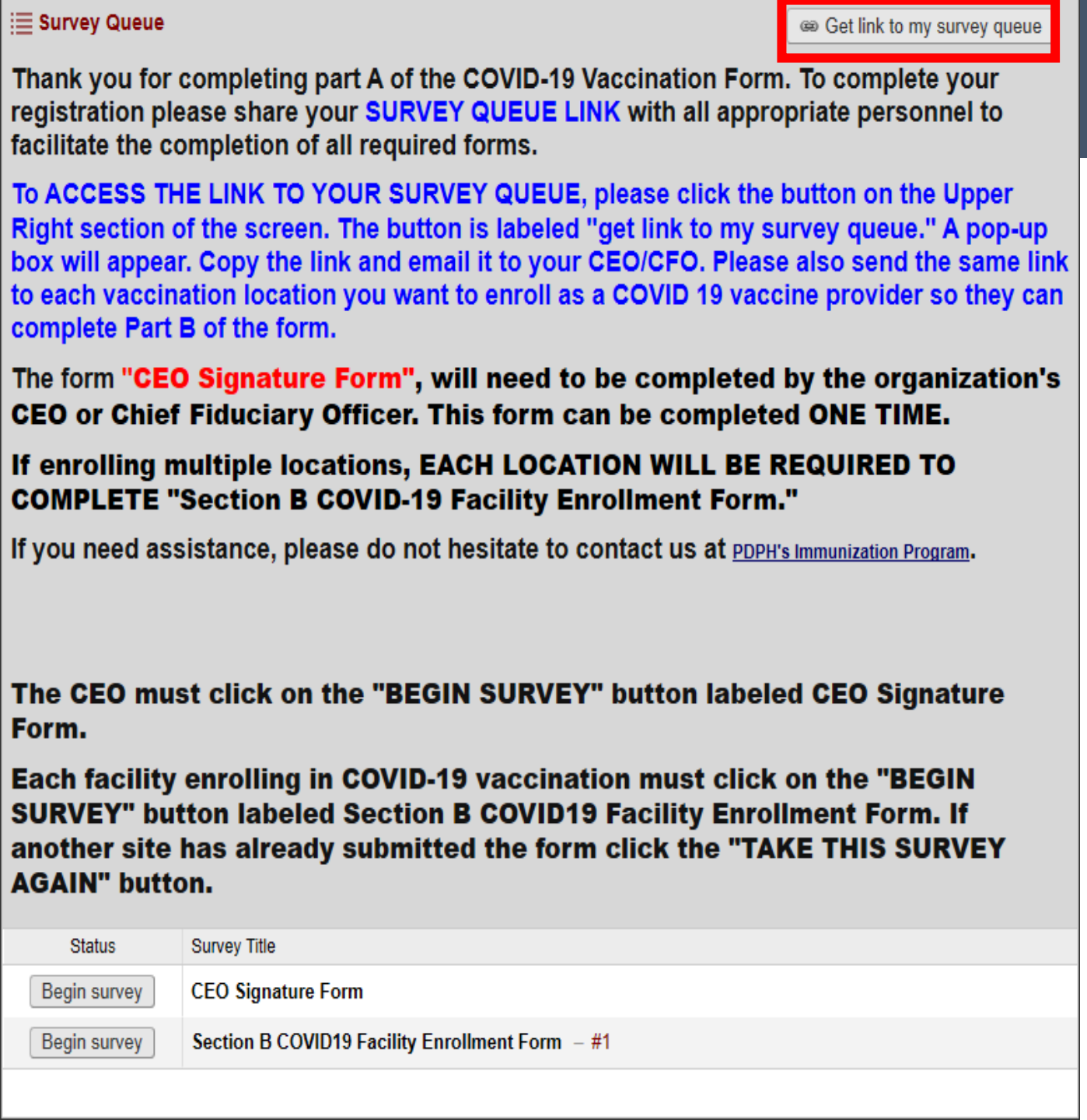
Instructions for Chief Medical Officer (CMO) or Equivalent:

Review this form in its entirety. Complete the **Chief Medical Officer (or Equivalent)** Information and Chief Medical Officer (or Equivalent) Signature Sections of **Section A.** After entering your signature and signature date, scroll to the bottom of the form and click **Submit.** After clicking submit you will be redirected to a **survey queue page** where there will further instructions.

The other sections of this form will be completed by the CEO and the office manager or other clinical person familiar with the requested information at **each vaccination location.** Multiple copies of Section B can be generated on the **survey queue page.** Each **vaccination location** will need to identify 2 individuals to serve as the primary and back-up contacts for COVID vaccine communication, referred to as the **COVID19 vaccine coordinators.**

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

ORGANIZATION IDENTIFICATION



COVID-19 Provider Enrollment

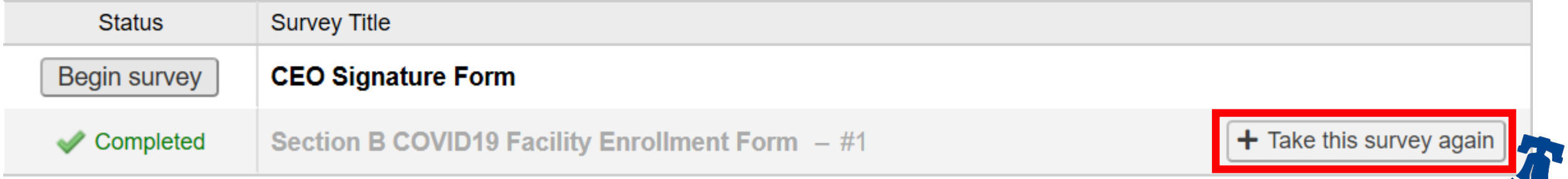
- Can send the “survey queue link” to CEO and staff member who is completing Section B
- Click “Begin Survey” to complete the next section
- CEO section and Section B must be completed entirely
- Section B – must list of vaccine administering providers and their license number (pharmacy & injectables), even rotating staff

COVID-19 Provider Enrollment

- Multi-sites: can submit one Section A and multiple Section Bs for their sites (click “Take this survey again” to add new location)
- Requires unique contact for each site (name, email, phone)
- Redistribution agreements may be an option for some multi-sites

The CEO must click on the "BEGIN SURVEY" button labeled CEO Signature Form.

Each facility enrolling in COVID-19 vaccination must click on the "BEGIN SURVEY" button labeled Section B COVID19 Facility Enrollment Form. If another site has already submitted the form click the "TAKE THIS SURVEY AGAIN" button.



COVID-19 Vaccination Provider Enrollment

PDPH will reach out to provide action steps necessary after completing enrollment form

1. Verify site can meet reporting requirements: PhilaVax-IIS and VaccineFinder
2. Cold storage (refrigerator and freezer) verification
    1. Units must have continuous data monitoring (DDL)
    2. Must be able to report temperature data
    3. DDL must have current and valid Certificate of Calibration
3. Create or update account for ordering (via PhilaVax)
    1. User agreement needs to be completed
    2. Inventory reconciliation and temperature log submissions will be required

PhilaVax

- Providers must submit vaccine administration data to the PhilaVax IIS either by establishing an EMR interface or daily electronic flat files
- PhilaVax will store COVID-19 vaccine data and track total numbers of vaccine administered across the city in all phases
- Providers will have the ability to query PhilaVax through their EHR or directly check for records utilizing their PhilaVax user accounts
- Orders placed in PhilaVax

IIS Reporting

Reporting immunizations to PhilaVax is required by the Board of Health, Health Code §6-210. Reporting of COVID-19 immunizations are required by CDC to the PhilaVax Immunization Information System (IIS).

There are two ways to report to PhilaVax. In order to determine the correct method of reporting IIS staff will need to know several key pieces of information:

- What is the name and version of your software?
- Can you pull data extracts from your system in the form a delineated text file or excel file?
- Does your system support HL7 either through a bridging company or direct connection?

If you are unable to report to PhilaVax you will not be eligible to order COVID-19 Vaccine

IIS Reporting Type

Because there are two different ways to report to the IIS it is important to draw clear distinctions between them.

The Main difference between the two are as follows:

Flat Files – These types of reporters must spend more time managing and moving data on their own. Since files are generated from reports that only they have access to. Though easier to setup than an HL7 connection it takes more time to manage on a daily basis than an HL7 connection.

HL7 - Once a connection has been built and tested users (most often) only need to enter data into their systems. It should then be automatically sent to PhilaVax. It setting up an HL7 connection may take more time up front but is easier to manage once it has been built.

Flat File Reporting

- User must run report in their system on their own
- User must ensure the required fields are captured
- User must access their SFTP account (created by IIS Staff) to upload their file.
- Users make create contingency plan for missed uploads.
- User must contact IIS staff immediately if locked out or unable to access their SFTP accounts.

HL7 Reporting

- Users must enter immunization data directly into their system
- User must ensure that the connection to PhilaVax is active
- If user is connecting through a bridging company (third party company contracted to build the HL7 connection) then a contact for the company must be supplied.
- User must meet HL7 messages standards and test before go-live is granted.
- User create a contingency plan for disconnects or down times in the data feed.

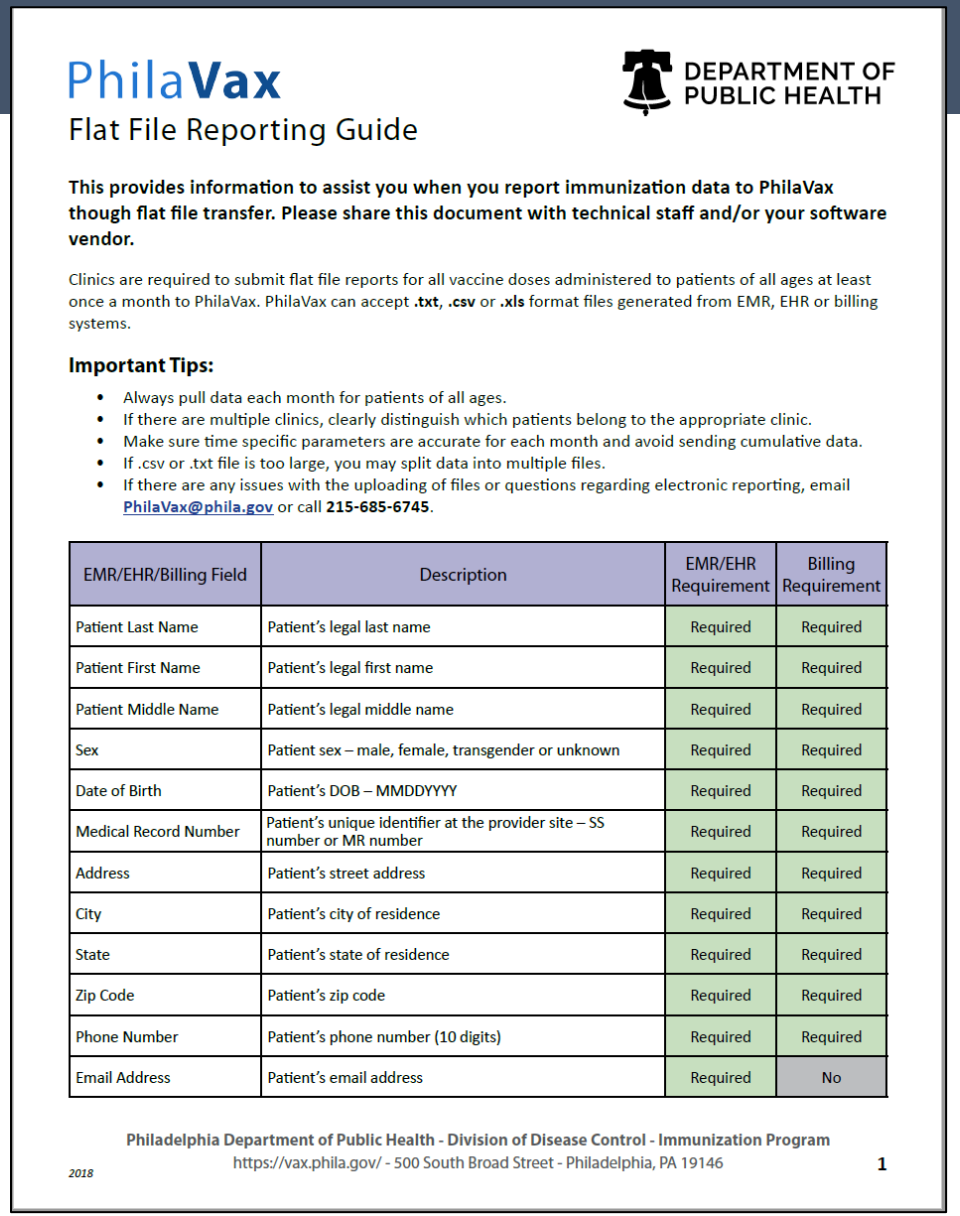
IIS REPORTING-Flat Files

If you are only able to extract data from your system using SQL or prepared reports then, but not able to generate HL7 messages than you are a flat file reporter.

Onboarding steps:

- IIS Staff will contact your site to enroll
  - Provide location Name, address, and point of contact. Tell the staff that you can report via flat file.
- IIS staff will send you a copy of the Flat file reporting Guide.
  - Flat files must contain the required information.
- IIS staff will create an SFTP account for you so that you may upload your file **DAILY** to a secure location (providers should make plans for missed or failed uploads).

Remember: It is the provider's responsibility to ensure that data is accurate and reaches the IIS. CDC will not grant additional vaccine to providers who fail to report to their respective IIS.



PhilaVax

DEPARTMENT OF PUBLIC HEALTH

Flat File Reporting Guide

This provides information to assist you when you report immunization data to PhilaVax though flat file transfer. Please share this document with technical staff and/or your software vendor.

Clinics are required to submit flat file reports for all vaccine doses administered to patients of all ages at least once a month to PhilaVax. PhilaVax can accept **.txt**, **.csv** or **.xls** format files generated from EMR, EHR or billing systems.

Important Tips:

- Always pull data each month for patients of all ages.
- If there are multiple clinics, clearly distinguish which patients belong to the appropriate clinic.
- Make sure time specific parameters are accurate for each month and avoid sending cumulative data.
- If .csv or .txt file is too large, you may split data into multiple files.
- If there are any issues with the uploading of files or questions regarding electronic reporting, email PhilaVax@phila.gov or call **215-685-6745**.

EMR/EHR/Billing Field	Description	EMR/EHR Requirement	Billing Requirement
Patient Last Name	Patient's legal last name	Required	Required
Patient First Name	Patient's legal first name	Required	Required
Patient Middle Name	Patient's legal middle name	Required	Required
Sex	Patient sex – male, female, transgender or unknown	Required	Required
Date of Birth	Patient's DOB – MMDDYYYY	Required	Required
Medical Record Number	Patient's unique identifier at the provider site – SS number or MR number	Required	Required
Address	Patient's street address	Required	Required
City	Patient's city of residence	Required	Required
State	Patient's state of residence	Required	Required
Zip Code	Patient's zip code	Required	Required
Phone Number	Patient's phone number (10 digits)	Required	Required
Email Address	Patient's email address	Required	No

Philadelphia Department of Public Health - Division of Disease Control - Immunization Program
https://vax.phila.gov/ - 500 South Broad Street - Philadelphia, PA 19146

2018 1

Please note this guide has not been altered for the COVID-19 Pandemic, Reporting is required on a **DAILY** basis.

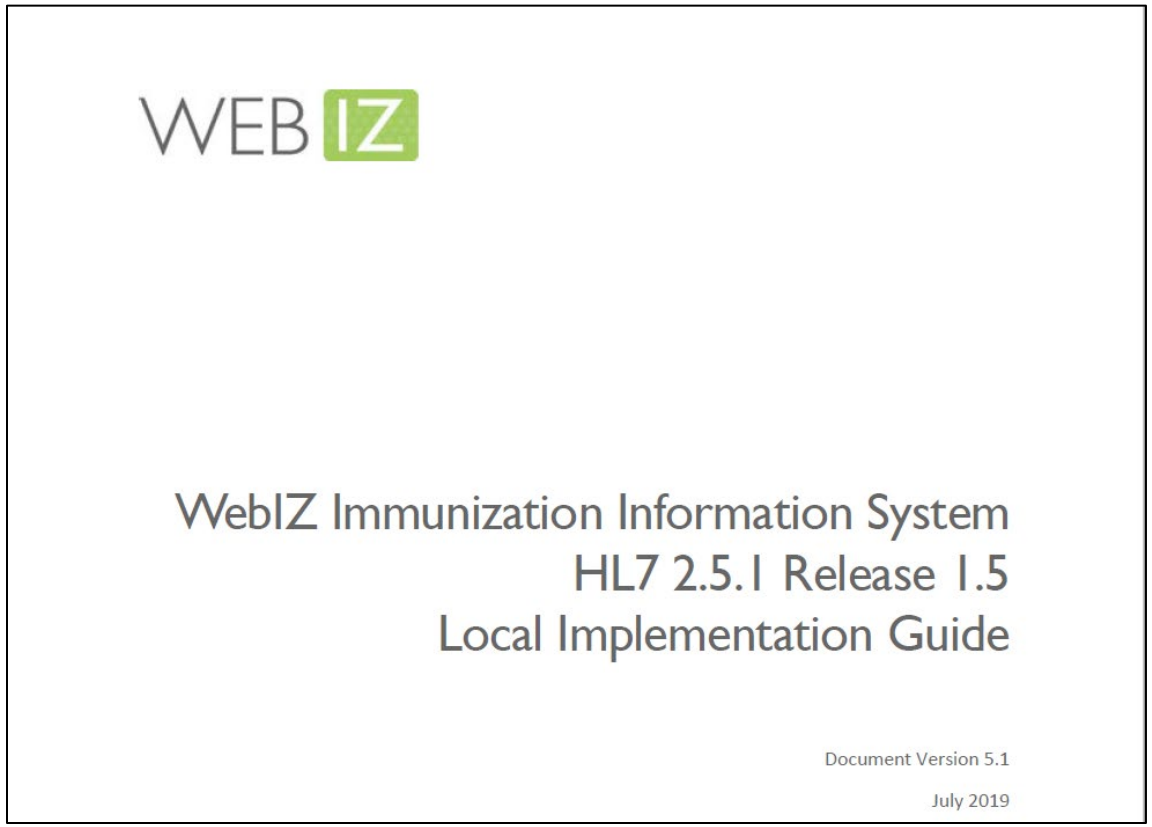
IIS Reporting – HL7

HL-7 reporting is only an option if you are able to meet the requirements for VXU messages and build a connection to the IIS using SOAP services and the CDC WDSL.

Onboarding Steps:

- IIS staff will contact your site to inquire about HL7 reporting
  - Fill out and return the Entity and clinical enrollment form
- If you are using an EHR, please provide a contact for IIS staff.
  - If you are using a bridging company, please provide a contact for IIS staff.
- Proceed with HL7 testing (site and vendor must be involved). If you fail to test you will not be granted permission to go-live.

Remember: It is the provider's responsibility to ensure that data is accurate and reaches the IIS. CDC will not grant additional vaccine to providers who fail to report to their respective IIS.



Please note that HL7 testing can vary in the amount of time it takes. It is typically dependent on how involved the provider and EHR/Bridging vendor are. The implementation guide should be provided to your technical contact.

VaccineFinder

- CDC requires reporting of doses on hand every 24 hours, including weekends
- Does not allow for retroactive reporting
- Registration link will be sent to organization COVID email address on enrollment form Section A. Email sent from: vaccinefinder@auth.castlighthealth.com
- Be sure to check spam/junk folder for email
- If you select individual reporting, registration emails will be sent to org email address, primary, and backup contact on enrollment form
- If you select centralized reporting, registration email will only be sent to org email address

Cold Storage

- Your site(s) will have to have appropriate refrigerator and freezer units to be able to store vaccines
- Temperature Monitoring (DDL): cold storage chain must be continuously monitored with capability to extract temperature reports
- **Transport**: requires a secure vaccine transport cooler with a DDL

Vaccine Products: Moderna

Moderna	
SHIPMENT Two separately shipped components: 1. Vaccine – direct to central distributor (-20°C); multidose vials (10 doses/vial) 2. Ancillary supply kits – direct to site from USG (at room temperature)	**ON-SITE VACCINE STORAGE** *Frozen (-20°C)* – storage is in normal frozen range *Refrigerated (2-8°C)* – must use within 30 days *Room temperature* – must use within 6 hrs.
ORDERS *Central distribution capacity required* • Required by December 2020; maintained at -20°C	**ADMINISTRATION** *2-dose series (28 days between doses)* – no on-site mixing required; administer by intramuscular (IM) injection
Initial Populations of Focus: • Healthcare personnel • Other essential workers • People at higher risk of severe COVID-19 illness (i.e., long-term care facility residents)	

Moderna Storage and Handling

Frozen Storage

Can be stored frozen until expiration date*

–25° to –15°C (–13° to 5°F)

Do not store on dry ice or below -40°C (-40°F).
Store in the original carton to protect from light.

*Confirm vaccine expiration date by looking up the lot number at modernatx.com/covid19vaccine-eua

Thaw Each Vial Before Use

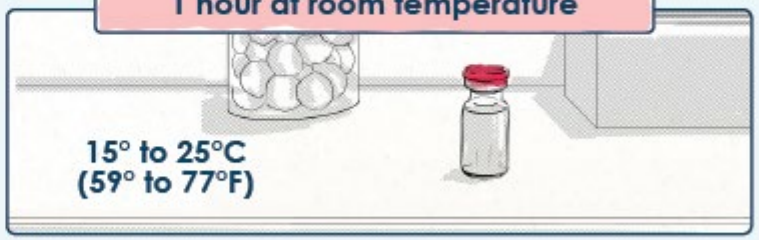
Vial images for illustrative purposes only

2 hours and 30 minutes in refrigerator

2° to 8°C
(36° to 46°F)

OR

1 hour at room temperature



15° to 25°C
(59° to 77°F)

Let vial sit at room temperature for 15 minutes before administering

Thawed Shelf Life

Unpunctured Vial

Maximum times

30 days — Refrigerator
2° to 8°C (36° to 46°F)

12 hours — Cool storage up to room temperature
8° to 25°C (46° to 77°F)

After First Dose Has Been Withdrawn

Maximum time

6 hours — Refrigerator or room temperature

Vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the vial label.

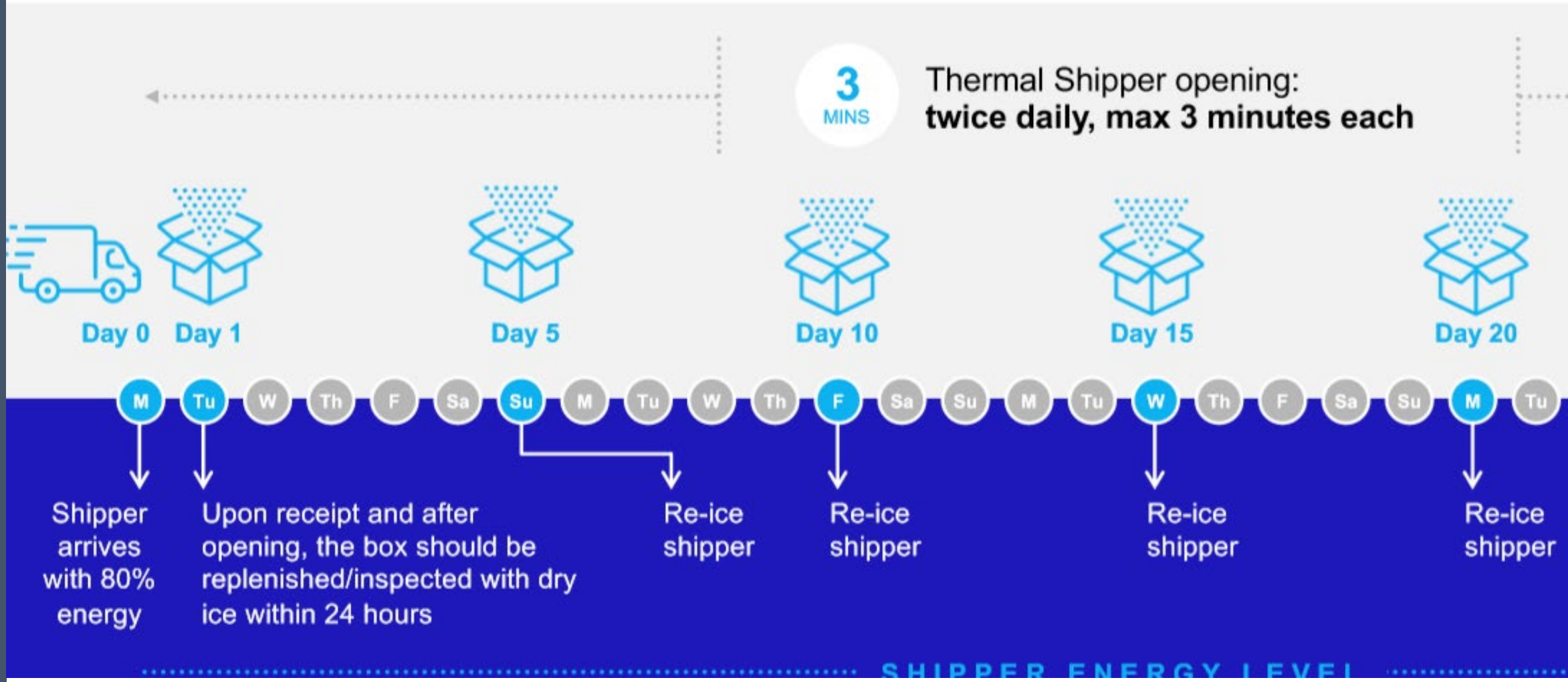
Discard punctured vial after 6 hours.

NEVER **refreeze thawed vaccine**

Vaccine Products: Pfizer

<table>
<tr><th colspan="2">Pfizer</th></tr>
<tr><td>SHIPMENT
Three separately acquired components (mixed on site):
1. Vaccine – direct to site from manufacturer (on dry ice); multidose vials (5 doses/vial)
2. Diluent – direct to site from USG (at room temperature)
3. Ancillary supply kits – direct to site from USG (at room temperature)</td><td>ON-SITE VACCINE STORAGE
Frozen (-70°C ± 10°C) – must be used/recharged within 10 days; storage in shipping container is acceptable (replenish dry ice as needed); 1st recharge within 24 hours, subsequent ones after 5 days, can use thermal shipper for up to 3 recharges
Thawed but NOT reconstituted (2-8°C) – must use within 5 days
Reconstituted (room temperature) – must use within 6 hrs.</td></tr>
<tr><td>ORDERS
Large quantities, to large administration sites only
• Minimum order: ~1,000 doses
• Maximum order: ~5,000 doses</td><td>ADMINISTRATION
2-dose series (21 days between doses) – on-site mixing required; reconstitute with diluent just prior to administration; administer by intramuscular (IM) injection</td></tr>
<tr><td colspan="2">Initial Populations of Focus:
• Healthcare personnel
• Other essential workers
• People at higher risk of severe COVID-19 illness (i.e., long-term care facility residents)</td></tr>
</table>

Pfizer Storage and Handling



PhilaVax

- Orders for vaccines are placed in PhilaVax
- PDPH will provide you with information on creating your account once your enrollment is processed
- Sites can order once per week at most
- Temperature logs and inventory reconciliation due in PhilaVax at time of order
  - Orders requested by Wednesdays at 5pm for the following week
  - Second dose orders are placed manually by PDPH. Will arrive to site automatically

COVID-19 Provider Enrollment Trainings

- COVID-19 Vaccine Training modules from the CDC: https://www2.cdc.gov/vaccines/ed/covid19/SHVA/00005.asp
- COVID-19 Vaccination Communication Toolkit: https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
- Ordering Training: Primary and backup vaccine coordinators will be sent a link to registration
- Cold Storage Training: Sites that require a DDL will receive additional information regarding training

Questions & Discussion