

Registering as a COVID-19 Vaccine Provider

1. 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.

2. 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".

Ordering Vaccine

1. With smaller doses for Pfizer, do we have a longer turn around to use?

You can continue to use the Pfizer vaccine until the expiration date, provided that the storage guidelines are followed.

2. 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.

3. Is there a mechanism to order lower quantities of Pfizer if we are a small office?

Orders for Pfizer doses can only be placed in increments of 450 or 1170. Smaller practices that cannot utilize an entire tray of Pfizer vaccine are encouraged to contact their local health department to inquire about a dose transfer

4. 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.

5. I just want to be clear that we can order either product?

Yes, providers can choose which COVID-19 vaccine product they would like to order. Please note that Pfizer COVID-19 vaccine is the only product currently approved for 12 to 17 year olds.

6. 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.

7. We had initially been told to do a weekly survey on Tuesdays. Is that no longer needed?

That is correct. The direct ordering process will replace the weekly surveys. Starting on Friday, June 11, providers will be able to directly order COVID-19 vaccine from 8 am to 4 pm. Providers can expect delivery of vaccine the following Monday or Tuesday.

Pfizer COVID-19 Vaccine Storage

1. 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.

2. 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 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.

3. What is the length of time the Pfizer vaccine can be stored in a regular freezer and refrigerator?

The 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.

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.

The combined time between the freezer and refrigerator cannot exceed 45 days.

4. Can you store the Pfizer COVID-19 vaccine in a regular freezer for 2 weeks and then move to the refrigerator for one month?

Yes. The 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. The Pfizer COVID-19 vaccine (undiluted) can be stored in a refrigerator between 2 and 8 degrees Celsius (36 to 46 degrees Fahrenheit) for up to 1 month (31 days).

5. 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. Alternatively, 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.

6. 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.

Storage Procurement

1. 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.

Pfizer COVID-19 vaccine

1. 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](#).

Temperature Monitoring

1. 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.

Vaccine Wastage

1. Is there a penalty if the office ends up wasting doses due to lack of interest before the expiration?

No, there is no penalty for wastage due to not finding people to vaccinate. 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 [Week 26 Bulletin](#), which has information about the updated vaccine wastage policy.

2. For VFC the doses are very closely tracked 1 for 1. How will this be tracked when we know there will (sadly) 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).

3. 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).

4. 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).

Reporting in ImmuNet

1. 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](#).

2. 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.

Consent

1. Do patients need to complete the pre-vaccine checklist before both doses or just the first 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.

2. 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.

Billing/Reimbursement

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.

CME

1. How do providers obtain CME from viewing the June 9 webinar?

Attendees can receive CME credit by completing [this evaluation](#) after each webinar. MedChi will then be in contact with the certificate. More details are found in the attached slides.

Transferring Doses

1. Can the minimum doses be split between 2 offices of the same organization?

Yes. Please ensure you follow the guidelines outlined in the June 9, 2021 webinar regarding maintaining the vaccine cold chain and documenting the transfer of vaccine from one provider to another. The receiving provider is responsible for reporting immunizations through ImmuNet. You must complete the [online form](#) when transferring doses, along with [the CDC Redistribution Agreement](#). It is recommended that practices keep copies of these agreements for their records.

2. As most of our patients went to mass vaccination centers, we have more vaccine now than we can use. Should we contact our local health department?

Yes. If you would like to explore partnerships with other practices or if your practice cannot utilize an entire tray of Pfizer vaccines (450 or 1170 doses), please reach out to your local health department or local pharmacies.

Other

1. 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](#).

2. When will Moderna be approved for the ages 12 and up population?

The application for Moderna is under review. We anticipate that Moderna may be approved for the 12+ population this summer.

3. MC revised guidelines for indoor facilities today, allowing vaccinated people to enter without masks. Have guidelines been eased for physician offices re masks?

Please visit <https://commerce.maryland.gov/Documents/BusinessResource/Mask-FAQ-COVID-19-Best-Practices.pdf> for the latest guidelines.

4. How are the detention centers providing vaccine in a timely fashion? Is the Johnson & Johnson COVID-19 vaccine available for this purpose?

The state detention facilities received COVID-19 vaccine shipments for incarcerated persons and staff members. County detention centers have usually worked directly with local health departments. Vaccines have been directly administered by health departments or in partnership with a detention center's medical provider.

If you would like to order this vaccine for your practice, please email

mdh.covidvax@maryland.gov