

Newsletter #89 January 13, 2021

Licensed and Certified Facilities

Aloha,

CTA is distributing this information which is approved by the Office of Health Care Assurance. It is being distributed to all CMAs and CCFFHs.

There are several important items in this newsletter. All pictures below can be printed by using the links included in this newsletter or by going to the CTA website <http://www.comties.com/> under COVID-19 Resources

1. See attached vaccine consent form. Note that the recipient of the vaccine/legal guardian/POA will need to sign.

For Oahu ARCH/CCFFH/DDDh: more instructions to follow shortly but please have this **signed/printed out by next week Monday, January 17.**

You can print the consent form from:

https://eb5eac17-3f2a-476a-ba06-d485b8db6304.filesusr.com/ugd/fcb480_25docea861904971afad5d5574af09e4.pdf

2. Please read the OCHA issued COVID-19 Vaccine Memorandum from today January 13, 2021.

You can find a printable one at:

https://eb5eac17-3f2a-476a-ba06-d485b8db6304.filesusr.com/ugd/fcb480_c9b71df7c5e84bad8b3869d5e2c5a74f.pdf

3. There are 8 Vaccine Information Sheets that you all should read as well as give to the person's signing the consent forms so they are informed and can decide whether or not to take the vaccine.

You can find the printable sheets at:

https://eb5eac17-3f2a-476a-ba06-d485b8db6304.filesusr.com/ugd/fcb480_8772b686203f45ba836582429e894d1e.pdf



Moderna® COVID-19 Vaccination Consent and Release

Select

Salutation (None, Mr., Ms., Mrs., Dr., Prof.) Select	Last Name	First Name	M.I.
Gender (Female, Male, Decline to Specify, Other)	Date of Birth	Phone Number	E-mail
Street Address	City	State	ZIP code

Ethnicity:	Hispanic or Latino	Not Hispanic or Latino	Unknown/Not Reported
Race:	American Indian or Alaska Native	Asian	Black or African American
	Native Hawaiian or Other Pacific islander	White	Unknown/Not Reported
List any medications:			
List any other relevant medical information:			

Primary Insurance	Insurance ID	Name of Primary Care Provider	PCP Phone Number:
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Considerations from the CDC

Administration of Moderna COVID-19 vaccine with other vaccines.

- You should wait at least 14 days after getting any other vaccine before you come to get the Moderna COVID-19 vaccine.
- It is not known if getting the Moderna COVID-19 vaccine within 14 days of another vaccine will affect how each vaccine works.

History of a previous or current COVID-19 infection

- You may receive a COVID-19 vaccine if you have had a previous COVID-19 infection.
- If you have a current COVID-19 infection, you should wait until you are better and have completed your isolation time before coming in to get a COVID-19 vaccine.
- There is no recommended minimum time between recovering from a COVID-19 infection and getting a COVID-19 vaccine.

History of unprotected exposure to a person who tested positive for COVID-19 in the last 14 days

- If you have had an unprotected COVID-19 exposure, you should wait to complete your quarantine before coming in to get a COVID-19 vaccine.

If you have been treated with a monoclonal antibody or convalescent plasma

- You should wait at least 90 days to get a COVID-19 vaccine after treatment with a monoclonal antibody or convalescent plasma for a COVID-19 infection.

Special populations:

- A COVID-19 vaccine may be administered to immunocompromised individuals, including people with HIV and those on immunosuppressive medications, but the vaccine has not been fully studied in this population.
- Women who are pregnant or breastfeeding should talk with their providers to decide on getting a COVID-19 vaccine. It is not known if the Moderna COVID-19 vaccine is safe and effective during pregnancy or when breastfeeding.

If you have any additional questions after reviewing the above information, talk to your doctor or healthcare provider before getting the Moderna COVID-19 vaccine.

Recipient Name _____ Date of Birth _____

Consent for Service Yes (please initial) _____

I verify that I have been provided with and have read (or had read to me) (1) the Fact Sheet for Recipients and Caregivers for the Emergency Use Authorization (EUA) of the Moderna COVID-19 vaccine ("Vaccine"); (2) this Moderna COVID-19 Vaccination Consent and Release Form; and (3) any additional information provided to me concerning COVID-19 vaccination. I acknowledge that I have had a chance to ask questions of a healthcare professional about the Vaccine. I understand that the Vaccine will be given in two separate doses, at least four weeks apart. I understand the known risks and the potential benefits of receiving the Vaccine, and I understand there may be risks to the Vaccine that are not known at this time. I understand that the FDA has authorized use of the Vaccine under an Emergency Use Authorization (EUA) and that there is currently not enough scientific evidence available for the FDA to fully approve this or any other COVID-19 vaccine. I nonetheless request and consent to the Vaccine being given to me.

Limitation of Liability Yes (please initial) _____

I understand that because this is not an FDA-approved vaccine but is being given under an FDA issued Emergency Use Authorization, CPESN Hawaii, its divisions and affiliates and their respective officers, directors, employees, agents and representatives are immune from civil liability under federal and state law for all claims for loss related to any known or unknown side effects and/or injuries, including but not limited to death, that I, or the person for whom I am authorized to make this request, may experience from this vaccine. This immunity means that if I file a lawsuit against CPESN Hawaii, the court must dismiss any such lawsuit, and the only exception to this immunity is for claims for willful misconduct.

Authorization to Release Information for Medical Treatment and/or Payment Yes (please initial) _____

I understand that I am giving CPESN Hawaii permission to release any medical or other information necessary to my physician, Medicare, Medicare HMO, or insurance company, as applicable, to enable CPESN Hawaii to process my insurance claims with respect to the vaccination.

Recipient/Parent/Legal Guardian/POA Name (Please Print)

Signature of Recipient/Parent/Legal Guardian/POA

Date

Vaccine Documentation (Pharmacy Use ONLY)

Vaccine	Dose #	Date Administered	Dose Size	Route/Site	Lot No.	Exp Date	Name/Title of Vaccine Administrator
Moderna COVID-19	#1 #2		0.5 ml	IM L / R Deltoid			

DAVID Y. IGE
GOVERNOR OF HAWAII



ELIZABETH A. CHAR, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE ASSURANCE
601 KAMOKILA BOULEVARD, ROOM 361
KAPOLEI, HAWAII 96707

In reply, please refer to:
File:

January 13, 2021

Dear ARCH/CCFFH/DDDH licensee/certificate holder:

RE: IN-HOME COVID-19 VACCINATIONS ON OAHU FROM JANUARY 17, 2021 THROUGH JANUARY 30, 2021 FOR ADULT RESIDENTIAL CARE HOMES (ARCH) COMMUNITY CARE FOSTER FAMILY HOMES (CCFFH) AND DEVELOPMENTAL DISABILITIES DOMICILIARY HOMES (DDDH)

The Office of Health Care Assurance (OHCA) is notifying you of in-home COVID-19 vaccinations that will be occurring on the island of Oahu from January 17, 2021 through January 31, 2021. Various pharmacies across Oahu will be administering the vaccine, these pharmacies include Pharmicare, 5 Minute Pharmacy, Times Pharmacy, Queens Medical Center Pharmacy, Foodland Pharmacy, and ElixRx Pharmacy. These home visits are being held specifically for persons included in Phase 1A of the U.S. Centers of Disease Control and Prevention (CDC) COVID-19 vaccination program and State of Hawaii COVID-19 Vaccination Plan.

These persons include:

- 1) Your residents/clients (up to 5)
- 2) Primary Care Giver
- 3) Substitute Care Giver (up to 3)
- 4) Relatives in your home over seventy-five (75) years of age

Please see the attached documents for consent and vaccine information. The consent form needs to be filled out for each individual and must be available to give to the pharmacy when they arrive in your home to administer vaccine to you and your residents. All persons receiving the vaccine must have separate documents. If your resident has a guardian/POA, that person must also sign the consent. See attached pages for further instructions. A follow-up visit will be scheduled for you and your residents/clients to receive the second dose.

If your resident transfers to another facility after receiving their first dose of vaccine, they will receive the second dose at the time that facility is scheduled to receive their second dose. All persons receiving the vaccine will have their information entered into a tracking system and will be provided a vaccination card for their records.

The pharmacy will contact you via telephone to arrange for scheduling. Please do not call the pharmacies as it will interrupt and delay their ability to schedule the home visits. Please accept phone calls for scheduling from the pharmacies listed above.

Commonly asked questions:

- 1) Will the same pharmacy administer both doses?
 - a. Yes, and the vaccine will be from the same manufacturer.
- 2) Will there be a pre-registration process?
 - a. No. The pharmacy will contact you via telephone to schedule the in-home visit.
- 3) Who will administer and monitor after the vaccine is given?
 - a. A medical professional will administer the vaccine and monitor for reactions for a minimum of fifteen (15) minutes.
- 4) My resident has a POA/Guardian who is on the mainland? How can they sign the consent form?
 - a. A scanned signature is fine for the consent form. If the guardian/POA is unable to sign, please let the pharmacy know when they call to schedule their visit. They can assist with getting the consent.

For any additional questions, please contact your nurse consultant or email OHCA at DOH.OHCAlicensing@doh.hawaii.gov. General information about the vaccine can be found at <https://health.hawaii.gov/coronavirusdisease2019/what-you-should-know/covid-19-vaccine-frequently-asked-questions/>

Sincerely,



JUSTIN LAM, R.N.
Section Supervisor
State Licensing Section

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HAWAII IMMUNIZATION REGISTRY INFORMATION

INFORMATION CONTAINED IN THE REGISTRY

- Immunization information including but not limited to vaccine type, date of vaccine administration, vaccine administration site and route, lot number, expiration date, patient's history of vaccine preventable diseases, contraindications, precautions, adverse reactions, and/or comments regarding vaccinations.
- Personal information including but not limited to an individual's first, middle, and last name, date of birth, gender, mailing address, phone number, parent/guardian name, parent/guardian relationship to the individual, their contact information, and mother's maiden name.

CONFIDENTIALITY AND PRIVACY INFORMATION

All authorized users and the Department of Health Immunization Branch acknowledge that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (PL 104-191 and 45 CFR Parts 160 and 164, "Standards for Privacy of Individually Identifiable Health Information") governs the use and disclosure of individually identifiable information by entities subject to the Privacy Rule. Although HIPAA standards for privacy were used as a guide to assist in the development of the Registry Confidentiality and Privacy policies, the Registry and the Department of Health Immunization Branch are not "covered entities" under HIPAA. Providers, health plans and other covered entities who are authorized users must comply with the HIPAA Privacy Rule.

Registry information will be entered by and available to authorized users for authorized purposes only. All authorized users will be required to safeguard the privacy of patient participants by protecting confidential information in the Registry in accordance with the Hawaii Immunization Registry Confidentiality and Privacy Policy, the Hawaii Immunization Registry Security Policy, as well as all applicable State and Federal Laws.

AUTHORIZED USERS

Authorized users of the Registry may include individuals and/or entities that require regular access to patient immunization and other individually identifiable health information to provide immunization services to specific patients, maintain a computerized inventory of their public and private stock of vaccines, assess immunization status to determine immunization rates, and/or ensure compliance with mandatory immunization requirements. All authorized users are required to sign a Hawaii Immunization Registry Confidentiality and Security Statement indicating that they have received a copy of the Hawaii Immunization Registry Confidentiality and Privacy Policy and the Hawaii Immunization Registry Security Policy, understand the terms, including penalties for violation of the policies, and agree to comply with the policies.

The Department of Health Immunization Branch is responsible for oversight of the Registry and therefore will be designated as an authorized user.

USES OF REGISTRY INFORMATION (AUTHORIZED PURPOSES)

Registry immunization data and other individually identifiable health information shall be utilized by authorized users for the purposes of:

- Consolidating, maintaining, and accessing computerized immunization records;
- Consolidating and maintaining vaccine inventory information;
- Determining the immunization history of individuals and delivering health care treatment accordingly;
- Generating notices for individuals who are due or overdue for immunizations and in the event of a vaccine recall;
- Staying abreast of the complex immunization schedule by utilizing registry-supplied immunization forecasting tools;
- Assessing the immunization rate of their patient population (or subsets thereof);
- Generating official immunization records (e.g. Student's Health Record);
- Ensuring compliance with mandatory immunization requirements;
- Recording the distribution of prophylactic and treatment medications administered or dispensed in preparation for and in response to a potentially catastrophic disease threat;
- Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures; and
- Other purposes determined at the discretion of the Department of Health Immunization Branch.

Registry immunization data and other individually identifiable health information shall be utilized by the Department of Health Immunization Branch for the following public health purposes including but not limited to:

- Ensuring compliance with mandatory immunization requirements;
- Performing Quality Improvement/Quality Assessment activities;
- Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures;
- Preventing and managing outbreaks of vaccine-preventable diseases and other public health emergencies;
- Producing immunization assessment reports to aid in the development of policies and strategies to improve public health;
- Managing and maintaining the Registry system; and
- Other purposes determined at the discretion of the Department of Health Immunization Branch.

AVAILABILITY OF IMMUNIZATION RECORD INFORMATION

An individual's immunization data and other individually identifiable health information in the Registry will be made available to the individual's immunization provider, the Department of Health, and other Registry authorized users for authorized purposes only.

OPT-OUT

Individuals may choose not to include their or their child's immunization data in the Registry ("opt-out"). Individuals must opt-out in writing by completing a "Hawaii Immunization Registry Opt-Out Form" which is available from the individual's immunization provider or the Department of Health Immunization Branch. The Registry will retain only core demographic information necessary to identify the individual has chosen to opt-out of the Registry. This information is necessary to enable the Registry to filter and refuse entry of immunization information for the individual. Core demographic data will be for Hawaii Department of Health use only and will be non-displaying to all other Registry authorized users. An individual's decision not to authorize the inclusion of immunization data in the Registry will not affect whether or not they receive immunizations.

REVOCACTION

An individual may revoke their decision to opt-out of the Hawaii Immunization Registry at any time. Revocations must be made in writing by completing a "Hawaii Immunization Registry Reauthorization Form" obtained from the individual's immunization provider or the Department of Health Immunization Branch.

RIGHT TO INSPECT, COPY, CORRECT OR AMEND PERSONAL AND IMMUNIZATION INFORMATION

Individuals may inspect, copy, correct or amend their or their child's immunization record information via their or their child's immunization provider or the Department of Health Immunization Branch. For information on how to inspect, copy, correct or amend your or your child's information, please speak with your doctor, call the Department of Health Immunization Branch at 586-4665 (Oahu) or 1-888-447-1023 (neighbor islands), or e-mail your request to RegistryHelp@doh.hawaii.gov.

QUESTIONS?

If you have any questions about the Registry, please speak with your doctor, call the Department of Health Immunization Branch at 586-4665 (Oahu) or 1-888-447-1023 (neighbor islands), e-mail your question to RegistryHelp@doh.hawaii.gov, or visit our website at: <http://hawaii.gov/health/immunization/HIR.html>.

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF
THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019
(COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?

It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?

No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction’s Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

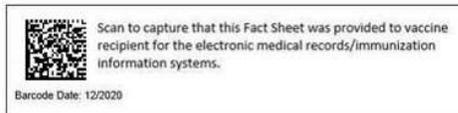
WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

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Patent(s): www.modernatx.com/patents
Revised: 12/2020





What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2pm local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

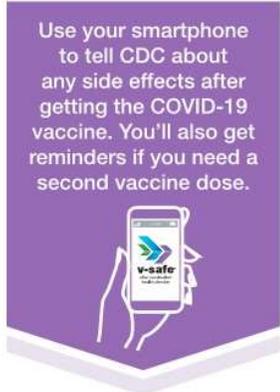
How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.*

*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.



Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

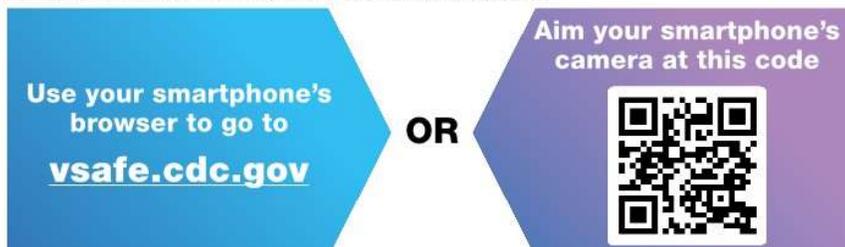


How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the **v-safe** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2pm local time, **v-safe** will start your initial health check-in around 2pm that day. If you register after 2pm, **v-safe** will start your initial health check-in immediately after you register—just follow the instructions.
You will receive a reminder text message from **v-safe** when it's time for the next check-in—around 2pm local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
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