COVID-19 Vaccine Frequently Asked Questions

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- 1. What is the advantage of signing up to participate as a Covid -19 vaccination provider?

As a healthcare provider, you play a critical role in helping to end the COVID-19 pandemic. For patients, you are one of the most trusted sources of information when it comes to vaccines. Patients may have questions and concerns about COVID-19 vaccines. You can help them understand the importance of vaccination, provide your strong recommendation, and build confidence in vaccines. Strong vaccine confidence leads to more people getting vaccinated, which leads to fewer COVID-19 illnesses, hospitalizations, and deaths.

2. What are the requirements for becoming a Covid-19 vaccination provider?

To become a COVID-19 vaccination provider, you must be licensed to administer vaccines in the state of Maine. Your health system or you, as an independent provider, are required to sign and abide by the terms of the CDC COVID-19 Vaccination Program Provider Agreement. The agreement requires that you follow best practices for storing, handling, and administering vaccine and that you collect and report certain vaccination-related information.

3. Can I charge patients a fee for administering Covid-19 vaccines?

No. COVID-19 vaccines are provided at 100% no cost to the vaccine recipient. COVID-19 vaccination providers cannot charge vaccine recipients for the vaccine (which is provided free to enrolled providers by the U.S. government) or for any administration fees, copays, or coinsurance. COVID-19 vaccination providers cannot deny vaccination to anyone who does not have health coverage, is underinsured, or is out of network.

COVID-19 vaccination providers cannot charge recipients for an office visit or any other fee if the only service provided is a COVID-19 vaccination. Additional healthcare services can be provided at the same time and billed as appropriate. However, providers cannot require additional services for a person to receive a COVID-19 vaccine.

If a vaccine recipient has health coverage, providers may seek appropriate reimbursement from the recipient's plan or program (e.g., private health insurance, Medicare, Medicaid) for a vaccine administration fee. However, providers cannot bill the recipient for the balance not covered by the recipient's plan or program.

4. Is it possible to get reimbursed for COVID-19 Testing, Treatment and Vaccine Coverage for Uninsured Individuals?

Effective March 18, 2020 and until the end of the COVID-19 federal <u>Public Health Emergency</u> (PHE), Maine residents who are uninsured, as defined in the <u>federal Families First Coronavirus</u> <u>Response Act</u>, are entitled to receive coverage for testing and diagnosis of COVID-19 at no cost, with coverage to be administered through the MaineCare program. Effective March 11, 2021, under the <u>American Rescue Plan Act (ARPA)</u>, this population is now also eligible to receive coverage for COVID-19 vaccine administration and treatment at no cost.

This coverage is for individuals who meet the following criteria:

- They are a Maine resident;
- They are a U.S. citizen, U.S. national, or eligible immigrant; and
- They are uninsured;

- Not eligible for or enrolled in MaineCare or CubCare;
- Not enrolled in another health care program funded by the federal government, including: Medicare, TRICARE and Veterans Administration, and federal employee health plans; and
- Not enrolled in a commercial group health plan or other health insurance coverage.

Covered Services and Billing Information

Coverage includes COVID-19 vaccine product and administration, testing, and treatment for the COVID-19 diagnosis as well as limited related services, such as office visits and evaluations and telehealth triage and screening.

For more information on billing, please refer to our <u>billing and codes guidance</u> and <u>code details</u>. For additional information on vaccination codes and billing, please refer to our <u>COVID-19</u> vaccination coverage guidance.

Helping Patients Apply for Coverage

To be eligible for this coverage, individuals must complete a short, special one- to two-page application that is available <u>online</u>. The application can be filled out electronically or be printed and filled out by hand. Applications may be returned to MaineCare via email, mail or fax. We ask providers to inform their patients about this coverage option and the application process either when their COVID-19 testing/evaluation/treatment and/or vaccination appointment is scheduled or at the time of the appointment. Providers are encouraged to print the application for individuals who may not have internet access or who did not apply prior to receiving services.

Providers are also encouraged to assist individuals to apply at the time of the appointment to expedite the process. Providers can also refer individuals to the Consumers for Affordable Health Care's Consumer Assistance Helpline at 1-800-965-7476.

As part of the application process, individuals will be asked to self-attest that they do not have health insurance coverage. Providers may want to inform their patients that if they are found eligible to receive this special coverage, they will be enrolled in the Maine Rx coverage category, which will enable them to receive the appropriate COVID-19 coverage. Maine Rx is a prescription assistance program to help with the cost of prescription medication. We utilized this coverage group so that we could implement system and process changes to provide this special coverage for COVID-19 services more quickly. Once an individual is enrolled in the MaineRx program, they will also be eligible to receive discounted prescriptions.

Applications can be mailed, faxed, or emailed.

Email: farmington.dhhs@maine.gov

Fax: 1-207-778-8429

Mail: Office for Family Independence

State of Maine – DHHS 114 Corn Shop Lane

Retroactive Eligibility and Coverage

Any uninsured individuals who have been tested for COVID-19 (and received related covered services) since March 18, 2020 can apply for this special coverage for up to three months after the date on which they received services. For example, if a person was tested on March 18, 2020, they have until June 18, 2020 to submit an application and receive retroactive coverage. Someone who is tested on May 5, 2020 has until August 5, 2020 to submit an application and receive coverage. This uninsured COVID-19 coverage option will be in effect until the end of the PHE, but we will continue to process applications after the end of the emergency. We will send a provider notification at the time the program is set to expire.

Providers who have delivered these covered services to and/or billed uninsured patients for COVID-19 testing and related services between March 18, 2020 and May 11, 2020 should contact these patients and encourage them to complete the application so the provider can submit a claim to MaineCare and the patients will not need to pay for the services, if they are found eligible.

5. Does the program require that I provide vaccines to anyone, even if they are not currently a patient?

If you are a private provider, you are not required to provide vaccination to anyone who is not currently a patient. However, CDC strongly encourages, when possible, that providers make vaccine available to others in their local communities, including patients' family members. Pharmacies, public health clinics and any clinics held in communities are required to offer vaccination to anyone who is eligible.

6. Does CDC recommend an observation period after vaccination?

ACIP currently recommends that providers should consider observing patients for a minimum of 15 minutes after receipt of a vaccine. Time should be increased to 30 minutes for recipients who have history of immediate allergic reaction of any severity to vaccine or injectable therapy or a history of anaphylaxis due to any cause.

7. I am already a VFC provider; do I also have to sign a Covid-19 Vaccination Provider Agreement?

Yes, all providers participating in the program are required to sign a COVID-19 Vaccination Provider Agreement. As a VFC provider, you will have already implemented or be familiar with many of the requirements of the program, including ordering vaccine and reporting to your

jurisdiction's immunization information system (IIS). You may also have already completed some of the training recommended to become a COVID-19 vaccination provider.

8. What training is available to learn how to prepare and administer Covid-19 vaccines?

CDC offers a variety of training resources for preparing and administering COVID-19 vaccines. Visit Training and Education for COVID-19 Vaccination for training information and core competencies for healthcare professionals. At a minimum, CDC recommends all providers complete the training module for the vaccine(s) they will be administering. The training modules can be found at COVID-19 Vaccine Training Modules. Additional vaccine preparation and administration resources can be found on CDC's web pages for each vaccine product at U.S. COVID-19 Vaccine Product Information. Providers who are enrolled in the VFC program may already have completed some of the training recommended to become a COVID-19 vaccination provider.

9. How do I order COVID-19 vaccine?

Vaccination providers will order COVID-19 through the Maine Immunization Information System, ImmPact. Vaccination providers must have an approved CDC COVID-19 Vaccine Provider Agreement, complete an educational training, and have at least two staff with active ImmPact User Agreements (a primary and secondary vaccine coordinator).

10. What are the storage and handling requirements for Covid-19 vaccines?

Each COVID-19 vaccine has its own storage and handling requirements. As a COVID-19 vaccination provider, you are required to ensure vaccines are maintained within proper temperature ranges by using a digital data logger (DDL) to monitor vaccine storage unit temperatures and recording temperatures daily. Once daily temperatures with minimum/maximum are acceptable. If DDL does not measure minimum/maximum, it must be read and documented twice a day with initials. A physical copy of daily recordings must be maintained for a minimum of three years.

Additional details are available on CDC's web pages for each vaccine (<u>U.S. COVID-19 Vaccine Product Information</u>) and in the <u>Vaccine Storage and Handling Toolkit</u>, COVID-19 Vaccine Addendum.

11. What are the reporting requirements for the CDC Covid-19 Vaccination Program?

COVID-19 vaccination providers are required to report information on vaccine supply, vaccine administration, and vaccine adverse events. Reporting this information is critical to help stop the COVID-19 pandemic.

Vaccine supply

All COVID-19 vaccination providers **must** report COVID-19 vaccine inventory by reconciling inventory within ImmPact a minimum of once every two weeks. Federal CDC has required that all COVID19 vaccine administration be documented within 24 hours of administration of vaccine. This data will be used to determine state uptake on vaccine and the need for further allocations.

Vaccine administration data

COVID-19 vaccination providers, after administering a dose of COVID-19 vaccine, must record all information marked by an asterisk below (if it is not already recorded in the vaccine recipient's record) and report the following required vaccine administration data, or other data elements if revised by CDC, to the appropriate entity noted in the agreement, within 24 hours of administering the vaccine:

- 1. Administered at location/facility name/ID
- 2. Administered at location type
- 3. Administration address (including company)*
- 4. Recipient name and ID*
- 5. Recipient date of birth*
- 6. Recipient sex*
- 7. Recipient race
- 8. Recipient ethnicity
- 9. Recipient address*
- 10. Administration date*
- 11. CVX (product)*
- 12. NDC (national drug code)
- 13. Dose number*
- 14. Lot number (Unit of Use [UoU] or Unit of Sale [UoS])*
- 15. MVX (manufacturer)*
- 16. Sending organization (name of the agency submitting the report)
- 17. Vaccine administering provider's name and suffix*
- 18. Administering provider's address, if different from the administration address*
- 19. Vaccine administration site (on the body)*
- 20. Vaccine expiration date*
- 21. Vaccine route of administration*
- 22. Vaccine series

Find more information about vaccine administration and reporting requirements.

Vaccine adverse events

Healthcare providers are **required** under Emergency Use Authorization (EUA) to report to the <u>Vaccine Adverse Event Reporting System (VAERS) external icon</u> the following adverse events (AEs) after COVID-19 vaccination (and other adverse events if later revised by CDC):

- Vaccine administration errors, whether associated with an AE or not
- Cases of COVID-19 that result in hospitalization or death
- Serious AEs regardless of causality, defined by the U.S. Food and Drug Administration (FDA) as:
 - Death
 - Life-threatening AE
 - o Inpatient hospitalization or prolongation of existing hospitalization
 - Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
 - Congenital anomaly/birth defect
 - An important medical event that, based on appropriate medical judgement, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of multisystem inflammatory syndrome

Healthcare providers are **encouraged** to <u>report to VAERS</u> any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event. Also report any additional select AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine being authorized under an EUA.

Vaccination provider requirements can be found at <u>COVID-19 Vaccination Provider</u> <u>Requirements and Support</u>.

12. How do I report a vaccine error or adverse event?

Visit the Vaccine Adverse Event Reporting System (<u>VAERS</u>) for information about all reporting requirements or to submit a report. COVID-19 vaccination providers are required to report vaccine administration errors to VAERS, even if the error is not associated with an adverse event. They are also required to report certain adverse events after COVID-19 vaccination (and other adverse events if later revised by CDC).

13. What information am I required to provide to patients?

You are required to provide patients with a COVID-19 vaccination record card, included in the ancillary supply kits for COVID-19 vaccines, and an <u>EUA Fact Sheet for Recipients and Caregivers</u> for the vaccine product administered. Vaccination providers should also provide

vaccine recipients with information about participating in <u>v-safe</u>, CDC's smartphone-based after-vaccination health checker that uses text messaging and web surveys to provide personalized health check-ins.

14. How can I make sure I am complying with all components of the provider agreement?

As we learn more about COVID-19 vaccines and how to best implement the CDC COVID-19 Vaccination Program, CDC posts <u>updates and amendments to the COVID-19 Provider</u>

<u>Agreement</u> on its website. COVID-19 vaccination providers are responsible for checking this web page regularly for any updates and are required to comply with these updates.

15. My facility does not stock vaccines. Are there other ways I can contribute?

Yes. Healthcare providers are the most trusted source of health information for their patients. Even if you are not participating in the CDC COVID-19 Vaccination Program, you play an important role in helping to educate and encourage your patients and others to get vaccinated. A provider's recommendation has been shown to be an important factor in vaccine acceptance. CDC has many resources to assist you with educating your patients, staff, families, and communities. Check your patients' vaccination status at routine appointments and, if they are unvaccinated, provide guidance on where they can get vaccinated. For example, you can use <u>Vaccines.gov</u> to locate vaccination sites or consider partnering with a COVID-19 vaccination provider to whom you can refer patients.

16. What additional helpful resources are available?

COVID 19 – Resource Guide for Providers		
Provider Details		
	Vaccination Training Programs and Reference Material for Healthcare Professionals	
Staff Training	New Vaccination Provider Trainings	
	Vaccine Administration Competencies Assessment Form	
	Training and Education Resources for Healthcare Providers	
Billing, Documentation, Vaccine Recipient Communication and Reporting		
EAU Factsheets	Healthcare Provider EUA Fact Sheets	
	EUA Fact Sheets for Recipients and Caregivers	

V-Safe	V-Safe Information Sheets	
Vaccine	Core Vaccine Administration Data Elements	
Administration Data		
	Pfizer-BioNTech BUD Tracking Labels	
T		
Tracking Use-By Times	Moderna Storage and Handling Labels	
Times	Janssen Storage and Handling Labels	
Advance Freeze	Managing Anaphylaxis	
Adverse Events	VAERS Form	
	VALKSTORM	
Storage and Handling Per Unit		
Pfizer Thermal	Pfizer-BioNTech Storage and Handling Summary	
Shippers and		
Controlant	COVID-19 Vaccine Shipper and Logger Return Instructions	
Temperature Logs	Pfizer-BioNTech Temperature Log: Fahrenheit	
	Pfizer-BioNTech Temperature Log: Celsius	
	Thzer-biolyrech remperature Log. Celsius	
	Moderna Temperature Log: Fahrenheit	
	Moderna Temperature Log: Celsius	
	Refrigerator Vaccine Temperature Log: Fahrenheit	
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	Refrigerator Vaccine Temperature Log: Celsius	
Vaccine Storage	Vaccine Storage Troubleshooting Record: Fillable	
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Do Not Disconnect	Do Not Disconnect Labels	
	Storage and Handling Sitewide	
	Transporting COVID-19 Vaccines Off-Site	
	Transport Temperature Log for Refrigerated Vaccines	
Vaccine Transport	<u>Vaccine Storage and Handling Toolkit</u>	
	Moderna Vaccine Transport Guidance	
	Janssen Vaccine Transport Guidance	
	COVID-19 Quick Reference Guide for Healthcare Professionals	
	Pfizer-BioNTech COVID-19 Vaccine Information	

Storage and Handling Recommendations	Moderna COVID-19 Vaccine Information	
	Janssen COVID-19 Vaccine Information	
	COVID-19 Vaccine Expiration Date Tracking Tool	
Expiration and Beyond-Use Dates/Times	Pfizer-BioNTech Vaccine Preparation and Administration Summary	
	Moderna Vaccine Preparation and Administration Summary	
	Janssen Vaccine Preparation and Administration Summary	
Vaccine Procedures		
	COVID-19 Quick Reference Guide for Healthcare Professionals	
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	Janssen COVID-19 Vaccine Information	
	Janssen Vaccine Preparation and Administration Summary	
	Vaccine Expiration Date Tracking Tool	
	Vaccine Storage and Handling Toolkit	
Vaccine Administration	Prevaccination Checklist for COVID-19 Vaccines	
	COVID-19 Vaccine Administration Errors and Deviations	
	Vaccine Administration: Preventing Vaccine Administration Errors	
	Summary Document for Interim Clinical Considerations	
	You Call the Shots Vaccine Administration Module	
	VAERS Homepage	
	Epidemiology and Prevention of Vaccine-Preventable Diseases	