

## Pediatric Providers: Administering Pfizer-BioNTech COVID-19 Vaccine

Frequently Asked Questions (FAQs)

Last updated November 15, 2021

Questions related to the adult/adolescent Pfizer vaccine for 12+ are marked in **purple**

Questions related to the pediatric Pfizer vaccine for 5-11 are marked in **orange**

### Receiving Vaccine as a Pediatric Provider

#### **1. What are the requirements to administer COVID-19 vaccine as a pediatric provider?**

1. Register in ImmuNet as a COVID-19 vaccine provider and receive a COVID PIN in the system;
2. Verify that your practice is reporting to ImmuNet; and
3. Verify that you have the appropriate capabilities to store Pfizer vaccine [for 12+](#) and [5-11 year olds](#)

More information on registering as a COVID-19 provider in ImmuNet can be found [here](#).

#### **2. Besides a pediatric practice, where can youth and young adults receive the Pfizer COVID-19 vaccine?**

Statewide locations providing vaccines to youth and young adults can be found here:

<https://coronavirus.maryland.gov/pages/vaccine#locator>.

#### **3. Which type of vaccine should I order?**

There is a Pfizer-BioNTech COVID-19 vaccine for individuals ages 12+ and a Pfizer-BioNTech COVID-19 vaccine for youth ages 5-11. These vaccines should not be used interchangeably.

On Monday, August 23, 2021, the Food and Drug Administration (FDA) gave full approval for Comirnaty, Pfizer-BioNTech's COVID-19 Vaccine, mRNA, for use as a two-dose series for individuals 16 years of age and older. Comirnaty is the official brand name of the Pfizer-BioNTech COVID-19 vaccine that was under FDA Emergency Use Authorization (EUA). **Comirnaty may still be used under the EUA to prevent COVID-19 in individuals aged 12 through 15 years.**

On October 29, the FDA issued an [Emergency Use Authorization \(EUA\)](#) for the Pfizer-BioNTech COVID-19 vaccine for youth ages 5-11.

### Pediatric Vaccine: Receiving Vaccine for Children Ages 5-11

#### **1. How can I receive the pediatric Pfizer vaccine for 5-11 year olds?**

The federal government is allocating the pediatric Pfizer vaccine to the states. Maryland is ensuring the pediatric Pfizer vaccine is available through local health departments, pediatricians, pharmacies, and health centers. If you have been allocated Pfizer 5-11 vaccine, you will receive an email

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notification that you are receiving a shipment. The email notification will be sent to the person listed as the “delivery contact” for COVID-19 vaccine in ImmuNet. To check this information, [please log into ImmuNet](#).

**2. My practice wasn’t selected for an initial order. How do I receive the pediatric Pfizer vaccine?**

Additional allocations will be made as additional supply arrives. Please plan to request additional doses you wish to receive in the next Federal allocation via the upcoming provider survey (to be sent weekly). MDH will seek to honor requests with consideration to the size of the allocation that Maryland receives. You will be notified if vaccine is allocated to your practice. In the meantime, if you require additional doses please connect with your Local Health Department and request a transfer of additional doses.

**NOTE:** The survey is for planning purposes only. Actual allocations for each provider will depend on doses made available to Maryland from the federal government. MDH will make every effort to distribute available doses equitably, but MDH cannot guarantee that all requests will be able to be fulfilled.

**3. Do practices order the 5-11 Pfizer vaccine in ImmuNet? Do you know when practices can start ordering the 5-11 Pfizer vaccine in ImmuNet?**

Maryland is currently allocating the pediatric Pfizer vaccine to providers throughout the state. We do not have a date when direct ordering in ImmuNet will start. Once direct ordering through ImmuNet is available, we will update providers about the change.

**4. Do we know the number of doses that will be shipped in future allocation waves?**

Maryland is allocated doses by the federal government. We do not know the number of doses that will be shipped in future allocation waves. For Maryland providers, the minimum number of doses of pediatric Pfizer vaccine that can be requested is 100. The Maryland Department of Health expects that vaccine doses allocated to providers are managed in a manner that ensures maximum utilization and minimal wastage. While these allocations include first and second doses, we do not anticipate any supply issues and ask providers to plan appointments and order doses accordingly. Pediatric Pfizer vaccine doses can be administered as first or second doses.

**5. Will practices be able to order more than 100 doses at a time?**

Yes, practices can request more than 100 doses at a time. Requests should be done through the survey emailed weekly.. Actual allocations for each provider will depend on doses made available to Maryland from the federal government. MDH will make every effort to distribute available doses equitably, but MDH cannot guarantee that all requests will be able to be fulfilled.

Pediatric Vaccine: Storing and Handling the Vaccine for Children Ages 5-11

**1. How will the vaccine arrive at my office?**

The Pfizer 5-11 vaccine will arrive in a single use shipping container. The shipping container will include dry ice. Please return the temperature logger using the materials in the shipping container. The empty shipping container should be destroyed upon removing the vaccine according to local site

procedures.

The single use shipping container should not be used to store vaccine. The vaccine can be placed immediately in a refrigerator (2° to 8° C; 36°F to 46°F) or an ultracold freezer (-90°C and -60°C; -130°F and -76°F). Do not place the vaccine in a regular freezer.

**2. How much vaccine will I receive?**

The pediatric Pfizer vaccine is packaged in cartons of 10 vials each, with 10 doses in each vial (100 doses total). Refer to the email notification from Pfizer for the total amount of vaccine you will receive.

**3. What are the storage requirements for the pediatric Pfizer vaccine?**

The pediatric Pfizer vaccine can be stored in a refrigerator (2° to 8° C, 36°F to 46°F) for 10 weeks. It can be stored in an ultra-cold freezer until expiration. Storage in a refrigerator and ultra-cold freezer cumulatively should not exceed 6 months.

The pediatric Pfizer vaccine should **not** be stored in a regular freezer.

**4. Will ancillary products be included with the pediatric Pfizer vaccine?**

Yes. Each shipment will include ancillary products. These include needles, syringes, diluent, alcohol swabs, limited PPE, and shot cards.

**5. Does the pediatric Pfizer vaccine require reconstitution?**

Yes. Diluent and mixing syringes will be included in the ancillary kit.

**6. Will the ancillary products include syringes appropriate for drawing up 1.3 mL of diluent?**

The syringes included with ancillary products include marked increments of 1.2 mL and 1.4 mL but do not include a marked increment of 1.3 mL. However, providers are welcome to use other syringes that they are comfortable with.

**7. Will the shipments include insulated gloves in the ancillary boxes for the purposes of handling dry ice?**

No, insulated gloves are not included in the ancillary supplies.

**8. I can only extract 9 doses (rather than 10 doses) from a vial of the pediatric Pfizer vaccine.**

If you are facing this issue, please contact Pfizer Vaccines US Medical Information at (800) 438-1985.

Pediatric Vaccine: Administration

**9. Can the previous Pfizer vaccine for 12+ be used interchangeably with the pediatric Pfizer vaccine?**

**No.** The pediatric Pfizer vaccine is a **new product** with a different NDC code and cannot be used interchangeably with the Pfizer vaccine for adolescents (12+) and adults. The pediatric Pfizer vaccine is a third of the dose size of the adolescent/adult Pfizer vaccine.

**10. Is the pediatric Pfizer vaccine a 1 or 2 dose vaccine?**

There are two (2) doses for the pediatric Pfizer vaccine. There are 21 days between the 1st and 2nd dose.

**11. Should I use a patient's age or weight to determine which vaccine product to use?**

Use a patient's age to determine the vaccine product. This is true even if a child's age changes between the 1st and 2nd dose.

**12. An 11 year old patient received a first dose of the pediatric Pfizer vaccine. This patient has returned for the second dose and they are now 12 years old. Which vaccine do I provide?**

In this circumstance, the second dose should be the Pfizer vaccine for adolescents (12+) and adults.

**13. How do I tell the difference between vials of the pediatric Pfizer vaccine and the adult/adolescent Pfizer vaccine?**

The pediatric Pfizer vaccine has an orange lid and orange border around the label. The age limit will be marked in red on the label. The adult/adolescent Pfizer vaccine has a purple lid. The age limit is marked in red on the label.

**14. What are the CPT codes for 5-11 vaccines and administration?**

The CPT code for the 1st dose of Pfizer vaccine (5-11 year olds) is 0071A. The CPT code for the 2nd dose of Pfizer vaccine (5-11 year olds) is 0072A.

**15. What is the expiration date for the 5-11 Pfizer vaccine?**

To calculate the expiration date for the pediatric (5-11) Pfizer vaccine, locate the manufacture date printed on the vial. Add 6 months to this date (including the month of manufacture). For example, a vial made in August 2021 (with 8/2021 on the vial) would expire at the end of January 2022.

Currently, there is no expiration look-up tool for the pediatric Pfizer vaccine.

**16. Will there be a pediatric Covid consent form?**

Informed consent must be provided; however, there is no standard consent language for the COVID vaccine. You should use your usual language for informed consent for COVID vaccine administration. You should also distribute the FDA EUA Fact Sheet information for the relevant vaccine to your patients and guardians. Here is the link to the Pfizer EUA Fact Sheet for pediatric Pfizer vaccine in [English](#) and [Spanish](#).

Register in ImmuNet as a COVID-19 Vaccine Provider

**1. I need assistance registering in ImmuNet as a COVID-19 vaccine provider.**

Please reference the [registration guide](#) or contact the ImmuNet Help Desk at [mdh.mdimmunet@maryland.gov](mailto:mdh.mdimmunet@maryland.gov) or (410) 767-6606. The Help Desk is open 8AM to 5PM

Monday through Friday.

2. **During the ImmuNet COVID-19 registration process, I have to enter an email and verify that an ImmuNet message arrived in the inbox. How long does it take to get the verification message?**

Once you create a profile, ImmuNet will send you an email to verify your email address.

3. **What is the turn-around-time for the ImmuNet COVID-19 registration application?**

In 3 to 5 business days, someone from the ImmuNet team will let you know the status of your application to be a COVID-19 provider.

4. **It seems that I can't enter some information now and then enter more information later. Should all the information be entered at the same time?**

If the registration cannot be completed in 30 minutes, the session will time out and clear all data that was entered. It will not "save" what was entered and let you come back to it. Please refer to the [Quick Reference Guide](#) and prepare your responses ahead of time to avoid losing your entered information.

5. **Who do we submit the CDC provider agreement to?**

The CDC COVID-19 provider agreement is completed electronically when registering as a COVID-19 provider in ImmuNet. Please refer to this [quick reference guide](#) for more information on registering as a COVID-19 provider in ImmuNet.

6. **We are registered to become a COVID provider. Is our COVID-19 ImmuNet PIN the same as our VFC PIN? If not, how do we find the PIN?**

If you are a VFC provider, your COVID-19 ImmuNet PIN will be the same as your VFC PIN. If you are a non-VFC provider, your PIN will be different. It will be preceded by "N", as in "N1234".

### Reporting COVID-19 Vaccinations

1. **Are providers required to report COVID-19 vaccinations in ImmuNet?**

Yes, all administered doses of COVID-19 vaccines must be reported to ImmuNet per the CDC Provider Agreement and within 24 hours per the Governor's Executive Order 21-01-05-01. To meet this requirement, the most efficient options to report to ImmuNet are through Electronic Health Records (EHRs) or csv file uploads. Please visit: <https://phpa.health.maryland.gov/OIDEOR/IMMUN/Pages/immunet-reporting.aspx>

2. **When I enter a vaccine into my EMR is it automatically uploaded into Immunet?** If your EMR is directly linked to ImmuNet, which it should be, then when you enter that information into your EMR it will go to ImmuNet. However, this is a question that you will need to specifically ask/follow up with ImmuNet to ensure that your EMR is compatible with this interface. More information on ImmuNet reporting requirements can be found [here](#).

### Ordering COVID-19 Vaccine in ImmuNet

1. **I am a COVID registered provider in ImmuNet. How can I order COVID-19 vaccine for my practice?**

As of August 26, 2021, **we will return to direct ordering from the federal government for adult/adolescent Pfizer, Moderna, and J&J vaccines.**

#### **Available vaccines:**

- Minimum orders for available vaccine:
  1. **Adult/adolescent Pfizer vaccine is 1170 doses (Pfizer 450 is not available for direct order)**
  2. **Moderna vaccine is 100 doses**
- Vaccines will be delivered directly from Pfizer or McKesson (Moderna).
- Vaccines will be delivered frozen (on dry ice) from Pfizer and McKesson.
- Ancillary kits will also be delivered with the vaccines.
- Refer to these delivery and handling guides for [Pfizer](#) and [Moderna](#).
- Your delivery contact listed in ImmuNet will receive information on delivery tracking.

**Less than minimum dose order:** If you need Pfizer or Moderna in a quantity less than the minimum order, please send an email to [mdh.covidvax@maryland.gov](mailto:mdh.covidvax@maryland.gov). Please review this [document](#) for instructions on how to place a COVID-19 vaccine order in ImmuNet.

2. **What temperature will the COVID-19 vaccine be shipped at? What will arrive with the vaccine?**

The Moderna vaccine and adult/adolescent Pfizer vaccine (12+) will be delivered frozen. The adult/adolescent Pfizer vaccine will be delivered on dry ice. Ancillary kits will also be delivered with the vaccines. Refer to these delivery and handling guides for adult/adolescent [Pfizer](#) and [Moderna](#).

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### **3. Are there limits to the amount of vaccine I can order?**

Ordering limits in ImmuNet are currently in place based on a provider's specialty. Not all providers will have the same ordering limit. If your office is in need of additional vaccine doses than the limit will allow, please submit a request to [mdh.covidvax@maryland.gov](mailto:mdh.covidvax@maryland.gov) with your PIN number, the number of requested doses, vaccine type (Pfizer, Moderna, J&J), and justification for the additional doses.

Note: Moderna will be available in quantities of 100 doses and adult/adolescent Pfizer will be available in quantities of 1,170.

### **4. Which staff in my office can place an order?**

Orders may be placed by any of the three contacts listed in the registration (e.g. responsible medical provider, primary vaccine contact and backup vaccine contact). If you need to update one or more of your contacts, please log into [ImmuNet](#) and make the change in your profile. Please note: If a change is made to the primary delivery contact, the email will need to be verified prior to your office being allowed to order.

### **5. How can I check the status of my vaccine order?**

You can check the status of your own COVID-19 order in ImmuNet. Please see this [guide](#) for information on how to check your ImmuNet COVID-19 vaccine order. If your order is not approved, a representative will reach out to discuss the issue and next steps. Your delivery contact listed in ImmuNet will receive information on delivery tracking.

### **6. What standard supplies will I receive with the COVID vaccines to help with administration?**

Every time you get additional vaccine doses, you will also receive a shipment with:

- Syringes
- Needles
- Alcohol prep pads
- COVID-19 vaccination record cards for recipients

These supplies will arrive in a separate shipment from the vaccines. There is currently not a way to order more ancillary supplies if you run low.

### **7. Do we need to enter our inventory in ImmuNet weekly or only when we are ready to order more?**

You only need to enter your inventory in ImmuNet when you are ready to order additional doses.

**8. Can providers in the Federal Allocation Program order Pfizer from the Maryland Department of Health (MDH)?**

Yes, providers in the Federal Allocation Program can order Pfizer COVID-19 vaccine from MDH through ImmuNet. To order vaccine, you will need to be fully registered as a COVID-19 vaccine provider and reporting in ImmuNet.

Concerns about Ordering Vaccine

**1. I missed the ImmuNet deadline or would like to make changes after it closed. Can I do that?**

If you missed the ImmuNet deadline, please email [mdh.covidvax@maryland.gov](mailto:mdh.covidvax@maryland.gov) . For the pediatric Pfizer vaccine, doses will be allocated (rather than directly ordered) for several weeks.

**2. We want to order COVID-19 vaccine this week but we are concerned about the amount we have to order. How can we get a smaller amount?**

Currently, the smallest quantity of adult/adolescent Pfizer COVID-19 vaccine that can be shipped directly to you is 1,170 doses. There are several options available:

- Use the shipment for both first and second doses;
- The Department has published a Vaccine Communication & Outreach guide; starting on Page 6 are ideas for reaching out to patients who haven't been vaccinated yet: [https://health.maryland.gov/mdpcp/Documents/Vaccine\\_Communication\\_and\\_Outreach\\_Strategies\\_in\\_Primary\\_Care.pdf](https://health.maryland.gov/mdpcp/Documents/Vaccine_Communication_and_Outreach_Strategies_in_Primary_Care.pdf);
- We are allowing practices to transfer vaccine doses amongst themselves. We can provide guidance on transporting the vaccine. We would recommend reaching out to other offices that you are familiar with or reviewing the list of providers on this website: <https://coronavirus.maryland.gov/pages/vaccine>. MDH can also connect your practice with another COVID-19 vaccine provider to initiate a provider-to-provider transfer; and
- We would be happy to share your practice information with a local immunization coordinator to discuss possibly receiving a smaller shipment.

Operationalizing the Process

**1. In trying to book our patients for COVID vaccines it is difficult to get people booked in multiples of 6. Would you rather have us get people in and vaccinated as quickly as possible, or is wasting doses more of a concern?**

Take every opportunity to vaccinate every eligible person. Our goal is to increase vaccine



confidence and for everyone who wants to be vaccinated to have every opportunity to be fully vaccinated once they become eligible. CDC and MDH are doing everything possible to minimize the amount of vaccine that goes unused.

To ensure providers do not miss an opportunity to vaccinate every eligible person, CDC recommends that providers follow [clinical best practice for vaccination as well as best practices when managing inventory](#) to maximize vaccination and minimize dose wastage. *Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose.*

Below are suggestions for minimizing wastage:

- Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.
- Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice
- Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
- As a contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a waitlist or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.

## 2. Is there a penalty for wasting vaccine?

No, there is no penalty for wasting vaccine. Please document any wastage [here](#).

If you realize you will not administer your remaining doses, please attempt to transfer these to a provider who can use them. MDH can assist you with this process. Each provider should have an anti-wastage plan. MDH and CDC's wastage policy states that if providers have a choice between vaccinating a person and turning them away until a full vial of vaccine can be used, the provider should vaccinate the person. Please refer to the [August 25 Vaccine Bulletin](#), which has information about the vaccine wastage policy.

## 3. What do I do if the vaccine is wasted or vials are providing fewer doses than expected?

If an accident or situation arises where your vaccines are no longer safe to use you must report this by completing the MDH wastage form [here](#). Similarly, if your vials draw fewer than the intended amount, you should complete the wastage form.

**4. What do I do if the vials are providing more doses than expected?**

This occurrence is common, do not be alarmed. Do still ensure you are being extremely cautious and vigilant in portioning the appropriate vaccine amounts. If this circumstance arises, we encourage you to plan to administer the extra doses to your patient population to further hasten the vaccine rollout. If this is for a two dose regimen, you may be able to get extra doses from the second dose shipment as well. If you do not get extra doses from the second dose shipment, you may use an allocated first dose for that purpose.

**5. For VFC the doses are very closely tracked 1 for 1. How will this be tracked when we know there will need to be some wastage when we cannot find enough patients to use an entire vial before expiration?**

Please use the [Vaccine Wastage Form](#) to submit this information after each clinic day. The form allows you to select this exact scenario (vaccine reconstituted and fewer than 6 doses given).

**6. When a vial is reconstituted and less than 6 doses are given before the 6 hour expiration time, do we need to send in a waste form for the unused/wasted doses after each clinic day?**

Yes, please use the [Vaccine Wastage Form](#) to submit this information after each clinic day. The form allows you to select this exact scenario (vaccine reconstituted and fewer than 6 doses given).

**7. Do we need to return (1) empty vials? (2) vials with 1-2 expired doses?** No, you do not need to return empty vials or vials with expired doses. Please use the [Vaccine Wastage Form](#) to submit wastage information after each clinic day. The form allows you to select this exact scenario (vaccine reconstituted and fewer than 6 doses given).

**8. I've run out of CDC vaccination cards, how do I order more?**

Unfortunately, there is no way to order additional CDC vaccination cards. Please reach out to [mdh.covidvax@maryland.gov](mailto:mdh.covidvax@maryland.gov) and we will aim to provide a PDF of the vaccination cards for you to use. This PDF may not be posted anywhere publicly or shared outside of your office. You are also not able to order any additional ancillary supplies. Like the vaccine, these supplies remain in high demand and limited supply and need to be allocated accordingly.

**9. Do I need to get a signed consent form from my patients prior to vaccinating?**

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Questions related to the adult/adolescent Pfizer vaccine for 12+ are marked in purple

Questions related to the pediatric Pfizer vaccine for 5-11 are marked in orange

Informed consent must be provided; however, there is no standard consent language for the COVID vaccine. You should use your usual language for informed consent for COVID vaccine administration. You should also distribute the FDA EUA Fact Sheet information for the relevant vaccine to your patients, as this document answers common questions and patients can make an informed decision about receiving the vaccine. Here is the link to the Pfizer EUA Fact Sheet in [English](#) and [Spanish](#).

Additionally, you may use the CDC pre-vaccination screening forms ([English](#) and [Spanish](#)) to screen patients prior to vaccination. Note that this form does not include a line for signed consent, so you should add your own consent language in addition to these screening forms.

9. **Are we required to keep the pre-vaccination checklists for COVID vaccine on file?** Yes, providers should retain the electronic or written pre-vaccination checklist as a part of the patient's permanent medical record. Providers should also continue to use their usual language/practice [used for routine vaccinations] for consent for COVID-19 vaccine administration.
10. **During our first COVID vaccine clinic, we had all the parents sign waivers for the minors. When they signed the waiver it did state that they will need two vaccines. Are we required to have them sign a waiver for the second vaccine as well?**

Regarding consent forms for the second dose, you should use the same established language and processes your practice typically follows for routine vaccinations when consenting patients for COVID-19 vaccine administration.

In other words, if your practice typically requires parental consent or a waiver be signed prior to each vaccine administration in a multi-dose vaccination series, then your practice should continue to follow this process when administering the second COVID-19 vaccine. If your practice typically requires a waiver to be signed only once (i.e., one waiver for the entire vaccine series), then you should continue to follow this process. Providers should retain the electronic or written pre-vaccination checklist as a part of the patient's permanent medical record.

11. **Do 16 and 17 year olds need parental consent for COVID vaccine in Maryland?**

According to the Maryland Department of Health Center for Immunization, parental consent is needed for all vaccinations for everyone under the age of 18 except for vaccines for HPV (human papillomavirus) and Hepatitis B. Each provider may develop

their own procedures for handling parental consent.

**12. If we order more than we are able to administer, would there be an option to "return" unopened vials within a certain time frame?**

At this time, we are not able to accept "returns" of vaccine from providers. We understand that the order may be larger than your need. The CDC asks that providers not miss any opportunities to vaccinate every eligible person who presents, even if it means puncturing a multi-dose vial to administer vaccine without having enough people available to receive each dose.

**13. I assume these are multi-dose vials? What is mL for the vial?**

The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration. After dilution, one vial contains 6 doses of 0.3 mL. For more information, please refer to [Pfizer EUA Fact Sheet](#).

**14. What diluent do we use for the Pfizer COVID-19 vaccine?**

The provider **must use only the diluent specified by the manufacturer**. 0.9% sodium chloride (normal saline, preservative-free) is required for reconstitution. Diluent is provided in the ancillary supplies (along with syringes, needles, and other needed supplies) for the Pfizer COVID-19 vaccine. Ancillary supplies are shipped separate from the vaccine.

If a provider chooses to use a larger volume of 0.9% sodium chloride injection, they can only use it once for reconstitution (i.e., after removing 1.8ml, discard the remaining diluent).

The Pfizer COVID-19 vaccine is a preservative free vaccine, meaning it does not contain the antiseptic and antifungal agent known as thimerosal which is added to some vaccines to prevent the growth of bacteria, fungus, or other microorganisms that might contaminate a vial when a needle is inserted. For this reason, COVID-19 vaccine providers are strongly advised to adhere to the Pfizer reconstitution instructions provided by the manufacturer and supported by the U.S. Centers for Disease Control and Prevention and the U.S. Food and Drug Administration.

Adult/Adolescent Pfizer Vaccine Storage

**1. How do we safely store the adult/adolescent Pfizer vaccine?**

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Questions related to the pediatric Pfizer vaccine for 5-11 are marked in orange

The adult/adolescent Pfizer COVID-19 vaccine (undiluted) can be stored in a freezer between -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Providers should monitor how long the vaccine has been in the freezer using CDC's beyond-use data labels. Providers can also use CDC's freezer storage temperature log to document storage unit temperatures.

The adult/adolescent Pfizer COVID-19 vaccine (undiluted) can be stored in a refrigerator between 2°C to 8°C (35°F to 46°F) for up to 1 month (31 days). Thawed vaccine should NOT be refrozen. Providers should monitor how long the vaccine has been in the refrigerator using CDC's beyond-use data labels.

***Total storage time for Pfizer in the freezer and refrigerator should not exceed 45 days.***

More information about revised storage is found on the Pfizer Fact Sheet for Healthcare Providers: <https://www.fda.gov/media/144413/download>

## **2. What are the freezer specifications and temperature monitoring requirements for COVID-19 vaccine storage?**

COVID-19 vaccination providers must have proper storage and temperature monitoring equipment to meet the specific needs of the COVID-19 vaccine product(s) they have in their inventory. This includes the correct vaccine storage unit(s), whether a refrigerator, regular freezer, or ultra-cold freezer. Purpose-built, also referred to as “pharmaceutical-grade,” units are preferred and designed specifically for storage of biologics, including vaccines. This can be either a stand alone freezer or a household size combination unit with a freezer. The registered COVID provider must have a freezer to store COVID -19 vaccination. Vaccines can not be stored in a dorm style unit.

It is essential for each vaccine storage unit to have a temperature monitoring device (often referred to as digital data loggers or DDL devices) to ensure that vaccines are stored within the correct temperature range. Staff must check and record temperatures at the beginning of each workday to determine if any excursions have occurred since the last temperature check. These devices should include a minimum and a maximum reading. More information about digital data loggers is found in the CDC's [Vaccine Storage and Handling Toolkit](#).

Any temperature reading outside the range recommended by the manufacturer is considered a temperature excursion and requires immediate action. To determine whether a vaccine is likely to still be viable, COVID-19 vaccine manufacturers will analyze information about the magnitude of the temperature excursion, including the total

amount of time that temperatures were out of range.

3. **How do I check the expiration date on the adult/adolescent Pfizer COVID-19 vaccine?**

The CDC maintains a database of COVID-19 vaccine lot numbers and expiration dates, which can be accessed here: <https://vaccinecodeset.cdc.gov/LotNumber>.

Providers should consider using the [COVID-19 Vaccine Expiration Date Tracking Tool](#) to record updated expiration dates for COVID-19 vaccine as additional stability data are available from the manufacturer. Document the current date, the vaccine lot number, and the updated expiration date in the appropriate columns, including the information source and the name of the person completing this form. When the current expiration date gets close, contact the manufacturer before discarding the vaccine. Keep this document for 3 years or longer if required by your jurisdiction.

4. **Is there any requirement that each freezer get registered in some way with the state or federal governments?**

The Center of Immunization reviews the storage unit the COVID Provider identified in the registration to ensure that the COVID Provider has an acceptable storage unit at the time of registration.

5. **Are there any resources for purchasing a freezer?**

At this time, there are no financial resources to help providers purchase a freezer. Please refer to the June 9, 2021 webinar for descriptions of appropriate and inappropriate units for vaccine storage.

6. **Is it possible to get the dimensions of a tray of adult/adolescent Pfizer vaccine so that we can confirm how many we can store?**

Adult/adolescent Pfizer vaccine can be ordered in doses of 1,170. An order of 1,170 doses comes as 195 multidose vials, 6 doses per vial. The dimensions of a vaccine tray is approximately 9 in x 9 in x 1.5 in. More information may be found at: [Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary \(cdc.gov\)](#)

7. **Who do we call if there is a problem with a vial that we receive?**

When you receive your vaccine shipment, please inspect it carefully. Check that you received the correct quantity and that the vaccine trays are not wet or appear to have been wet. The vials should be secure, closed, and not punctured. If there are issues with the vaccine shipment, contact the vaccine manufacturer's customer service. This information will be in the vaccine shipment. Ancillary supplies are typically sent by

McKesson. Please contact McKesson customer service for any issues with ancillary supplies.

8. **How hard is it to reach the manufacturer? What is the usual wait time?** The response time by vaccine manufacturers customer service has been good. Because they are serving the nation, there may be delays at times. We recommend using both the provided email and phone methods to contact customer service.

9. **How long does it take for the frozen COVID vaccine to thaw? How soon can you give the vaccine after removing it from the freezer?**

For adult/adolescent Pfizer COVID-19, remove 1 vial for every 6 recipients. The vaccine takes 3 hours to thaw in a refrigerator at 2°C to 8°C (35°F to 46°F) . Otherwise, it takes 30 minutes for undiluted, unopened Pfizer COVID-19 vaccine to thaw at room temperature. Post-dilution, the vaccine must be used within 6 hours.

The Moderna COVID-19 vaccine should be thawed in the refrigerator over 2.5 hours. The vaccine should then sit for 15 minutes at room temperature before administration.

9. **What is the typical shelf life of the vaccines?**

Vials stored in an ultracold storage unit can be used until the last day of the month printed on the tray and each vial.

Per the FDA, the shelf life of properly stored (between -90°C to -60°C (-130°F to -76°F)) cartons and vials of the adult/adolescent Pfizer vaccine with an expiration date of August 2021 through February 2022 printed on the label may remain in use for **three months beyond the printed date** as long as authorized storage conditions have been maintained. This means that vaccines with an expiration date of August 2021 through February 2022 can be stored at ultra-cold temperatures for up to 9 months. This does not apply to vials dated July 2021 or earlier. Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are **NOT** eligible for extension.

Adult/adolescent Pfizer vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Undiluted vaccines thawed under refrigeration, may be stored in the refrigerator 2°C to 8°C (35°F to 46°F) for up to 1 month. Undiluted vials may be stored at room temperature for no more than 2 hours.

**10. You recommended adding water bottles to the refrigerator that is storing vaccine. Is this recommendation for all models or only certain models of refrigerators?** We recommend using water bottles in all models of refrigerators. They can also be used in freezers; keep in mind that the water will expand as it freezes. Water bottles will keep the vaccine out of areas of the refrigerator where they do not belong. They will also assist in maintaining proper temperature in the event of a power outage or unit malfunction.

**11. Is the backup DDL already supposed to be in the fridge/freezer with the current DDL? If you're pulling your backup DDL out of the box the probe is going to be too warm and out of range.**

In the event that you are planning to transport the vaccine, you do need to condition the probe for your backup DDL. If you are experiencing a power outage or mechanical failure, go ahead and transport the primary DDL with the vaccine.

### Partnering with Others

**1. Can I distribute the vaccine I receive to other providers?**

A provider who has been allocated doses from Maryland may transfer doses to another vaccine provider. The receiving vaccine provider must have completed the [CDC provider agreement](#).

Providers must keep records of what doses have been transferred and must complete a transfer request [here](#). The form will ask to/from, date, type (1st or 2nd) and amount. Both the transferring provider and the receiving provider are responsible for ensuring that their part of the transfer is executed correctly ( i.e., transfer paperwork, chain of custody, storage and handling, etc.).

Receiving providers must have the proper reporting mechanism in place and are responsible for reporting the vaccinations to ImmuNet. The original provider must ensure that the receiving provider has access to second doses.

**2. Do ancillary supplies need to be redistributed along with vaccine?**

Yes, in addition to transferring vaccine, you must also transfer ancillary supplies (needles, syringes, alcohol prep pads, masks, and other personal protective equipment). Make sure you have enough supplies for the doses you are transferring.

**3. Are sites who receive vaccine through transfer required to be COVID-19 vaccine**



## providers?

Yes, each site receiving vaccines must make sure they are fully registered as a COVID-19 vaccine provider. Receiving providers must have the proper reporting mechanism in place and are responsible for reporting the vaccinations to ImmuNet.

To contact the ImmuNet Help Desk, email [mdh.mdimmunet@maryland.gov](mailto:mdh.mdimmunet@maryland.gov) or call (410) 767-6606 (8 AM-5 PM Monday through Friday).

4. **Who is responsible for reporting COVID-19 vaccinations to ImmuNet?** Receiving providers must have the proper reporting mechanism in place and are responsible for reporting the vaccinations to ImmuNet. More information on reporting requirements can be found [here](#).

## Who Should I Be Vaccinating?

### 1. Who can I vaccinate?

We highly urge practices to continue to prioritize their vaccine outreach to those with [underlying medical conditions](#) and African American and Hispanic patients to achieve equity in vaccine administration. You may vaccinate your practice's patients as well as community members, family members, or others who are not patients at your practice.

### 2. Can I vaccinate patients who do not live in Maryland?

In general, you may vaccinate patients who live outside of Maryland. Of course, since Maryland gets vaccine allocations from the federal government in proportion to Maryland's population, most patients you vaccinate should live in Maryland. But it is generally acceptable to vaccinate patients who live in other states (including VA, DC, and other nearby states as well). Make sure when you vaccinate patients who live in other states that they will be able to come back to your practice for their second dose appointment.

### 3. How can I find out my patients' vaccination status?

You can use the CRISP vaccine tracker (<https://vacctrac.crisphealth.org>) to view your patients vaccination status and see if they were vaccinated elsewhere. You can use this [quick guide](#) to understand how to access and use the Vaccine Tracker.

### 4. How can I use CRISP's Vaccine Tracker to target my COVID vaccine outreach?

You can filter in CRISP by age, race, and presence of underlying medical conditions to target outreach.

## 5. What resources are available when parents have questions?

The CDC's [Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit](#) has web pages and print materials to help providers answer questions and address concerns.

### Billing and Coding

#### 1. How do we bill?

Information about reimbursement may be found at:

- <https://www.hrsa.gov/covid19-coverage-assistance>
- <https://www.hrsa.gov/coviduninsuredclaim>
- <https://www.cms.gov/medicare/covid-19/coding-covid-19-vaccine-shots>

The CARES Act mandates comprehensive coverage of COVID-19 vaccination for most people with private health insurance. This applies to all non-grandfathered major medical plans in both the individual/family market and group (employer-sponsored) market.

The CARES Act does not apply to grandfathered health plans. These are plans purchased on or before March 23, 2010, and account for roughly 14% of all employer-sponsored health plans in the United States. For these plans, COVID-19 testing is covered with no cost-sharing for the duration of the public health emergency under the Families First Coronavirus Response Act. What may not be covered is the cost of the vaccine or its administration.

There is a HRSA program called the Coverage Assistance Fund to reimburse COVID vaccine providers for any private insurance plans that have denied coverage for a patient for the COVID vaccine administration fee. See [here](#) for details on how to submit these claims to HRSA for reimbursement. Note that this is a different portal from the HRSA reimbursement for uninsured patients.

#### 2. Are we able to bill insurance for an administration fee when giving the vaccine?

Yes, you may bill insurance an administration fee. You cannot accept a copay from the patient. As of March 15, Medicare reimbursement amounts to \$40 for a single dose or \$80 for two doses (\$40 per dose).

- Details from CMS on billing can be found [here](#)
- CPT codes for billing can be found [here](#)
- To collect reimbursement for uninsured patients, you may submit claims to HRSA

using the information [here](#)

- Note that HRSA asks for patient SSN or state identification/driver's license when submitting for reimbursement. If you cannot obtain SSN or other identification for any reason, HRSA also notes that you can attest that you attempted to obtain SSN or other identification but were unable to. See [here](#) for details.

**3. Do all private insurers cover the COVID vaccine administration fee?** The [CARES Act](#) mandates comprehensive coverage of COVID-19 vaccination for most people with private health insurance. This applies to all non-grandfathered major medical plans in both the individual/family market and group (employer-sponsored) market.

**4. What about health plans exempt from the CARES Act?**

The CARES Act does not apply to [grandfathered](#) (exempt) health plans. These are plans purchased on or before March 23, 2010, and account for roughly 14% of all employer-sponsored health plans in the United States. For these plans, COVID-19 testing is covered with no cost-sharing for the duration of the public health emergency under the Families First Coronavirus Response Act. What may not be covered is the cost of the vaccine or its administration. *See question below for how to get reimbursed if you are denied claims from private insurers.*

**5. Private insurers are denying claims I submitted. What can I do?**

There is a HRSA program called the Coverage Assistance Fund to reimburse COVID vaccine providers for any private insurance plans that have denied coverage for a patient for the COVID vaccine administration fee. See [here](#) for details on how to submit these claims to HRSA for reimbursement. Note that this is a different portal from the HRSA reimbursement for uninsured patients.

**6. Can my practice bill private insurance that is not in-network for my practice?**

Yes, you [may](#) bill private insurance that is out-of-network for your practice.

Other

**1. How can patients view their vaccination records (COVID and otherwise) online?**

Patients can view their immunization records online via Maryland MyIR (stands for My Immunization Record). Maryland MyIR gets data directly from ImmuNet. You can instruct patients to go to <https://md.myir.net/>, click "Register Today", and follow the prompts to view their immunization records. Patients who find errors or need to have their immunization record updated in MyIR can complete this [form](#).

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Questions related to the adult/adolescent Pfizer vaccine for 12+ are marked in **purple**

Questions related to the pediatric Pfizer vaccine for 5-11 are marked in **orange**

2. **How do I add my practice to the [Maryland COVID-19 Vaccination Sites map](#) public listing?** The weekly survey will ask if you would like your practice added to the public map. Please provide enough information (practice name, address, and appointment information) for a public listing.

3. **My practice is listed on the [Maryland COVID-19 Vaccination Sites map](#), but I'd like to update our information. How do I do so?**

At the bottom of your listing, there is a link titled "Site operators: submit an update for this information" (see screenshot below). You may click on that link to update your information.



4. **How do I know I am reporting vaccinations into ImmuNet?**

As your practice continues to receive vaccine doses, we need to ensure that all doses administered are successfully recorded in ImmuNet. Please take some time to regularly take the steps below to compare the total administered doses for your practice in ImmuNet versus your EHR:

1. View your total administered doses in ImmuNet through CRISP:
  - a. Open CRISP Reporting Services:  
<https://reports.crisphealth.org/#dashboard>
  - b. Select the COVID-19 vaccination reports by selecting "Public Health" then "COVID-19" then "COVID-19 Vaccinations"



- c. Once you are in the Covid-19 reports select the “Doses Administered by Demographics” report (the 6th tab)
- d. Finally, filter the information down to only your practice by selecting your practice from the practice list presented under “Administrating Facility”  
Tip: Be sure to uncheck “(all)” , then find your facility from the list.
- e. View your practice’s total first and second doses administered in the top left box of the report:

### Doses Administered by Demographics

Total First Doses Administered: **693**

Total Second Doses Administered: **179**

Total Single Doses Administered: **183**

Totals above reflect current filter selections

Vaccine data through: **May 6, 2021**

2. Obtain your total number of administered first and second doses from your EHR or other tracking system
3. Compare the data from ImmuNet (CRISP) and your EHR. If the reported doses are off by more than ~5%, please notify MDH by filling out the variance request for research form [here](#). After filling out the form, an MDH team member will investigate and you will be contacted to resolve any issues.

#### **5. Many of our 18-22 year olds got their vaccines out of state in college. Will this information be captured by ImmuNet?**

Out-of-state immunizations will only appear in ImmuNet if a patient asked their Maryland-based provider to enter the information. Patients who need to have their immunization record updated in MyIR can complete this [form](#).

#### **8. Can you comment on the myocarditis/pericarditis issue in older kids with the MRNA vaccine?**

Since April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna),

particularly in adolescents and young adults. There has not been a similar reporting pattern observed after receipt of the Janssen COVID-19 Vaccine (Johnson & Johnson). In most cases, patients who presented for medical care have responded well to medications and rest and had prompt improvement of symptoms. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older. Onset was typically within several days after mRNA COVID-19 vaccination, and cases have occurred more often after the second dose than the first dose. CDC and its partners are investigating these reports of myocarditis and pericarditis following mRNA COVID-19 vaccination, CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older given the risk of COVID-19 illness and related, possibly severe complications, such as long-term health problems, hospitalization, and even death. Additional clinical considerations from the CDC can be found [here](#).

**10. Are there training or video tutorials available on vaccine administration?**

- Centers for Disease Control and Prevention (CDC)'s "You Call the Shots!" Training Modules for [Vaccine Administration](#) and [Vaccine Storage and Handling](#)
- CDC's updated training modules for Pfizer, Moderna and Janssen training module: [COVID-19 Vaccine Training Modules \(cdc.gov\)](#)
- Pfizer BioNTech: [Preparation and Administration Video](#)