

COVID-19 Vaccination Playbook for Pennsylvania's Independent Community Pharmacies

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Table of Contents

- 1) **Becoming a COVID-19 Vaccine Provider in PA**
- 2) **Training**
 - a) Vaccine Storage and Handling
 - b) COVID-19 Vaccines
 - c) PA-SIIS
- 3) **COVID-19 Vaccines**
 - a) Vaccine Products
 - b) Vaccine Storage and Handling
- 4) **Equipment and Supplies for Storage and Handling**
 - a) Refrigerators and Freezers
 - b) Temperature Monitoring Devices
 - c) Vaccine Transport for Off-site Clinics
 - d) Vaccine Kits
 - e) Other Supplies
- 5) **Staffing your Pharmacy**
- 6) **Phased Vaccination Plan and Targeted Populations**

7) Ordering and Documenting Vaccination

- a) Ordering COVID-19 Vaccines
- b) Documenting COVID-19 Vaccine Administration
- c) COVID-19 Vaccination Record Cards

8) Communication with the Public

- a) VaccineFinder
- b) Pharmacy Website
- c) Social Media
- d) Interactive Voice Response (IVR)

9) Scheduling Patients

- a) Scheduling Resources
- b) Pre-Screening/Intake Forms
- c) VIS and EUA Fact Sheets
- d) Second Dose of COVID-19 Vaccines

10) Provision of Vaccine

- a) Vaccine Clinics
- b) Vaccinations Within Workflow
- c) Curbside or Drive-Thru Vaccinations
- d) Disposal of Personal Protective Equipment (PPE)

11) Vaccine Safety and Monitoring

12) Security and Crowd Control

13) Payment of Administration Fee

14) Pharmacy Readiness Checklist

1) Becoming a COVID-19 Vaccine Provider in PA

In order to participate in COVID-19 vaccinations through the PA DOH, pharmacies must complete the CDC COVID-19 Vaccination Program Provider Agreement available here: <https://expressforms.pa.gov/apps/pa/DOH/CDC-COVID-19Vaccination-Provider-Agreement>. Pharmacies must fill out both Section A and Section B of this form. The PA DOH will then determine whether the pharmacy meets the criteria to become an approved provider of COVID-19 vaccine. *Please note that Philadelphia is a separate jurisdiction with a separate enrollment process.*

2) Training

The CDC's *Immunization Education & Training* webpage is the best location to get all of your vaccine-related training. It can be accessed here: <https://www.cdc.gov/vaccines/ed/index.html>. This PDF form created by the CDC is excellent and has all COVID-19-specific training in one place: <https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf>.

- a. Vaccine Storage and Handling. The PA DOH requires that at least one person at each pharmacy complete the CDC's training entitled, "You Call the Shots: Storage and Handling" (Module 10) available here: <https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp>. This training covers storage and temperature monitoring equipment for vaccines as well as vaccine transport. Pharmacists can get immunization CE credit for completing this module.
- b. COVID-19 Vaccines. The CDC will have COVID-19 vaccine-specific training for each vaccine that becomes available in the US. Immunizers are required to complete training on each vaccine product they plan to administer. This training will be located here: <https://www.cdc.gov/vaccines/ed/index.html>.
- c. PA-SIIS. The Pennsylvania Statewide Immunization Information System (PA-SIIS) will be used for ordering and documenting COVID-19 vaccines and managing vaccine inventory. Pharmacies that are not already enrolled as providers will receive information on how to enroll after completing the CDC COVID-19 Vaccination Program Provider Agreement with the PA DOH. information on PA-SIIS is available here: <https://www.health.pa.gov/topics/Reporting-Registries/PA-SIIS/Pages/PA-SIIS.aspx>. **PA-SIIS training is required for all users** and available through *TRAIN PA* at <https://www.train.org/pa/welcome>. The training module is entitled, "PA-BHSR: Mandatory Reporting of COVID-19 Vaccine Inventory and Patient Vaccination Information to PA-SIIS."

3) COVID-19 Vaccines

- a. Vaccine Products. There are several COVID-19 vaccine products that are anticipated to be available (see Table 1). Pfizer's product requires ultra-cold storage (-70 C) and will most likely not be used by most community pharmacies since they lack proper storage capabilities.

Table 1. US COVID-19 Vaccine Products[^]

Manufacturer	Type	Storage	Administration
Pfizer/BioNTech	mRNA	Ultra-cold frozen up to 6 months; Frozen for 5 days; Refrigeration for 5 days	-2 doses (0, 21d) -Second dose has a 4 day grace period (day 17-21) -Requires reconstitution -Multidose vials
Moderna	mRNA	Frozen (-25° to -15°C) up to 6 months; Refrigerated (2° to 8°C) for 30 days*; room temperature for 12hrs	-2 doses (0, 28d) -No reconstitution -No preservative -Multidose vials
Oxford/AstraZeneca	Viral vector	Refrigeration for up to 6 months	-2 doses (0, 28d)
Sanofi/GSK	Protein subunit	Refrigeration	-2 doses
Novavax	Protein subunit	Refrigeration for 6 months; room temperature for 24hrs	-2 doses (0, 21d) -No reconstitution
Johnson & Johnson	Viral vector	Frozen up to 2 years; Refrigeration up to 3 months	-1 or 2 doses (0, 56d) are both being studied

[^]The information in this table may change as more data becomes available

*30 day storage only if the vial has not been entered

- b. Vaccine Storage and Handling. In addition to the “You Call the Shots: Storage and Handling” vaccine training, the CDC has a **Vaccine Storage and Handling Toolkit** that is an excellent resource for pharmacies. It is available here: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>.

4) Equipment and Supplies for Storage and Handling

- a. Refrigerators and Freezers. Community pharmacies can use purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze. These units can be compact, under-the-counter style or large. Household-grade units are acceptable under certain circumstances but must only be used for refrigerated vaccine. Freezers that are a part of a combination unit (e.g. refrigerator and freezer) cannot be used. Frozen vaccine can only be stored in a stand-alone freezer unit. Vaccine cannot be stored in a dorm-style refrigerator unit. For more information on vaccine storage, refer to the CDC’s *Vaccine Storage and Handling Toolkit* referenced above.

- b. Temperature Monitoring Devices. Each refrigerator or freezer storing vaccine must have a temperature monitoring device (TMD). The CDC recommends a “digital data logger” (DDL) as the primary TMD. DDLs that use a buffered temperature probe are the most accurate way to measure actual vaccine temperature. DDLs must have a current Certificate of Calibration Testing. Detailed information TMDs and can be found in the *Vaccine Storage and Handling Toolkit*. Each storage unit should also have a backup TMD. The CDC does NOT recommend TMDs used for food or alcohol or mercury thermometers.
- c. Vaccine Transport for Off-Site Clinics. The CDC outlines planning considerations before, during, and after a vaccine clinic here: <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html>. Ensure proper cold chain storage and handling to promote viability of vaccine and decrease loss of vaccine.
- d. Vaccine Kits. Ancillary supplies will *automatically* be shipped to match vaccine orders placed by pharmacies. Each kit will be shipped separately from the vaccine and will have supplies for 100 doses. The kits will contain needles, syringes, alcohol pads, 4 surgical masks and 2 face shields, and COVID-19 vaccination record cards. The personal protective equipment (PPE) recommended by the CDC for COVID-19 vaccine administration is located here: <https://www.cdc.gov/vaccines/hcp/admin/downloads/COVID-19-vaccine-administration-PPE-508.pdf>. All needles for vaccine administration will be safety needles. For vaccines that require mixing with a diluent, the kits will contain additional supplies, including diluent, to perform this function. There are seven different vaccine kit configurations, however, only adult kits will be available initially. Specific requests for needles or syringes are not possible due to the limited supply.
- e. Other supplies. Pharmacies may need additional supplies to those provided in the Vaccine Kits. Pharmacies will need **sharps containers and bandages**. Pharmacies may want to purchase extra PPE such as **gloves**, surgical masks, and gowns. Pharmacies may also want to consider these additional supplies:
- Hand sanitizer with at least 60% alcohol for hand hygiene
 - Additional cleaning and disinfecting supplies for more frequent cleanings of surfaces and equipment
 - Face coverings for patients who arrive without one
 - Additional signage, tape, ropes, and cones to encourage physical distancing and provide one-way flow through the clinic
 - Emergency response items (e.g. epinephrine for anaphylaxis)
- A more detailed list of recommended vaccine clinic supplies is provided in the [CDC’s Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist](https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/vaccination-clinic-supply-checklist.html) at <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/vaccination-clinic-supply-checklist.html>.

5) Staffing for Vaccine Provision

Some options to support staffing during COVID-19 vaccination are:

- Hold vaccine clinics when the pharmacy is closed for regular business.

- Partner with other pharmacies in your area to host clinics together and share staff. If both pharmacies are bringing vaccine to the clinic, it is recommended that the vaccine be from the same manufacturer and the inventory be kept separate to avoid confusion.
- Work with Pennsylvania School of Pharmacy programs to reach out to potential student volunteers. Students can help with crowd control, intake processes, patient education, and in some cases vaccine administration. In Pennsylvania, pharmacy student interns with appropriate training and documentation can now administer COVID-19 vaccines to adults with direct supervision by a pharmacist. Pennsylvania pharmacy schools have agreed to share information on COVID-19 vaccination clinic volunteer opportunities with their students. Pharmacies in need of student support for COVID-19 vaccine clinics should email Kim Coley at coley@pitt.edu with the following information:
 - Pharmacy and pharmacist contact information (pharmacy name, pharmacist name, email, phone number)
 - Vaccine clinic information (clinic location name, clinic location address, clinic date, clinic time)
 - Number of students needed
 - Anticipated student activities

6) Phased Vaccination Plan and Targeted Populations

There will be a phased approach to distributing COVID-19 vaccines due to limited initial supply. During Phase 1a, the very first supplies of the Pfizer vaccine will be limited to hospitals and long-term care facilities. Some pharmacies may be participating in Phase 1b once additional vaccine that does not require ultra-cold storage becomes available. The vast majority of pharmacies will be eligible to receive vaccine as part of Phase 2 where widespread distribution of vaccines will occur. Pharmacists should refer to the ACIP website located at <https://www.cdc.gov/vaccines/acip/index.html> for the most up-to-date information on COVID-19 vaccine prioritization.

7) Ordering and Documenting Vaccination

- a. Ordering COVID-19 Vaccines. For pharmacies enrolled as COVID-19 providers with the PA DOH, all COVID-19 vaccines will be ordered through the PA-SIIS web application. The PA DOH will approve vaccine orders based on the populations that each pharmacy serves, the pharmacy's ability to handle and store vaccine, and existing vaccine inventory. *Please note that Philadelphia has a separate IIS for reporting.* Pharmacies should not order more vaccine than they can administer to patients as a first dose over a reasonably short amount of time. Pharmacies should not save vaccine for a second dose for patients. Instead, pharmacies should order additional vaccine for second doses after administering the majority of their first doses to patients.
- b. Documenting COVID-19 Vaccine Administration. The PA DOH states that pharmacies must document COVID-19 vaccine administration within 24 hours of administering a dose in their prescription dispensing systems and in PA-SIIS. Documentation for pharmacies that have an interface between their dispensing systems and PA-SIIS will occur automatically. Pharmacies that do not have an interface must enter the required information manually through the PA-SIIS web

application. The online PA-SIIS training module provides detailed instructions on this process.

- c. COVID-19 Vaccination Record Cards. Pharmacies are required to provide patients with a completed COVID-19 vaccination record card to document their administered dose. Vaccine information on these cards should include vaccine manufacturer, lot number, date of first dose, and second dose due date. These cards will be provided in the ancillary vaccine kits provided with every vaccine order. Pharmacists should ask patients to take a picture of their completed Record Card with their cellphones in case they lose their card. Patients should be encouraged to return to the same provider that they received their first dose from for their second dose.

8) Communication with the Public

There are many ways that pharmacies can communicate to their patients and to the public about their COVID-19 vaccine services including planned vaccine clinics. These include use of VaccineFinder, the pharmacy's website, social media and store signage. The PA DOH provides some messaging that can be used on social media or in your pharmacy as posters or flyers. That information is available here: <https://www.health.pa.gov/topics/disease/coronavirus/Pages/Social-Media.aspx>. The CDC also has information on how to talk to your patients about COVID-19 vaccines as well as **how to make a strong vaccine recommendation**. Those links are located here: <https://www.cdc.gov/vaccines/covid-19/hcp/index.html>. Review these materials in advance and anticipate that patients will have more questions than normal given that this is a new vaccine.

- a. VaccineFinder. VaccineFinder is a free, online resource where users can search for locations that provide vaccinations. You can register for an account and once approved you can list your vaccine services. Access VaccineFinder here: <https://vaccinefinder.org/>. When you report your COVID-19 vaccine inventory through PA-SIIS, PA-SIIS will push that information to VaccineFinder for you.
- b. Pharmacy Website. Pharmacies can utilize their websites for a variety of public-facing communications. Websites can be used to:
 - Advertise COVID-19 vaccine availability including vaccine clinics
 - Facilitate sign-ups for COVID-19 vaccine appointments through a scheduling app
 - Provide a COVID-19 vaccine intake/screening form (when available from the CDC) for patients to take with them at their scheduled time
 - Provide patient access to the COVID-19 vaccine EUA fact sheet or Vaccine Information Statement (VIS)
- c. Social Media. Social media (e.g. Facebook, Instagram, Twitter) is an additional way to alert the public about COVID-19 vaccine information and vaccine availability at your pharmacy. When promoting availability of COVID-19 vaccines at your pharmacy or an upcoming vaccine clinic, the CDC recommends that you are clear about who the vaccines are for based on recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP). Direct patients to your website where you can post more detailed information as well as

information on pre-scheduling of appointments if applicable. Additionally social media resources can be found here: <https://www.nih.gov/news-events/covid-19-social-media-resources>

- d. Interactive Voice Response (IVR). Consider modifying your IVR/Phone Tree to include information on how patients can gather more information about vaccination services, including COVID-19 vaccines, at your pharmacy.

9) Scheduling Patients

Pharmacies should consider scheduling appointments for COVID-19 vaccinations, particularly during the initial surge. Pharmacies may also experience an influx of new patients that have not previously received a prescription or vaccination from that pharmacy location. Scheduling services may aid in the collection of critical information for vaccine provision before the patient arrives. Scheduling will also help with the following:

- Crowd control at your pharmacy or vaccine clinic
 - Planning for use of all vaccine inventory in a timely fashion; Many vaccines will come in 100 dose increments (with the exception of the Pfizer vaccine) and should be used up as soon as possible
 - Access to contact information for patients who have signed up to be vaccinated
- a. Scheduling Resources. There are several free scheduling platforms/apps that can be utilized by pharmacies to schedule vaccination appointments (see Table 2). These platforms do not need to be HIPAA-compliant because no protected health information is collected by the platform. There are HIPAA-compliant scheduling resources available for health care settings if a pharmacy chooses this option, however they often come with a monthly fee.

Table 2: Sample Free Scheduling Programs/Apps

Functionalities	Scheduling Programs/Apps		
	Appointlet	Calendly	Setmore
Allows pharmacy to build vaccine intake form/questions to be taken by patient when scheduling	✓		
Calendar sync to Google and Office 365	✓	✓	✓
Calendar sync to Outlook		✓	
Calendar sync to iCloud		✓	
Sends reminders for appointment	✓	✓	✓
Integrates with pharmacy website	✓		✓
Allows patients to self-schedule	✓	✓	✓
Allows patient to cancel/reschedule appointments	✓		✓
Works on any electronic device	✓	✓	✓

- b. Pre-Screening/Intake Forms. A COVID-19 vaccine pre-screening form will be made available electronically from the CDC. In order to facilitate patients through the pharmacy or clinic, pharmacies may choose to have patients complete the pre-screening form *ahead of their appointment*. These forms can be made available via the Pharmacy's website. Pharmacies will need to have paper copies of these forms available for patients arriving for vaccination.
- c. VIS and EUA Fact Sheets. The CDC suggests the use of electronic communication, where appropriate, to allow patients to download or review the Vaccine Information Statement (VIS) or Emergency Use Authorization (EUA) fact sheets before coming to the pharmacy or vaccine clinic. Pharmacies will need to provide patients with access to these forms either an electronic or paper copy prior to vaccination. One option to consider is using a QR code that links to these documents. Several free QR code generators are available online.
- d. Second Dose of COVID-19 Vaccines. The majority of COVID-19 vaccines will require a second dose. Pharmacies should have a process in place to schedule and notify patients for a return vaccination. This may include adding the second vaccine into the pharmacy's dispensing system and for automatic refill at the appropriate time frame. Some pharmacy management systems offer text messaging for patient reminders. All patients must also be given a COVID-19 Vaccination Record Cards provided in the Vaccine Kits from the federal government.

10) Provision of Vaccine

- a. Vaccine Clinics. Vaccine clinics will likely be the preferred format for when the vaccine first becomes available due to the large demand. Consider scheduling clinics after regular pharmacy hours or on a day the pharmacy is usually closed (e.g. Sunday). The CDC offers several suggestions for pre-, during, and post-clinic activities. This information can be found here: <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html>. The CDC also has a Checklist of Best Practices for Vaccination Clinics for transporting refrigerated vaccines. This checklist is located here: <https://www.izsummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf>.
- b. Vaccinations Within Workflow. There will be opportunities for pharmacies to offer COVID-19 vaccine during workflow. This will most likely occur after the initial surge and when vaccines become more widely available. Pharmacies will need to continue mechanisms to prevent crowding. This may include the use of patient scheduling or other mechanisms such as having patients wait in their cars until they can be notified (e.g. via text message or phone call) that their vaccination time has arrived.
- c. Curbside or Drive-Thru Vaccinations. Providing vaccinations to patients in their vehicles either at curbside or via a Drive-Thru may be an option for some community pharmacies. The advantages to this method is that the vaccines are provided outside where risk of COVID-19 transmission may be lessened. However, weather conditions may inhibit patient and staff comfort as well as the

ability to easily access patients' deltoid muscles. Large parking areas are also needed for vaccination by this process so that there is space for vehicles to wait during the post-vaccination observation period. The CDC provides Considerations for Curbside or Drive-Thru Vaccine Clinics located here: <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/curbside-vaccination-clinics.html>

- d. Disposal of Personal Protective Equipment (PPE). PPE such as masks, gloves, and face shields used during the provision of COVID-19 vaccinations can be treated as regular municipal waste. The OSHA guidance on solid waste management is located here: <https://www.osha.gov/SLTC/covid-19/solid-waste-wastewater-mgmt.html>

11) Vaccine Safety and Monitoring

Monitoring for safety of COVID-19 vaccines is important for pharmacists and your patients may have many questions for you. Pharmacists should report any vaccine side effects through the Vaccine Adverse Event Reporting System (VAERS) available here: <https://vaers.hhs.gov/>. VAERS is a national early warning system to detect possible safety problems with vaccines. Also, the CDC is asking for providers to encourage the first vaccine recipients (e.g. health care staff, essential workers) to enroll in V-SAFE on their smartphones. V-SAFE is an after-vaccination health checker that uses text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. The system also will provide telephone follow-up to anyone who reports significant adverse events to any COVID-19 vaccine. Instructions on how to enroll in v-safe will be forthcoming from the CDC.

12) Security and Crowd Control

Pharmacies receiving COVID-19 vaccines may want to consider security and crowd control measures. Contacting local law enforcement in advance to help with security, crowd, and traffic control is one option. Additionally, the following steps may help to minimize crowding at vaccine clinics:

- a. Have a pre-screening tool available for patients to fill out in advance.
- b. Ensure the clinic flow moves in one direction in order to minimize face-to-face interactions of patients and staff.
- c. Use signage to demonstrate proper clinic flow and social distancing and utilize supplies like ropes and cones to manage direction of patients.
- d. Establish a waiting area that allows for appropriate social distancing.
- e. Designate areas for special-needs patients including those with limited mobility.
- f. Provide vaccine information to patients in advance if possible.
- g. Communicate wait times with patients prior to entering the clinic area.

13) Vaccine Billing and Payment of Administration Fee

Pharmacies and other providers can not sell or seek reimbursement for COVID-19 vaccines or any supplies that they receive at no cost from the federal government. Pharmacies that sign the CDC's COVID-19 Vaccination Program Provider Agreement agree to administer COVID-19 vaccines regardless of a person's ability to pay an administration fee. Pharmacies may seek reimbursement from a program or insurer that covers COVID-19 Vaccine administration fees. This CMS announcement includes information on Medicare, Medicaid, private insurers, and uninsured:

<https://www.cms.gov/files/document/2020-10-28-mlnc-se.pdf>. Vaccine administration fees for all Medicare patients will be billed through Medicare Part B. This link provides a table with Medicare Part B codes and payment allowances for COVID-19 Vaccines: <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>. This APhA document provides information on how pharmacies can best position themselves for reimbursement as a COVID-19 vaccine provider: https://www.pharmacist.com/sites/default/files/audience/APhACOVIDReimbursementforAdmin_1220_web.pdf. More information on administration fee billing will be shared with pharmacies as it becomes available.

14) Pharmacy Readiness Checklist

The following checklist will help you assess your pharmacy's readiness to participate in COVID-19 vaccinations:

<ul style="list-style-type: none"><input type="checkbox"/> Complete the CDC COVID-19 Vaccination Program Provider Agreement.<input type="checkbox"/> Training: Complete "You Call the Shots: Storage and Handling - Module 10."<input type="checkbox"/> Training: Complete "PA-BHSR: Mandatory Reporting of COVID-19 Vaccine Inventory and Patient Vaccination Information to PA-SIIS" on the TRAIN PA site.<input type="checkbox"/> Training: Complete each vaccine-specific training when they become available.<input type="checkbox"/> Identify what additional supplies including PPE you need to obtain.<input type="checkbox"/> Ensure that your pharmacy has refrigerator and/or freezer units that meet CDC's guidelines.<input type="checkbox"/> Ensure your pharmacy has digital data loggers with Certificates of Calibration Testing for your storage units.<input type="checkbox"/> Ensure that your pharmacy is registered with PA-SIIS.<input type="checkbox"/> Ensure appropriate pharmacy personnel have log-on credentials for PA-SIIS.<input type="checkbox"/> Develop a plan for holding vaccine clinics<ul style="list-style-type: none"><input type="checkbox"/> Identify space to meet clinic and infection control needs<input type="checkbox"/> Develop a plan for staffing the clinic<input type="checkbox"/> Develop a plan on the format and organization of the clinic<input type="checkbox"/> Communicate with local law enforcement<input type="checkbox"/> Develop a communication strategy to inform your community about vaccine availability at your pharmacy.<ul style="list-style-type: none"><input type="checkbox"/> Register your pharmacy in VaccineFinder.<input type="checkbox"/> Update your website and social media sites<input type="checkbox"/> Identify a method to schedule patients for vaccines<input type="checkbox"/> Ensure that your pharmacy can bill through Medicare Part B
