Comprehensive Provider Guide to the Enrollment Process

Philadelphia Department of Public Health

Overview

Thank you for your interest in becoming a PDPH COVID-19 vaccine provider. Here is a guide to help you through the process.

WHO can be a provider?

In order to be a provider, you must meet the following requirements:

- Be located within Philadelphia city limits
- Store vaccine within Philadelphia city limits
- Administer vaccine within Philadelphia city limits
- Have a CMO who is an MD/DO, Nurse Practitioner, or Pharmacist with an active license
- Have an active, up-to-date license in good standing for all providers
- Have an ability to report electronically by either method (HL7 or flat file)
- Have a DDL with a valid certificate of calibration
- Comply with CDC storage and handling requirements

HOW do you become a provider?

Step 1: Submit Provider Enrollment Form in RedCAP.

- PDPH will review your RedCAP form. If additional information is needed, our staff will contact you.
- Complete a pre-enrollment survey to determine more details about your vaccine site's operations. As
 vaccine allocations from the CDC are limited, enrollments may also need to be prioritized based on
 priority populations and distribution needs.
- Verify that your onsite cold storage (ULT/fridge/freezer/DDL) meet the requirements in the Storage and Handling section below.

Disclaimer: Providers that are unable to adhere to Immunizations Programs standards and timelines will not be allowed to continue receiving or administering vaccines.

Step 2: Reporting verification

- PDPH will confirm that your site can transmit vaccine administration data every 24 hours to the PhilaVax IIS either through direct HL7 connection via your EHR platform or flat file (excel, .csv, delineated text file) transmission through a secure account.

Step 3: Cold storage verification

- Your site(s) will have to have appropriate refrigerator and freezer units to store vaccines and monitor temperature continuously. You will also need to be able to extract temperature data reports from your monitoring system. To verify that your units are working and within the appropriate temperature range, we ask for 2 days (48 hours) of temperature logs created using a Digital Data Logger (DDL) thermometer.

Step 4: PhilaVax setup

- PDPH will create your Philavax account only after all steps in the enrollment process have been completed. Both primary and backup coordinators listed on the enrollment form will need to attend PhilaVax online ordering training before granted access to the Inventory and Clinic Tools Modules for ordering. This training will also cover submitting temperature logs and reconciliations weekly.

Disclaimer: Please note that submitting a COVID-19 Vaccine Provider Enrollment Form in RedCAP does not guarantee that you will receive COVID-19 vaccine from the City of Philadelphia. The Philadelphia Department of Public Health reserves the right to deny any entity enrollment into its COVID-19 Vaccine Program at its sole discretion at any point in the process.

HOW LONG does it take to enroll and start vaccinating?

Every provider site is unique, and we anticipate that processing time will vary. However, there are a few things you can do to speed up the process:

- Make sure your forms are completed correctly. Missing information will delay your enrollment.
- Reply to PDPH requests for information quickly.
- Ensure that you can fulfill vaccine reporting and storage/handling requirements outlined below in this guide.

If we receive no email communication from you within a six-week time frame, we will ask you to resubmit enrollment forms.

Enrollment

Your site must complete the RedCAP enrollment form. For detailed instructions click here. This includes:

- Section A: legal agreement (needs to be completed by the Chief Medical Officer or CMO equivalent)
- Chief Executive Officer (or Chief Fiduciary) Information: CEO contact info and signatures (needs to be completed by the CEO or Chief Fiduciary)
- Section B: provider profile and information section (needs to be completed by CEO/CFO and members of staff who are familiar with vaccination facility/facilities)

Tips for the Enrollment Section!

- Fill out all red sections before submitting or else you will have to complete the form again in its entirety.
- If your organization's CMO/CMO equivalent is also your organization's CEO/CFO and is familiar with the vaccination facility, they can fill out the <u>entire agreement</u> and submit it for review. If the CMO is different from the CEO/CFO then the enrollment form must be filled out in 3 parts.
- Your organization's CMO must sign the CDC Provider agreement in Section A. This may not be signed by any other member of your organization.
- You will need to submit license #s for all providers at your site. You will need to submit both license # and injectables # for pharmacists.
- If your organization has multiple vaccination facilities, you will need to fill out a Section B for each of these facilities!

Important Tip: The CDC requires doses on hand reporting every 24 hours (across sites - even on weekends) via a platform called VaccineFinder. VaccineFinder registration links are sent directly to sites from castlighthealth closer to the time when they are placing their first order. VaccineFinder does not allow for retroactive reporting so reporting must be completed daily. This inventory reporting is in addition to weekly reconciliations in PhilaVax and IIS dose administration reporting. When registering for your account: if individual reporting is selected, then the main organizational email address, and primary and backup contact at each location listed on your VaccineFinder page will be sent registrations. If you select centralized reporting, only the organizational COVID email address from section A will receive registration.

Once all sections listed have been completed, your organization is finished with their enrollment agreement form! The survey does not generate an automatic confirmation email, but the Philadelphia Department of Public Health will review your form and reach out with next steps.

We appreciate your patience as we work to get additional sites enrolled and expand vaccination opportunities as our allocation permits.

Questions about the enrollment form? Email vaccines@phila.gov.

Reporting

- 1. You will receive an email inquiring about your reporting capabilities, with the goal of establishing a reporting method (ex. HL7 Live real time reporting or Secure FTP manual 24hr uploads)
 - a. We highly recommend new providers utilize our Secure FTP reporting method (SFTP).
 - b. The Secure FTP reporting method typically averages 1-3 days to complete, while HL7 Live reporting method varies and can take as long as 3 months to complete.
- 2. Test the established reporting method.
 - a. For Secure FTP reporting we need to ensure that you are able to log-in without issues and that all required reporting information will be correctly documented and submitted to the Secure FTP account successfully. Below is an example of the email that you will receive:

To approve your site for reporting, we only need you to send data for **1 test patient**, using our excel template, "Flat file layout.xlsx" (attached to this email). I've also attached a guide you can use as a reference to fill this information out (Test Flat File Layout-Examples.docx). You can return the "Flat file layout.xlsx" directly to this email thread.

Documents utilized during testing:

Document Type	Name of Document	Purpose
Word document	Test Flat File Layout - Examples.docx	This document can be used as a reference on how to properly fill out your "Flat File Layout" excel
Microsoft Excel	Flat File Layout.xlsx	This excel will be used to filled out your COVID-19 vaccine data and used for testing. When reporting COVID-19 data, this excel needs to be uploaded to your SFTP account.
PDF	SFTP User Agreement 2021	This pdf is utilized to collect the information needed to create the SFTP account.

- 3. Analyzing testing method and approval.
 - a. Once your test flat file is reviewed, corrected, and approved, you will receive an email. Please follow ALL instructions in your approval email. Below is an example of an email you will receive:

"I reviewed your test flat file. Thank you, everything is documented correctly! When you upload your actual covid data, please ensure to name your flat file the following: "CV.[site name].[Date file was uploaded]". If multiple files are uploaded, indicate so by adding a letter at the end of the file name, "a,b,c,d,etc." Correctly following the file naming format is very important and essential for workflow purposes. In addition, please DO NOT manipulate the column names or change the layout of the excel without checking with PhilaVax first. Also, DO NOT send any vaccination data via email, it will NOT be accepted. Negligence to any of the requirements above WILL effect eligibility for additional vaccines. You are officially approved for reporting enrollment. Our COVID-19 Coordinator will follow up with the next steps.

Flat File name examples:

Single file: CV.PhilaVax.3-4-21

Multiple Files: CV.PhilaVax.3-4-21.a, CV.PhilaVax.3-4-21.b, CV.PhilaVax.3-4-21.c

Questions about reporting? Email erica.groomes@phila.gov.

Storage and Handling

- 1. You will receive an email from tempcheck@phila.gov inquiring about your storage units and digital data loggers (or DDLs).
- 2. Respond to the email with pictures of your storage units (outside of each unit, inside of each unit, "do not unplug" sign on the unit, digital data logger, and outlet. The unit must be plugged directly into the wall (not on a power strip or a GFCI outlet) and two full days (48 hours) worth of temperature files from your digital data logger (DDL).
 - a. Refrigerator temperature logs are required for enrollment and ordering. If you plan to freeze vaccine, freezer temperature logs are also required. At minimum, you must have a refrigerator with appropriate temperature settings. These logs are a backup to the DDL electronic data.
 - b. DDL temperature files must be sent electronically. We are unable to accept handwritten temperature logs.
 - c. All refrigerators should have temperatures falling between 36° to 46° F / 2° to 8° C. All freezers should have temperatures falling between -13° to 5° F / -25° to -15° C (with the exception of ULT freezers which should be between -112° to -76° F / -80°C to -60°C).
 - d. The Storage & Handling Team will review this information and determine if your DDL is adequate or needs to be replaced with a DDL from the Department of Public Health. If your DDL needs to be replaced, the Storage & Handling Team will mail a new one to your organization location.
 - PDPH uses the LogTag VFC 400 digital data logger.
- 3. The Storage & Handling Team will then set up the virtual vaccine location for your site in PhilaVax.

Storage & Handling approval cannot continue without e-mail responses – please answer all correspondence as soon as possible!

Important Tip: COVID-19 Vaccine Providers are unable to reallocate their doses to other sites, transport doses, or store doses in unapproved locations/cold units without prior approval from PDPH.

In order to transport vaccine from the location to which it was delivered, you are required to have a transport cooler with a DDL that also must meet certain refrigeration requirements. For questions about the specific requirements, click here to view the Vaccine Transport Guide.

Questions about storage and handling? Email tempcheck@phila.gov.

PhilaVax

- 1. You will receive an email from PDPH with a link to sign up for a COVID-19 PhilaVax Ordering Training. This training is required for both the primary and secondary contact for your site.
- 2. Attend the PhilaVax training.
- 3. The Education Team will update your permissions in PhilaVax if you already have an account.
- 4. PhilaVax accounts will only be created for primary and backup coordinators. If you do not already have an account, a PhilaVax account will be created for you once all enrollment processes (enrollment, reporting, storage and handling verification, and PhilaVax COVID-19 ordering training) have been completed and verified. Each user will receive a welcome email from phila.gov with their username and temporary password. It typically takes about a week for an account to be created.
- 5. PDPH will reach out once you are ready to order.
- 6. Once you have completed all steps necessary to place orders, you will receive an email granting your site an allocation for the following week. Make sure to read the email in its entirety!
- 7. Submit temp logs and place your first order (reconciliations aren't required for the first one but will be mandatory for any subsequent orders).

Questions about PhilaVax or the ordering process? Email dphproviderhelp@phila.gov.

FAQs

Enrollment:

Who can sign the CDC provider agreement?

The CMO of your organization must sign your provider agreement.

How do I update my enrollment form?

Please email vaccines@phila.gov and let them know your site name and what information you'd like to update.

Should I submit another enrollment form if I have not heard from PDPH recently?

No, please do not submit another enrollment form. Duplicate enrollment forms will slow down your enrollment as we cross-check forms. If you have questions about the status of your application, please reach out to vaccines@phila.gov.

Reporting:

Can I report through PA SIIS?

No, PA SIIS is completely different than PhilaVax.

How many SFTP accounts can I have?

You may have up to two accounts, a primary uploader and a backup.

Can I use FTP software to automate my upload?

Yes, this can be done during the onboarding process by requesting a service account.

What if I do not have an EHR (electronic health record) system?

SFTP reporting does not require an EHR system, only HL7 reporting does.

How do I know if my data uploaded correctly to my SFTP account?

You can always contact the IIS reporting team to confirm if your data uploaded successfully. We will always reach out if there are any issues regarding your data, and may ask for it to be re-uploaded. SFTP reporting does not require an EHR system, only HL7 reporting does.

Ordering/Philavax:

Can I share my PhilaVax account with other staff at my office?

No, PhilaVax accounts may not be shared. They are designed for individual use. Sharing an account will result in the account access being revoked.

What do I need to do in PhilaVax to be able to place an order for COVID vaccine?

There are a couple of steps that you MUST complete every time you place an order for COVID vaccine. These steps should be completed as often as once a week and at least once a month. You need to submit your temperature logs from your DDL, complete and close a reconciliation, and complete and submit a COVID-19 vaccine order by Wednesdays at 5pm. You should be completing all of these steps on the same day. We recommend that you check in on your order status on Fridays by 12pm to make sure everything is completed and approved.

What do I do if my site has wasted COVID doses?

Wasted COVID doses can classified as doses that were not used in time (expired) or if you were unable to draw the full number of doses out of the vial. Wasted COVID doses cannot be returned. We require sites to fill out a form detailing how many does were wasted and the reason why so that PDPH can adjust your inventory in PhilaVax. If you have more questions about wastage, click here to view further COVID-19 vaccine wastage information.

How do I accept shipments of vaccine in Philavax?

Go to Inventory \rightarrow Vaccines \rightarrow On-Hand and click on the blue link that says "Pending Vtrcks Shipments". Sometimes the link may be a bit early or a couple days late.

If you are sent to the duplicates screen, make sure to click "Proceed with Create" to avoid merging different vaccines together.

How do I place an order for second doses?

Currently all second dose orders are placed automatically and shipped to you ~3 weeks after your first order.

Storage and Handling

What kind of refrigerator or freezer is allowed? Does it have to be a Pharmaceutical grade?

While a Pharmaceutical grade storage unit is always the preferred option, it is not a requirement to store vaccine. We allow commercial grade cold storage if they can hold temperatures at the appropriate ranges. However, we do not allow storage in dorm-style units or freezers in household combination refrigerator-freezers. For more information, please see <u>Section 3</u> of our <u>Storage and Handling website</u>.

Do I need an Ultra Low Temp (ULT) Freezer?

No, this is not a requirement. Pfizer's COVID-19 vaccine is shipped at Ultra Low Temperatures (-80°C to -60°C) and can be stored in a ULT freezer, there are a variety of storage alternatives. Reach out to TempCheck@phila.gov to learn more about storing the Pfizer vaccine in its original shipping box or a conventional freezer or refrigerator.

Do I need Dry Ice?

Only if you plan to store the Pfizer COVID-19 in its original shipping container where it can be stored up to 30 days so long as dry ice (50 pounds) is added every 5 days. Contact TempCheck@phila.gov to arrange for a free supply of dry ice.

How do I transport vaccine?

If your site has permission to transport vaccine (reach out to Kiara Benson for approval), it must always be transported using a purpose built cooler. We have a limited supply of coolers which we can loan to you for offsite clinics and planned transports. For more information, please see out <u>Vaccine Transport Guide</u>.

I check the min/max temperature on our unit every day. Can I fax you my paper logs to verify our units? While the CDC still recommends the practice of manually checking the temperatures every day and notating the min/max on a paper log, this alone is not enough to verify the units. Your site must have a digital data logger (or DDL) thermometer with a valid certificate of calibration and the ability to record temps at least every half hour. For more information on DDLs and where to get one, please contact TempCheck@phila.gov.