



**Date Revised 1/11/2022**

## **Pennsylvania COVID-19 Vaccine Program**

### **All Provider Call - FAQs**

**Note: Provider calls are not currently being recorded**

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#### **Provider Network: Enrollment, Billing and Ordering**

##### **Q: Who can enroll into the PA COVID-19 vaccine program?**

A: The Pennsylvania Department of Health (Department) encourages any provider who is credentialed or licensed in Pennsylvania to vaccinate individuals to enroll as a COVID-19 vaccine provider. The Department's Division of Immunizations (DOI) already works with provider partners through Pennsylvania's Immunizations Programs (e.g., Vaccines for Children, TotTrax). Currently, the Department is working with more than 3,000 provider partners to promote the success of the COVID-19 Vaccination Program in Pennsylvania. Please fill and submit [DOH's COVID-19 Vaccination Provider Agreement Form](#) if you want to enroll with our program.

##### **Q: Who can administer COVID-19 vaccines in PA?**

A: Providers must be credentialed or licensed in Pennsylvania to vaccinate individuals. A full list of the credentialed and licensed provider types in Pennsylvania authorized to administer vaccination is available on the [Department's website](#). The list includes doctors, physician assistants, nurses, nurse practitioners, pharmacists, and others.



**Q: Can we bill insurance for the COVID-19 Vaccine?**

A: COVID-19 vaccines will be available at no cost to individuals. A vaccine administration fee may be charged to the recipient's insurance or to the Medical Assistance program. However, lack of insurance or other health care coverage will not be a barrier to receiving the vaccine. The U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) will be reimbursing providers for the cost of vaccinating uninsured individuals. In addition, the Centers for Medicare and Medicaid Services (CMS) has [released a set of toolkits](#) to providers about the vaccine and reimbursement options through Medicare.

More information regarding COVID-19 vaccine coverage is available in an FAQ on the [Pennsylvania Insurance Department's website](#).

**Q: How do we order COVID-19 vaccines?**

A: After enrollment in our vaccine program, providers are required to complete a mandatory PA-SIIS training. After completion of the training, they will be issued a unique PA-SIIS ID and user credentials. By using that information, providers can log into PA-SIIS and directly place orders for vaccines they want for their facility.

**Q: Is there still a minimum amount of COVID-19 vaccines that can be ordered?**

A: Yes.

- Pediatric formulation of Pfizer vaccine is denoted as Pfizer-P in PA-SIIS ordering screen. The minimum order you can place is for 100 doses and anything over must be ordered in increments of 100. This formulation can be used among children 5 through 11 years.
- The adolescent/adult Pfizer vaccine for use among 12 years and older has been made available in two formulations: purple cap and gray cap (Tris). Please remember that as of Dec. 23, we have retired the purple cap Pfizer vaccine from PASIIS (meaning that it is no longer available for ordering) and fully transitioned to the gray cap formulation. Gray cap is available as a six dose multi-dose vial. It is denoted as Pfizer-T on the PA-SIIS ordering screen. The minimum order you can place is for 300 doses and anything over must be ordered in increments of 300.
- The minimum order for Moderna vaccine is 100 doses. It is available as a 10-dose multi-dose vial. The minimum order you can place is for 100 doses and anything over must be ordered in increments of 100.
- Janssen/J&J is no longer available for ordering until further notice.

**Vaccines.gov**

**Q: Should all sites offering COVID-19 vaccines in within the jurisdiction of PA DOH appear in vaccines.gov?**

A: Yes, that's correct. If the sites receiving vaccines via state allocation have issues appearing in vaccines.gov, they need to contact our program. The sites receiving vaccines through federal allocation or



through both federal and state allocations must work directly with the CDC to resolve these issues.

**Q: How long after submitting our sites' info in vaccines.gov until the sites are visible?**

A: Please allow 24-48 hours for it to update and appear on the website.

**Q: If our facility is listed on vaccines.gov but not showing correct appointment availability/walk-ins accepted should we also use the JotForm for corrections?**

A: Yes, but be sure to complete all fields even if currently correct, not just those that need updated. The JotForm can be found here- <https://form.jotform.com/210525763344049>

### **Vaccine Administration**

**Q: Does DOH know if/when single dose vials will become available?**

A: We currently do not have any knowledge/update on that. We will keep you updated as soon as we receive information on this matter.

**Q: Any info on Moderna and 12+ approval?**

A: At this time Moderna has submitted application to the FDA for the EUA approval of vaccine for use among 12 years and older. However, we do not have any information as to when it will be approved.

**Q: We have people asking us for a second dose, so they don't have to travel as far or have a difficult time getting into the clinic that gave the first dose. Should we turn them away or give the dose?**

A: If you have the vaccines available, and it is the same brand that was originally received please feel free to administer doses. Please ask the patient to notify the original site that they will not need a second dose from them so that they do not order more vaccines than needed.

**Q: Can you tell me where I can find a vaccine consent form?**

A: You may look online for an example provided by the manufacturer, as well as from other sources.

**Q: Does another vaccine consent form need to be filled out for the second dose?**

A: This entirely depends on the policy of your facility; you can either refill the form again or just require a patient to re-sign the form. That being said, a consent form for vaccine has to be signed and dated with each encounter between the patient and the provider.

### **Vaccine Clinics**

**Q: Can we partner with a community group without doing the vaccines off-site? We would be happy to schedule them at our facility but have not done off-site clinics yet.**

A: Yes, that would be fine. We strongly encourage partnerships. If you want to host it on-site at your location, versus off-site, that is okay. [Vaccination Clinic Partnership Form \(jotform.com\)](#)



## Vaccine Information

**Q: We have received several questions from families regarding the COVID vaccine and its effect on fertility. Do you have any FAQs or information we can provide to families to help reduce vaccine hesitancy? We would like to do our part in helping educate families on the importance of vaccinating children 12 years and older.**

A: There is currently no evidence that any vaccines, including COVID-19 vaccines, cause female or male fertility problems. CDC does not recommend routine pregnancy testing before COVID-19 vaccination. If you are trying to become pregnant, you do not need to avoid pregnancy after receiving a COVID-19 vaccine. Like with all vaccines, scientists are studying COVID-19 vaccines carefully for side effects now and will report findings as they become available. (CDC, 2021)

**Q: How soon can a pediatric patient receive the vaccine after having a positive case of COVID-19?**

A: People who have had COVID-19 are recommended to get vaccinated with an EUA COVID-19 vaccine. People who are currently symptomatic with COVID should wait until their symptoms are resolved and they are out of the isolation period until they get vaccinated. For most adults with COVID-19, the period of isolation extends for 10 days after symptom onset. For persons with more severe COVID-19 illness, the period of isolation may extend for up to 20 days. The guideline is the same for adolescents except for a child who was diagnosed with MIS-C in which case the recommendation is to wait 90 days. (CDC, 2021)

**Q: Does data exist on how long natural immunity lasts with or without the vaccine?**

A: If patients acquire COVID, then there is a certain level of immunity built up in the body. However, a person should be vaccinated regardless of whether they had COVID-19. In terms of immunity, it's difficult to tell how long natural immunity lasts from vaccination. This is still being studied.

**Q: What does a fully approved COVID-19 vaccine mean?**

A: A: FDA approval of a vaccine means that data on the vaccines effects have been reviewed by the Center for Drug Evaluation and Research (CDER), and the vaccine is determined to provide benefits that outweigh its known and potential risks for the intended population. The vaccine approval process takes place within a structured framework that includes:

- Analysis of the target condition and available treatments
- Assessment of benefits and risks from clinical data
- Strategies for managing risks

**Q: How do we respond to patients who ask why Moderna and Janssen vaccines aren't fully approved by the FDA?**

A: It is important to remember that in public health emergencies, such as a pandemic, the development process may not follow routine procedures. However, these COVID-19 vaccines are going through clinical trials that are being conducted according to the rigorous standards set by the FDA. With advanced technology available today, this process can be expedited. For an Emergency Use Authorization (EUA) to be issued for a vaccine, the FDA must determine that the known and potential benefits outweigh the known



and potential risks of the vaccine.

**Q: How should we respond to patients who are concerned about long term side effects of the vaccine?**

A: Providers should remind patients that the research shows that nothing out of the ordinary occurs in terms of side effects from the vaccine. The vaccine is much better to receive than the long-term side effects of the actual COVID-19 disease.

**Vaccine Storage and Handling**

**Q: Where can I find the latest information on vaccine storage and handling?**

A: The most recent information on vaccine storage and handling can be found here [Vaccines Storage and Handling Toolkit | CDC](#). You may also visit the vaccine manufacturer's website for the latest updates on this area.

**Q: How are the different COVID vaccines stored?**

A: Please refer to the following:

**Pfizer**

**Pfizer for ages 12 and older (Purple Cap)**

- Ultra-cold freezer: keep between -90°C and -60°C (-130°F and -76°F) until expiration
- Vaccines expire 9 months after the manufacture date
- Freezer: keep between -25°C and -15°C (-13°F and 5°F)
- Refrigerator: store for 1 month between 2°C and 8°C (35°F and 46°F)
- During the 2 hours preceding any thawing, the vaccine may be stored at 8°C to 25°C (46°F to 77°F)
- Discard after 6 hours after first puncture at room temperature

**Pfizer Tris for ages 12 years and older (Gray Cap)**

- Ultra-cold freezing: until expiration, vaccines can be stored between -90°C and -60°C (-130°F and -76°F)
- Vaccines expire 9 months after manufacture
- **Freezer: DO NOT STORE**
- Refrigerator: Up to 10 weeks at 2°C to 8°C (35°F to 46°F)
- Before puncture, store between 8°C and 25°C (46°F and 77°F) for 12 hours (including the thawing period)
- Discard after 12 hours after first puncture at room temperature
- **DO NOT DILUTE THIS FORMULATION**
- Don't use a vial if the vaccine is not enough to obtain a complete dose. Never combine vaccine from multiple vials to get the whole dose.

**Pfizer for children ages 5-11 (Orange Cap)**



- Once the vaccine has been delivered, follow the manufacturer's instructions for opening it
- Store vaccines in ultra-cold freezers between -90°C and -60°C (-130°F and -76°F) until the expiration date
- The expiration date for vaccines is nine months after the date of manufacture
- **DO NOT STORE in a freezer**
- It can be stored up to 10 weeks between 2°C and 8°C (35°F and 46°F) in the refrigerator
- Store at room temperature between 8°C and 25°C (46°F and 77°F) for 12 hours prior to diluting (including the time for thawing)
- When first punctured at room temperature, discard after 12 hours

#### **Moderna**

- Refrigerate or freeze vaccines
- Vials that are not punctured should be stored in the freezer between -50°C and -15°C (-58°F and 5°F)
- You can store unpunctured vials in the refrigerator for 30 days at 2° to 8°C (36° to 46°F)
- The punctured vials can be stored between 2°F and 25°C (36°F and 77°F) for a maximum of 12 hours
- Regardless of whether the 12-hour time limit has been met, a vial should be thrown away after being punctured 20 times

#### **Janssen/J&J**

- Vaccines should be stored in a refrigerator between 2°F and 8°F (36°F to 46°F)
- Vials that are not punctured can be used until the expiration date whereas punctured vials can be used for up to 6 hours

#### **Q: What is the difference between Pfizer purple cap and gray cap formulation?**

A: COVID-19 vaccine from Pfizer has transitioned from a purple to gray cap. Currently, Pfizer only offers gray caps, which are indicated for individuals aged 12 years and older. It is not necessary to dilute gray cap Pfizer vaccine prior to administration. This is a change from the purple cap. In addition, the gray cap Pfizer vaccine has different storage and handling specifics than the purple cap vaccine. To learn more, visit the CDC's website on Pfizer-BioNTech COVID-19 Vaccines by Age and Cap Color-[Pfizer-BioNTech COVID-19 Vaccines | CDC](#)

#### **PA-SIIS**

#### **Q: If we have a PA-SIIS account for VFC, do we need to get another account for the COVID vaccine program?**

A: Typically, the accounts are the same, however, you do still need to enroll as a COVID-19 vaccine provider. If you are unsure, please email the resource account. If we know you have a VFC account and you enroll as a COVID-19 vaccine provider, we add COVID ordering ability to your VFC account so it will have the same PIN and staff access.



**Q: Do we need both a PA-SIIS account and PA TRAIN account? I have been unable to do this with the instructions from the enrollment letter from PA DOH.**

A: PA Train is where you take the training on how to access and use the PA-SIIS account. When this training is completed, PA-SIIS will email your user account and you will then have access to PA-SIIS, which is where you will order and manage your COVID vaccine inventory.

**Q: How can a provider obtain a VFC PIN number?**

A VFC PIN number is a unique ID issued to providers who are enrolled with PA DOH's Vaccine for Children (VFC) program. All the COVID-19 vaccine providers who are already enrolled as a VFC provider will be using the same VFC PIN number issued by DOH earlier to request vaccines. However, newly enrolled COVID-19 vaccine providers who are not VFC providers are issued a new VFC PIN number which will be used to request COVID19 vaccines. First, providers must sign and submit the COVID-19 vaccine provider enrollment agreement application with the Division of Immunizations. As providers are approved and applications are being processed, PA-SIIS will send notifications to providers on mandatory PA-SIIS training requirements. Once they have completed the mandatory training, they will be issued a PA-SIIS account. Follow the steps below to access a VFC PIN number:

1. Log into the PA-SIIS account with your username and password.
2. Select the clinic settings button on the left-hand side of the Avanza System screen.
3. Verify that your facility name is in the clinic name field and update any additional info as needed.
4. On the upper right corner, you can see the VFC PIN number for your facility.
5. If unable to login to PA-SIIS, please reach out directly to our PA-SIIS team at [RA-DHPASIS@pa.gov](mailto:RA-DHPASIS@pa.gov).

**Q: Is the PA-SIIS PIN the same as the VTrckS number?**

A: The VTrckS number is a completely different number that will not appear in PA-SIIS. If you need your VTrckS number, reach out to the PA-SIIS resource account at [RA-DHCOVIDVAX@pa.gov](mailto:RA-DHCOVIDVAX@pa.gov). Providers can't see their VTrckS number in PA-SIIS. (VTrckS is the number associated with the CDC.)

**Q: If we place an order in PA-SIIS, what is the estimated time of delivery?**

A: After your order is entered in PA-SIIS, you will be able to see its status updates by logging into PA-SIIS. You can use the tracking number that's provided for every shipment to check the estimated time of delivery.

**Q: Can we add another user to an existing account?**

A: Yes, you can. The turnaround time for this is uncertain but be sure to include in the subject line that you'd like to add an additional person. Doing so will flag the request on our end.

**Q: We have a Clinic ID and PIN, but why are we not listed on vaccines.gov?**

A: If you have a Clinic ID and PIN, then you are a registered provider, but your facility might not be listed if you haven't received vaccines in PA-SIIS yet. If you are receiving and reporting vaccines through a centralized hub, then you don't have an active inventory in PA-SIIS and therefore your facility won't be listed in vaccines.gov.



**Q: What does “orders pending approval” mean? What about “on hold”?**

A: “Orders pending approval” is a temporary status that you might see as our team is placing the order into PA-SIIS. Once the order is fully entered into the system, it will show as complete. “On hold” means that your COVID-19 provider agreement has been processed by DOH, but your clinic is not active to receive vaccine yet. This status is used internally to assist us in managing the program and automating the process.

**Q: What does “incomplete” mean on order status?**

A: We are investigating this and trying to determine why this status is associated with some providers. We encourage you to send an email to [RA-DHCOVIDVAX@pa.gov](mailto:RA-DHCOVIDVAX@pa.gov) if you are experiencing this issue.

**Q: Is PA-SIIS going to require the consent or confirmation as part of what is submitted for the patient?**

A: No, you don’t need to enter consent confirmation into PA-SIIS. However, follow your organization's best practice guidance and policy while obtaining and recording consent.

**Q: Should we report if we notice other providers are missing a large amount of administration data in PA-SIIS?**

A: Please notify us of this using our resource accounts ([RA-DHPASIS@pa.gov](mailto:RA-DHPASIS@pa.gov) and [RA-DHCOVIDVAX@pa.gov](mailto:RA-DHCOVIDVAX@pa.gov)). It would be very helpful for us to be aware of this issue and we can reach out to work with them on this. As with all providers, COVID-19 vaccine administration data submission is mandatory. We will work with them to see what issues might exist and how we can ensure that all administered doses are being recorded, as is required.

**Q: Does the 24-hour rule to document vaccines administered still apply?**

A: Yes, that is one of the conditions of the provider agreement set by CDC and we do not foresee that changing.

**Q: Can we now place more than one order per week if needed?**

A: Yes. We want to maximize efficiency and not have more doses out than needed. If ordering multiple times per week is efficient for you, we will do our best to facilitate that.

**Q: Do we need to request the ancillary kit if we order vaccines via PA-SIIS, or will they automatically be sent?**

A: The ancillary kits will still come exactly as they have before. Ancillary kits are attached to orders in VTrckS, after they are transmitted there from PA-SIIS. Regardless of if we originate the order in PA-SIIS, or you do yourself, the process for ancillary kits will remain the exact same. However, if you have excess of ancillary kits and want to opt out of receiving them with future orders, please notify us of so before placing the vaccine orders.

**Q: How will the providers be notified if an order is approved in PA SIIS?**

A: Providers will have visibility on order status directly in PA-SIIS. The PA-SIIS system and VTrckS send an automated email to the contact email on file when the order is ready.



**Q: Is there a database we can access to determine which vaccine a patient received if they're from another state?**

A: Unfortunately, we are unable to access individual records from other states. If the patient has their vaccination card it should be annotated on that.

**Q: Sometimes we're unable to pull full doses from the adult/adolescent formulation Pfizer vials. How do we document this?**

A: Please notate in PA-SIIS anything you are unable to administer. If you are unable to extract 6<sup>th</sup> dose from a multidose vial of Pfizer vaccine for 12 and older, please record it as a waste while reconciling inventory. **Additionally, please do not extract more than the recommended doses of vaccines from a given multi dose vial in any circumstances.**

**Q: How should we be managing Moderna doses in PA-SIIS since boosters are half doses?**

A: Please refer to the following guidance:

- Count shots in arms as doses administered (regardless of full or half)
- Report waste based on doses administered, NOT discarded volume
- You will report waste only when fewer than 14/10 doses (half/full) are administered out of a vial. This is true even when full doses are discarded.
- You will never document more than 14/10 doses as administered in PA SIIS, even if more doses are given. You will not "adjust in" any doses.
- Do not extract more than 20 doses from any vial.

### **Additional Dose of m-RNA COVID-19 Vaccine for Immunocompromised Population**

**Q: Can you explain this new guidance for immunocompromised persons?**

A: CDC recommends that people who are moderately to severely immunocompromised receive an additional dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) at least 28 days after completion of the initial mRNA COVID-19 vaccine series. With emerging evidence showing some people who are immunocompromised experiencing a reduced immune response to the initial COVID-19 vaccine series, this update aims to prevent serious and possibly life-threatening COVID-19 within this population.

**Q: Who is eligible to get the additional dose?**

A: The additional vaccine should be considered for people with moderate to severe immune compromise due to a medical condition, or receipt of immunosuppressive medications or treatments. This includes people who have:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of a solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich)



syndrome)

- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids ( $\geq 20$ mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and another biologic agent that are immunosuppressive or immunomodulatory.

**Q: Are the patients who were receiving immune suppressants at the time of their 1<sup>st</sup> and 2<sup>nd</sup> dose administration, but have since stopped that treatment eligible for an additional dose of mRNA vaccines?**

A: Please have these patients consult their health care provider who have knowledge about their health history and can provide them with correct recommendations.

**Q: What is the difference between an “additional dose” and a “booster dose?”**

A: An “additional dose” refers to people who are moderately to severely immunocompromised receiving an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the initial mRNA COVID-19 vaccine series. This is because they may not have received adequate protection from their initial 2-dose vaccine series.

A “booster dose” is a supplemental vaccine dose given to people when the immune response to a primary vaccine series is likely to have waned over time.

**Q: Will providers accept anyone who says they’re immunocompromised to receive a third dose? Will people need to show a doctor’s note/prescription or other documentation?**

A: Immunocompromised individuals may discuss with their health care provider whether getting an additional dose is appropriate for them. If their health care provider is not at a site administering vaccines, these individuals can self-attest and receive the additional dose wherever vaccines are offered. This will help ensure there are not additional barriers to access for this vulnerable population receiving a needed additional dose. CDC is providing further information regarding vaccine administration to immunocompromised individuals to states, pharmacies, health centers, and all vaccine providers.

**Q: How long after completion of the initial vaccine series are you recommending the additional dose?**

A: CDC recommends the additional dose of an mRNA COVID-19 vaccine for immunocompromised individuals be administered at least 28 days after completing the initial two-dose mRNA COVID-19 vaccine series (such as for Pfizer-BioNTech and Moderna). The exact timing can be determined in consultation with a person’s healthcare provider to optimize both immunosuppressive treatments, as well response to vaccination.

**Q: Should I get an antibody test before I get a third dose?**

A: According to the CDC, antibody testing is not recommended as different tests may show different results. There is no data to support if the results will correlate with protection against COVID-19.

**Q: How are we documenting a third dose on the Vaccine Card?**

A: Please use the ‘other’ section of the vaccine card to record the third dose received by the patient.



**Q: Do you recommend those who have lost their vaccine cards to wait until they have a replacement immunization record before offering them the third dose of vaccine?**

A: Providers can log into PA-SIIS for confirmation of the vaccine administration records of the patients who received their vaccines within the jurisdiction of PA. Please use your EMR or PA- SIIS to confirm the administration dates and type of vaccine received by the patient before giving them the third dose.

**Q: How do we bill for a third dose? What are the coding instructions?**

A: According to the [CMS announcement](#) made on 8/13/2021, Medicare will continue to pay the rate of \$40 to all eligible immunizers for each dose of a COVID-19 vaccine given on or after March 15, 2021. The announcement also confirmed that this reimbursement rate will apply to all third doses of the COVID-19 vaccines. Please use this [link](#) for details on coding and payment allowances.

**Q: Should family members of immunocompromised people get a third dose?**

A: A family member of an immunocompromised person should get the third dose only if they too fall in this category. Anyone who is eligible for COVID-19 vaccines, should get vaccinated to protect themselves and those around them.

### **COVID-19 Vaccine Boosters**

**Q: Is proof of occupation required for individuals who work /reside in high-risk settings?**

A: People who work or reside in high-risk settings do not need to submit proof of employment. We expect people to self-attest, or self-report, that they fall under the guidelines set forth by the CDC.

**Q: Is an individual required to bring his/her vaccine card to third dose/booster dose appointment?**

A: Yes. People need to bring their vaccine cards for their third or booster dose appointments. If patients have lost their cards, but you can locate their records, you can still issue a new CDC vaccine card and provide booster dose to them.

**Q: Does definition of fully vaccinated change now since boosters are available?**

A: No, it doesn't. According to the CDC, everyone is still considered fully vaccinated two weeks after their second dose in a 2-shot series, such as the Pfizer-BioNTech or Moderna vaccines, or two weeks after a single-dose vaccine, such as the J&J/Janssen vaccine.

**Q: Who is eligible for booster doses of COVID-19 Vaccines?**

A: All people ages 12 years and older should receive a booster dose of COVID-19 vaccine, even if they were age 11 years or younger at the time of the primary series. Among people ages 18 years and older, as per the CDC, use of an mRNA COVID-19 vaccine for a booster dose is preferred (Moderna or Pfizer-BioNTech) even for those who received Janssen COVID-19 vaccine for their single dose primary series. However, if an mRNA vaccine cannot be given, offering the Janssen COVID-19 vaccine as a booster is preferable to not providing any COVID-19 vaccine booster. In people ages 12–17 years, only Pfizer-BioNTech COVID-19 vaccine can be



used for the booster dose at this time.

CDC recommendations now suggest that, in most cases, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over Johnson and Johnson (Janssen) COVID-19 vaccines, based on an updated risk-benefit analysis of post-vaccination blood clotting disorders.

Consult [Considerations for COVID-19 vaccination in moderately or severely immunocompromised people](#) for guidance on the use of booster doses in people who are moderately or severely immunocompromised.

**Q: Can a prescriber write a prescription for a Comirnaty (Pfizer-BioNTech) vaccine to be used off label? Can we use this as authorization even if not included in FDA authorization/EUA?**

A: Currently, off-label use of COVID-19 vaccines is not recommended. Please note that this violates the CDC's vaccine provider agreement. Additionally, health providers are not covered by the [Countermeasures Injury Compensation Program \(CICP\)](#) in the case of adverse effects during off-label use.

**Q: Someone requested and received a first dose Moderna vaccine. After entering PA-SIIS, discovered he received Johnson and Johnson in March. Should we administer the second dose of Moderna in 28 days?**

A: No, the person is considered fully vaccinated two weeks after receiving single dose of J&J/Janssen COVID-19 vaccine. Therefore, a second dose of Moderna is not required to complete the series.

**Q: Should an individual eligible for a booster shot receive the same or a different vaccine product than the primary series?**

A: The CDC says eligible individuals can choose which vaccine they receive as a booster dose. It is recommended that they consider individual risks and benefits and/or discuss the matter with their health care provider to make an informed decision.

**Q: Some people have already received a third full dose. Do they still require a booster?**

A: Moderately and severely immunocompromised people aged  $\geq 18$  years who completed an mRNA COVID-19 vaccine primary series and received an additional mRNA vaccine dose **may** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose. In such situations, people who are moderately and severely immunocompromised may receive a total of four COVID-19 vaccine doses. A person who is moderately or severely immunocompromised and has received two doses of an mRNA vaccine and  $\geq 28$  days has elapsed since the second dose, should receive an additional mRNA dose immediately (if Moderna COVID-19 vaccine is used, administer 100 $\mu$ g in 0.5ml), followed  $\geq 6$  months later by a single COVID-19 vaccine booster dose (if Moderna vaccine booster is used, administer 50 $\mu$ g in 0.25ml) (CDC, 2021)

## Dosing Information

**Q: What is the schedule and dosing information for the different series of COVID-19 vaccines?**

A: Please see the guidance from the CDC below:

## Primary Series

Vaccine manufacturer	Age indication	Vial cap color denoting formulation	Dose	Injection volume	Number of doses in primary series (interval between doses)	Additional primary dose in immunocompromised people (interval since second dose)
Pfizer-BioNTech	5-11 years	Orange	10 µg	0.2 mL	2 (21 days)	1 (≥28 days)
Pfizer-BioNTech	≥12 years	Purple or gray	30 µg	0.3 mL	2 (21 days)	1 (≥28 days)
Moderna	≥18 years	Not applicable	100 µg	0.5 mL	2 (28 days)	1 (≥28 days)
Janssen	≥18 years	Not applicable	5×10 <sup>10</sup> viral particles	0.5 mL	1 (Not applicable)	Not applicable

Pfizer COVID-19 Vaccines—there are two formulations of Pfizer-BioNTech that are FDA-approved for use in persons aged 16 years and older and FDA-authorized for use in persons aged 12-15 years:

- A formulation supplied in a multiple dose vial with a purple cap and label with a purple border, and which must be diluted prior to use. It uses phosphate buffered saline (PBS). Each diluted 0.3 mL dose contains 30 µg of modified mRNA.
- A formulation supplied in a multiple dose vial with a gray cap and label with a gray border, and which that does not require dilution prior to use. It uses tromethamine (Tris) buffer. Each 0.3 mL dose contains 30 µg of modified mRNA.

For children aged 5-11 years, the Pfizer-BioNTech 10 µg formulation is FDA-authorized for primary vaccination. It is supplied in a with an orange cap and label with an orange border and must be diluted before use. It uses a Tris buffer. Each diluted 0.2 mL dose contains 10 µg of modified mRNA.

Moderna COVID-19 vaccine is FDA-authorized for use in persons 18 years of age and older. It is administered as a primary series of 2 doses 28 days apart. Each 0.5 mL primary series dose contains 100 µg of modified mRNA. The FDA-authorized booster dose is 0.25mL and contains 50 µg of modified mRNA.

Janssen COVID-19 Vaccine is FDA-authorized for use in persons 18 years and older. It is administered as a single dose (0.5 mL) for primary vaccination. Although mRNA vaccines are preferentially recommended in most situations compared to Janssen COVID-19 vaccine, the Janssen COVID-19 vaccine may be considered in some situations. Please visit [Johnson & Johnson’s Janssen COVID-19 Vaccine Overview and Safety | CDC](#) for more information.



**Additional dose**

- Pfizer-BioNTech:  
30 µg in a volume of 0.3 mL (purple or gray cap formulation) for people ages 12 years and older  
10 µg in a volume of 0.2 mL (orange cap formulation) for people ages 5–11 years
- Moderna:  
100 µg in a volume of 0.5 mL for people ages 18 years and older

**Booster dose**

The booster dose and volume are the same regardless of whether the dose is homologous (same as primary series) or heterologous (different than primary series).

Vaccine completed for primary series	Authorized age for vaccine booster	Interval between last primary dose (including additional dose, when applicable) and booster dose	Number of doses	Injection volume and product that may be given as booster dose**
Pfizer-BioNTech	≥ 12 years	≥ 5 months	1	0.3 mL Pfizer-BioNTech*, or 0.25 mL Moderna, or 0.5 mL Janssen†
Moderna	≥ 18 years	≥ 5 months	1	0.25 mL Moderna, or 0.3 mL Pfizer-BioNTech, or 0.5 mL Janssen†
Janssen	≥ 18 years	≥ 2 months	1	0.5 mL Janssen†, or 0.3 mL Pfizer-BioNTech, or 0.25 mL Moderna

\*Only Pfizer BioNTech can be used as a booster dose in those ages 12–17 years.

†Use of an mRNA vaccine for a booster dose is preferred over Janssen vaccine.

**Q: My patient received a booster dose early. Should this be repeated?**

A: If a booster dose is given at any time earlier than the recommended interval (i.e., earlier than 2 months after completion of Janssen primary dose, or earlier than 5 months after completion of mRNA primary series), do not repeat the dose.

Administering booster doses prior to the 4-day grace period is considered a vaccine administration error.

Determine how the error occurred and implement strategies to prevent it from happening again.

Additionally, you are required to report COVID-19 vaccine administration errors to the Vaccine Adverse Event Reporting System [Vaccine Adverse Event Reporting System \(VAERS\) \(hhs.gov\)](https://www.hhs.gov/vaers)

**Q: What is the dosage volume for the Moderna booster and what is the recommended interval after primary series?**



A: Moderna COVID-19 Vaccine boosters contain 0.25 mL, or 50 micrograms. It is half of the primary series dose.

To individuals 18 years of age and older, it may be administered at least 2 months after the primary vaccination with the J&J/Janssen COVID-19 Vaccine.

As outlined by the CDC, it can also be given as a booster dose at least six months after completing the primary vaccination series with Moderna or Pfizer.

**Q: Do we still do a half dose of Moderna if they had Johnson and Johnson or Pfizer and wanted Moderna?**

A: Yes, regardless of which vaccine was given in the first series, if a booster is given with Moderna, the dosage will be half that given in the first series. Moderna boosters are always 0.5 ml (50 micrograms).

**Q: Are there additional ancillary kits that come with Moderna orders, so we have enough supplies to address boosters?**

A: Yes. Moderna vaccine orders placed on or after October 30th, 2021 will receive an extra Moderna 10 ancillary kit in addition to the regular Moderna 14 ancillary kit. A syringe of either 3 ml or 1 ml is included in the Moderna 14 ancillary kit. The Moderna 10 ancillary kit, however, comes with only 1 ml syringes. We recommend that you use 3 ml syringes for primary series vaccination and one ml syringe for booster doses.

**Q: If an immunocompromised individual received the Janssen vaccine and they are asking for the Moderna vaccine as their booster 2 months later, is the dose 0.25ml or 0.5ml?**

A: Additional doses (full doses) are recommended only for immunocompromised patients who have already received m-RNA vaccines at least 28 days previously. Therefore, in an immunocompromised individual who had received a Janssen vaccination 2 months prior, a Moderna booster shot will be given at half dose - 0.25 ml (50 micrograms).

**Q: What is the maximum number of times we can draw from the vial for the Moderna 1/2 doses?**

A: Do not puncture a Moderna vial more than 20 times.

**Q: Is there any news on when Moderna will be authorized for adolescents?**

A: Moderna has requested FDA approval for its COVID-19 vaccine for the adolescent population. However, it has not been authorized yet. We will update our provider network as soon as we have any news on this topic.

**Q: Is there a waiting period for a booster if the patient recently had a breakthrough case?**

A: If a patient recently had COVID-19, they would need to complete the isolation period and be free of symptoms before they can get a booster shot.

**Q: As a small pediatric provider, we don't have enough patients to order the large quantity of the adolescent/adult Pfizer vaccine. Can we use 0.6 ml of the pediatric version for adolescents 12 years and older?**

A: No. Please use the recommended formulation, dosage, and volume of the Pfizer vaccine for those 12



years and older.

**Q: Any word on how long patients is considered fully vaccinated with the 1 or 2 dose series before they are considered no longer covered without a booster?**

A: The definition of fully vaccinated has not changed. People are considered fully vaccinated 2 weeks after completion of the second dose of the primary series if they had received m-RNA vaccines and 2 weeks after receiving a single dose of Janssen vaccine.

**Q: What is the dosage volume for the Janssen booster and what is the recommended interval after the primary series?**

A: The Janssen booster dose is the same product and same dosage as the primary series. The booster dose of the Janssen COVID-19 Vaccine is 0.5 ml.

It may be administered at least 2 months after primary vaccination with the J&J/Janssen COVID-19 Vaccine, to individuals 18 years of age and older.

It can also be administered as a booster dose at least 6 months after completion of the primary vaccination series with Moderna or Pfizer to certain populations as outlined by the CDC.

**Q: My patient received a booster dose early. Should this be repeated?**

A: If a booster dose is given at any time earlier than the recommended interval (i.e., earlier than 2 months after completion of Janssen primary dose, or earlier than 5 months after completion of mRNA primary series), do not repeat the dose.

Administering booster doses prior to the 4-day grace period is considered a vaccine administration error. Determine how the error occurred and implement strategies to prevent it from happening again.

Additionally, you are required to report COVID-19 vaccine administration errors to the Vaccine Adverse Event Reporting System [Vaccine Adverse Event Reporting System \(VAERS\) \(hhs.gov\)](https://vaers.hhs.gov)

## **COVID-19 Vaccine Cards**

**Q: Does DOH have any plans to issue digital records of COVID-19 vaccination or smart cards?**

A: Currently, we are not in planning to implement a smart card system. If individuals have misplaced their CDC COVID-19 vaccination card and you are unable to provide a copy, they can request a copy of their immunization record from PA- SIIS which will include all immunizations recorded in the system, including COVID-19. Individuals can authorize a release of immunizations records by submitting this webform- Authorization for Release of Immunization Records

**Q: How do we handle individuals asking for replacement vaccine cards if lost?**

A: If an individual received their first dose at your location and lost a vaccine card, please confirm the vaccine administration in your EMR and PA-SIIS first, then issue a replacement CDC vaccination card to the patient. However, if the person received his/her vaccines at a separate facility like a mass vaccination site or mobile clinic, please ask the person to submit a request to obtain their Immunization record from PA-SIIS's Immunization registry. Patients can request the release of immunization records by filing this webform -



[Authorization for Release of Immunization Records](#). Please allow us 7-10 days to process these requests.

**Q: We have had several people report to us that when they request their vaccination records, the resource account denies the request and directs them back to the location they were vaccinated. Is this true?**

A: We likely were not able to find a record of their COVID immunization in PA-SIIS and are referring them back to the facility to make sure they reported their immunization.

**Q: My patient laminated their vaccine card and is due for a next dose. How should I record this on the card?**

A: Remind all patients to bring their vaccination record card to their appointment, even if they laminated it. If your patient presents a laminated vaccination card at their appointment, you can:

- Add a label or sticker to the card that fits within the appropriate space.
- Provide a new card, transfer the original information, and destroy the old card.

### **Vaccine Redistribution**

**Q: If our hospital has providers within its system, can we share any of our doses with these providers and transfer these doses over to them?**

A: Yes, you can. Every single facility receiving the vaccine must be enrolled with our program as a COVID-19 vaccine provider. Additionally, every time vaccines are moved from one location to the other, a CDC supplemental COVID vaccine redistribution agreement form should be submitted and approved. The form can be found here: [Redistribution Form](#)

**Q: We receive vaccine at our central location but want to administer at a second location. Is this considered “repositioning”?**

A: Yes. Repositioning is when you receive a vaccine at a location but there are occasions where you want to administer at a different location. Redistribution is giving vaccine to another provider to administer separately. Redistributions must be approved by DOH. Please report all vaccinations through your central location in PA-SIIS.

**Q: Does redistribution, within a healthcare system, still require preapproval from DOH?**

A: Yes, a CDC’s supplemental COVID vaccine redistribution agreement must be filed with our program before moving any COVID vaccine from one location to another permanently. The form can be found here: [Redistribution form](#). Please remember that every facility receiving, storing, or administering COVID-19 vaccines must be fully enrolled with our program as a COVID –19 vaccine provider.

**Q: What is a hub and spoke model?**

A: Hub and spoke model is a new process of COVID-19 vaccine redistribution adopted by DOH.

A hub is a centralized location that will order vaccines through PA-SIIS and store them. Spokes are the sites that will receive redistributed vaccines from the main ‘hub’ on a recurrent basis. All hubs and spokes must



be enrolled with our program as a COVID-19 vaccine provider. Please email [RA-DHCOVIDVAX@pa.gov](mailto:RA-DHCOVIDVAX@pa.gov) for more details.

**Q: How do we reconcile inventory in PA-SIIS after redistribution of vaccines?**

A: Please use this [reference sheet](#) for guidance on reconciling vaccine inventory after redistribution.

### Disposal of Vaccine-related Waste

**Q: What should we do with empty vials? Is there any guidance on recycling?**

A: Vaccine disposal guidelines vary by circumstance, according to the CDC.

- For expired or compromised vaccine: Sometimes unused vaccine and diluent doses, unopened vials, expired vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded.
- For open and broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccine pre-drawn by providers: these cannot be returned and should be discarded according to state requirements.
- For empty vaccine vials: Most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container.
- However, to prevent the counterfeit of vaccine related products, we encourage providers to dispose of all COVID-19 vaccine related waste in as a biomedical waste.

**Q: How are we disposing of expired doses of COVID vaccine? Do we request a return label as we do for VFC?**

A: Please dispose of the expired vaccines according to the local guidelines on disposal of medical waste. Please record the expired vaccine in PA-SIIS as wasted. There is no return process for COVID-19 vaccines at this time, unlike the VFC program.

### Temperature Excursions

**Q: Who should we contact if we have problem with a COVID-19 vaccine (temperature excursion)?**

A: If the vaccine experienced problems during shipment (for example, damage or temperature excursion), contact:

- Directly distributed vaccine (Pfizer): 800-666-7248 (option 8) or [CVGovernment@Pfizer.com](mailto:CVGovernment@Pfizer.com)
- Centrally distributed vaccine (for example, Moderna): McKesson Specialty Customer Service at (833) 343-2703, Monday–Friday, 8 AM–8 PM Eastern Time.

If the vaccine experienced problems after it was received and placed into storage, contact the vaccine manufacturer for guidance on improper storage and handling.

For temperature excursions (out-of-range temperatures), take immediate action:

- Label the vaccine “Do Not Use” and store at the recommended temperature range until you receive manufacturer guidance.



- Document the date and length of time of the excursion, storage unit temperature, room temperature, and inventory affected.
- Record any other relevant information.
- Contact the manufacturer for guidance on whether to use affected vaccines and whether patients need to be recalled for revaccination.
- Document the event and action taken for record-keeping requirements.

### **Coadministration of COVID Vaccines**

#### **Q: Can a flu vaccine be co-administered with COVID-19 vaccine?**

A: According to the CDC, "COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, as well as coadministration within 14 days. It is unknown whether reactogenicity of the COVID-19 vaccine is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines. When deciding whether to co-administer an(other) vaccine(s) with COVID-19 vaccine, vaccination providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection administered at different sites in the muscle."

### **Other Topics**

#### **Q: Will the providers be billed for the vaccine from the Department of Health?**

A: No. COVID-19 vaccines are free, and providers shouldn't be billed for them.

#### **Q: With the extension of the stamped expiration date on the vial, how are sites supposed to have the extended expiration (3 months) to represent this on documentation? The original or the extended?**

A: Please enter the extended expiration in EMR as well as in PA SIIS while entering patient's administration.

#### **Q: Has the Johnson and Johnson vaccine expiration been expanded any further than the already expanded date?**

A: No, the manufacturer has announced that there will be no further extension to the expiration date of its J&J/Janssen vaccines. Please discard the expired vaccines following local protocols for hazardous waste management. Additionally, all the expired vaccines must be recorded in PA SIIS as wasted.

#### **Q: What happens if an expired dose is used for a patient?**

A: It would be a vaccine administration error. Hence, a [VAERS report](#) would be needed in such a case.

#### **Q: How do we obtain monoclonal antibodies and oral antivirals for COVID-19 from the state?**



A: You may email [covidtherapeutics@pa.gov](mailto:covidtherapeutics@pa.gov) with the subject line "Monoclonal Antibodies" for inquiries regarding monoclonal antibodies and "COVID Therapeutics" for inquiries regarding oral antivirals.