Providers Serving Youth Ages 12+: Administering Pfizer-BioNTech COVID-19 Vaccine
Frequently Asked Questions (FAQs)
Last updated May 26, 2021

<u>Receiving Vaccine as a Provider Serving Youth Ages 12+</u>

1. **We have heard that the MD mass vaccination clinics have already started to dispense the vaccine to the 12 to 15 year olds. So, what is the next step for private practitioners?**
   Yes, currently a majority of Maryland's mass vaccination sites are serving youth ages 12+ to receive the Pfizer vaccine. Additionally, nearly 400 pharmacies across the state, several Local Health Departments and hospital systems are providing Pfizer COVID-19 vaccinations to youth ages 12 and older. All these locations can be found at: https://coronavirus.maryland.gov/pages/vaccine#locator.

   MDH is conducting outreach to determine the readiness of practices to administer the Pfizer vaccine to those 12 to 15. To begin this process, please follow these steps:

   1. Has your practice registered to become a COVID provider in ImmuNet? (additional documentation completed and approved via ImmuNet) https://www.mdimmunet.org/prd-IR/portalInfoManager.do.
   2. Does your practice have the capacity to store 1,170 or 450 doses in a freezer or refrigerator according to the latest FDA guidelines?

   For those unable to store the vaccine or use 1,170 doses or 450 doses, we are working to link practices with their local health departments or pharmacy partners to coordinate efforts.

2. **I need assistance registering in ImmuNet as a COVID-19 vaccine provider.**
   For VFC providers to complete their profile registration to receive COVID vaccines, you need to:
   1. Sign in to ImmuNet;
   2. Go to edit your Profile;
   3. Check the box indicating you would like to order COVID vaccines; and
   4. Complete the COVID sections in your profile.

   Please reference pages 5 and 6 of the registration guide or contact the ImmuNet Help Desk at mdh.mdimmunet@maryland.gov or (410) 767-6606. The Help Desk is open 8AM to 5PM Monday through Friday. Each organization that orders vaccines in ImmuNet is assigned a PIN in ImmuNet.

<u>General</u>

1. **Which type of vaccine will I receive?**
   As a provider serving youth 12 years and older, you will be receiving the Pfizer-BioNTech COVID-19 vaccine. This is the only COVID-19 vaccine currently approved for 12 to 15 year olds. Information on the vaccine is found here:
   https://www.fda.gov/media/144413/download

2. **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.

3. **Where can I administer the vaccine?**
   You MUST administer vaccine doses only at the site chosen to receive the vaccine. All vaccines allocated and ordered for your practice site are intended for the chosen practice site, and that site only.

4. **Which sites are eligible to receive doses?**
   Sites that serve youth ages 12 and older are eligible to receive doses. To receive doses, sites will need:
   - Approval in ImmuNet and corresponding COVID PIN
   - Ensure ImmuNet reporting capabilities have been defined
   - Appropriate storage of the Pfizer-BioNTech vaccine. Details are found here:
     https://www.fda.gov/media/144413/download

5. **Can I defer participating once eligible?**
   Yes, please indicate those details in your survey response, by indicating you would like 0 first/single doses the following week. We will include you in subsequent survey rounds. However, we encourage all providers to push to ready themselves for the program as soon as possible for Maryland to fulfill its ambitious vaccination goals and leave no Marylander behind.

What is the timing for dose allocations? When should I expect information each week?

1. **How can I make sure I do not receive any vaccines one week if I want to skip a week?**
   If you request to receive 0 doses on the survey, you will not be sent any vaccines that week. This will not keep you from receiving doses in future weeks.

2. **Can I request fewer than 1,170 doses?**
   Starting in June 2021, limited quantities of 450 Pfizer doses will be available for request. This will be in addition to the option for 1,170 doses.

3. **When do I find out if I get the number of doses I requested each week?**
   Vaccine orders must be placed by 12PM (noon) on Tuesdays for orders for the following week. You will receive notification on Friday about how many doses were placed for your practice. If you do not receive notification on Friday, you will not receive any doses the following week. If you request 0 doses in the survey, you are guaranteed to receive 0 doses. Pfizer doses are typically delivered on the following Monday.

4. **I missed the survey deadline or would like to make changes after it closes. Can I do that?**
   No, our team works with a very lean and refined process to fulfill orders for providers across the state. Late submissions compromise with accuracy and disrupt our statewide process.

5. **By when do I need to administer my vaccine doses?**
   As you know, the quicker we administer doses, the better. Your goal should be to administer all your requested vaccines in a given week. That said, we understand not all practices are the same, practices range in size and levels of demand. The primary goal of the program is to not miss any opportunity to vaccinate a patient, and with that it is understood that wastage will occur. Regardless of these differences, we still want all practices to participate, so do not refrain from continuing to request doses if you cannot fully meet this goal every week. Vaccine doses must be utilized by the expiration date, and must be stored appropriately as per guidelines.

Who Should I Be Vaccinating?

1. **Who can I vaccinate?**
   The Pfizer-BioNTech COVID-19 vaccine is approved for anyone 12 years and over. More information is found here: https://www.fda.gov/media/144413/download.
   We highly urge practices to continue to prioritize their vaccine outreach to those with underlying 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.

Operationalizing the Process

1. **How should I document vaccinations I administer?**
   All doses should be documented and reported to ImmuNet within 24 hours of administration. This can be done through your EHR or through the CSV reporting method. More information about reporting requirements is found here: https://phpa.health.maryland.gov/OIDEOR/IMMUN/Pages/immunet-reporting.aspx

2. **How can I make sure I don't end up with wasted vaccine?**
   Other practices have found having a long standby list can be helpful to make sure no doses are wasted. However, today many practices are struggling with vaccine hesitancy and low demand. We should remember that the highest priority is to not miss any

opportunity to vaccinate a patient, and *if wastage occurs as a byproduct, that is acceptable*.

3. **Can I transfer vaccines to another facility?**
No. Due to the obstacles of storing the Pfizer vaccine, at this time, all the vaccines allocated and ordered for your private practice are intended for your practice only. Facilities that have ordered doses are strategically selected based on confirmed eligibility and careful analysis of how to best fulfill the State's goals for expeditious and equitable roll-out. MDH is currently exploring how to best handle vaccine transfers among practices. There are strict guidelines and documentation that must be adhered to.

4. **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.

5. **What do I do if the vials are providing more doses than expected?**
This occurrence is common, do not be alarmed. Continue staying vigilant and extremely cautious 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.

6. **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 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.

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

<u>Billing and Coding</u>

1. **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.

2. **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.

3. **Grandfathered Plans**
   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. *See question below for how to get reimbursed if you are denied claims from private insurers.*

4. **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.

5. **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.

Storage
1. **How do we safely store the vaccine?**
   FDA has amended the Pfizer emergency use authorization (EUA) to allow undiluted, thawed Pfizer COVID-19 vaccine vials to be stored in the refrigerator at 2°C to 8°C (35ºF to 46ºF) for up to 1 month. The Pfizer COVID-19 vaccine vials must remain undiluted to remain at 2°C to 8°C (35ºF to 46ºF) for 1 month. The up to 1-month 2°C to 8°C (35ºF to 46ºF) storage duration must be within the labeled expiration date (i.e., not cumulative).

   Step down storage and handling for Pfizer COVID-19 vaccines is now as follows:

   1. All Pfizer configurations are shipped ultra-cold.
   2. Ultra-cold (-70°C) may be stored in an ultra-low temperature (ULT) freezer or temporarily in the shipper with regular dry ice replenishment.
   3. Frozen (-20°C) Pfizer COVID-19 vaccine vials may remain frozen at -20°C for up to 2 weeks. (unchanged)
   4. Refrigerated (2°C to 8°C) (35ºF to 46ºF) Pfizer COVID-19 undiluted vaccine vials may remain at 2°C to 8°C (35ºF to 46ºF) for 1 month (31 days).

Total storage time for Pfizer in the freezer and refrigerator should not exceed 45 days. More information about revised storage is found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf

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 cannot 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. **Is there any requirement that each freezer get registered in some way with the state or federal governments?**
MDH's Center for Immunization reviews the storage unit the COVID Provider identified in their ImmuNet registration to ensure that the COVID Provider has an acceptable storage unit at the time of registration.

4. **The shipping container allows you to recharge temperature every 5 days with dry ice for a total of 30 days per training video. Can we keep half of the shipment in the shipping container recharging with dry ice until it's time to get ready to administer 2nd doses?**
FDA has amended the Pfizer emergency use authorization EUA) to allow undiluted, thawed Pfizer COVID-19 vaccine vials to be stored in the refrigerator at 2°C to 8°C (35ºF to 46ºF) for up to 1 month (31 days). We recommend storing the Pfizer vaccine vials in a freezer (-20°C) for up to 2 weeks and a refrigerator (2°C to 8°C) (35ºF to 46ºF) for up to 31 days rather than using the shipping container. Total storage time for Pfizer in the freezer and refrigerator should not exceed 45 days.

Due to the revised storage instructions from the FDA, the manufacturers are requesting the thermal shipping container be returned within 10 days. Follow the manufacturer's

instructions for returning; a return shipping label will be included in the shipping container at delivery.

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

5. **Is it possible to get the dimensions of a tray of vaccine so that we can confirm how many we can store?**
Pfizer can be ordered in doses of 1,170 or 450. 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. An order of 450 doses comes in 3 trays with each tray containing 25 multidose vials. Each tray is approximately 3.5 in X 3.5 in X 1.5 in.

More information may be found at: Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary (cdc.gov)

6. **Do you know if the CDC will provide a deep freezer to store vaccines? If so, how do we go about getting set up?**
At this time, providers must provide their own ultra-low temperature freezers. Vendors can be found here: https://www.cvdvaccine-us.com/product-storage-and-dry-ice

Becoming a COVID-19 Vaccine Provider

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. For more information on reporting, please visit:
https://phpa.health.maryland.gov/OIDEOR/IMMUN/Pages/immunet-reporting.aspx

2. **Are there training or video tutorials available on vaccine administration?**
Yes, there are several options for training, including:

- 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](#)
- Additional training is being prepared by MDH. We will provide updated information as soon as possible.

Partnering with Others

1. **I am willing to serve as a vaccination clinic to others outside of my patient panel, once I understand how that process works in terms of logistics, documentation and reimbursement.**
   If you are willing to open your clinic to those outside of your patient panel, it would be your responsibility to organize all of the logistics to complete the vaccinations. This includes ordering the vaccine, storing the vials, and scheduling first and second dose appointments. If you would like to explore partnerships with other practices, please reach out to your local health department or local pharmacies. Information about reimbursement may be found at:

   - https://www.hrsa.gov/covid19-coverage-assistance
   - https://www.hrsa.gov/coviduninsuredclaim
   - [Coding for COVID-19 Vaccine Shots | CMS](#)

2. **Can I distribute the vaccine I receive to other providers?**
   At this time, providers should not distribute vaccine ("redistribute") to other providers. If a provider cannot order vaccine on their own, MDH highly recommends working with local health departments to coordinate vaccine distribution. Further information about redistribution possibilities will be forthcoming.

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). 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.

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 would 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.