Sagepoint
SENIOR LIVING SERVICES

12/18/2020

Dear Resident and/or Representatives,

Please find enclosed in this packet the consent form that will be necessary for your loved one to receive the COVID vaccine. The vaccine will not be provided by Sagepoint's long standing pharmacy partner and instead will be provided by Walgreens pharmacy as required by federal agencies. As many media outlets have reported, no recipients will be charged for the vaccine. You will, however, likely see a charge to your loved ones Medicare B services for ancillary supplies and the administration of the vaccine by the federally approved pharmacy which, in this instance is Walgreens. We have included as much detail about the vaccine as has been made available to us. Included in this packet is the consent form, frequently asked questions and some details on the Pfizer vaccine. As of this time, we have not been informed if we will receive the Pfizer or Moderna vaccine. We further do not have any additional information from Moderna as they have just completed the FDA review and approval process. Please do not hesitate to follow the CDC (Center for Disease Control) as they are routinely posting updates on vaccines for COVID-19.

We have attached the contact information, (301-934-1900 ext. 487) for you to reach out to your provider/attending physician if you have any additional questions or concerns. Please leave a voicemail with as much detail as reasonable and contact information for a return call. You may mail the signed consent form back to us; however, this is not required. We will be making phones call next week to confirm your consent for administration of the vaccine, assuming you are the representative on file to speak on behalf of a resident that is not able to make their own medical decisions. Otherwise we will, as required by law, speak to the resident for consent.

While we do not have a date for vaccine administration yet, we are collecting this consent now in order to be ready to support the distribution and administration of the vaccine as soon as it becomes available. As of the information we have to date, Walgreens is limited under their current contract to arriving onsite no more than three times to administer the vaccine. As we know the vaccine requires two doses, so we are expected to have the necessary mandated documents on file in order to support vaccine administration in a limited window. In order to assist in expediting answers, please direct your questions to the appropriate person. If your questions are logistics of the distribution of the vaccine, please do not hesitate to reach out to us directly. Your Unit Managers will be informed of the distribution plans. If your questions are related to the vaccine and medical information such as side effects or other concerns, they should be directed to the physicians and nurse practitioner at 301-934-1900 ext. 487.

Finally, as of this time, the vaccine will be administered to skilled nursing facility residents and healthcare workers only. We have not received any information on the administration of the vaccine to assisted living residents however we continue to advocate to make it available to them as soon as possible.

Thank you in advance. We are all very relieved to finally have this opportunity to help protect the residents. We have lobbied vigorously to ensure nursing home residents were not left out of the vaccination programs as priority one. Please take full advantage of the historic event and offer your loved one the best opportunity to stem the rising curve of this global pandemic.

Best Regards,

Andrea S. Dwyer, CEO, NHA, MBA

Sagepoint Senior Living Services

Vaccine Administration Record (VAR)

Informed Consent for Vaccination in Long Term Care Facility (LTCF)

Walgreens

SECTION A-1 Please print clearly.

First name: _____ **Last name:** _____

Date of birth: _____ **Age:** _____ **Gender:** ☐Female ☐Male **Phone:** 301-934-1900

LTCF Name: Sagepoint Senior Living Services **Address:** 10200 Laplata Rd

City: Laplata **State:** MD **ZIP code:** 20646 **Patient Email address:** _____

I want to receive the following vaccination(s): COVID-19 Vaccination

SECTION A-2 I certify that I am: (a) the patient and at least 18 years of age; (b) the legal guardian of the patient; or (c) a person authorized to consent on behalf of the patient where the patient is not otherwise competent or unable to consent for themselves. Further, I hereby give my consent to Walgreens or Duane Reade and the licensed healthcare professional administering the vaccine, as applicable (each an "applicable Provider"), to administer the vaccine(s)) I have requested above. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) and have received, read and/or had explained to me the EUA Fact Sheet on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised that the patient should remain near the vaccination location for observation for approximately 15 minutes after administration. On behalf of the patient, the patient's heirs and personal representatives, I hereby release and hold harmless each applicable Provider, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above.

I acknowledge that: (a) I understand the purposes/benefits of my state's vaccination registry ("State Registry") and my state's health information exchange ("State HIE"); and (b) the applicable Provider may disclose my vaccination information to the State Registry, to the State HIE, or through the State HIE to the State Registry, or to any state or federal governmental agencies or authorities ("Government Agencies"), such as state, county, or local Departments of Health or the federal Department of Health and Human Services, the Center for Disease Control and Prevention, or their respective designees as may be required by law, for purposes of public health reporting, or to my healthcare providers enrolled in the State Registry and/or State HIE for purposes of care coordination. I acknowledge that, depending upon my state's law, I may prevent, by using a state-approved opt-out form or, as permitted by my state law, an opt-out form ("Opt-Out Form") furnished by the applicable Provider: (a) the disclosure of my vaccination information by the applicable Provider to the State HIE and/or State Registry; or (b) the State HIE and/or State Registry from sharing my vaccination information with any of my other healthcare providers enrolled in the State Registry and/or State HIE. The applicable Provider will, if my state permits, provide me with an Opt-Out Form. I understand that, depending on my state's law, I may need to specifically consent, and, to the extent required by my state's law, by signing below, I hereby do consent to the applicable Provider reporting my vaccination information to the Government Agencies, State HIE, or through the State HIE and/or State Registry to the entities and for the purposes described in this Informed Consent form. Unless I provide the applicable Provider with a signed Opt-Out Form, I understand that my consent will remain in effect until I withdraw my permission and that I may withdraw my consent by providing a completed Opt-Out Form to the applicable Provider and/or my State HIE, as applicable.

I understand that even if I do not consent or if I withdraw my consent, my state's laws or federal law may permit certain disclosures of my vaccination information to or through the State HIE or to Government Agencies as required or permitted by law. I further authorize the applicable Provider to: (a) release my medical or other information, including any communicable disease (including HIV), and mental health information, to, or through, the State HIE or Government Agencies to my healthcare professionals, Medicare, Medicaid, or other third-party payer as necessary to effectuate care or payment; (b) submit a claim to my insurer for the above requested items and services; and (c) request payment of authorized benefits be made on my behalf to the applicable Provider with respect to the above requested items and services. I further agree to be fully financially responsible for any cost-sharing amounts, including copays, coinsurance and deductibles, for the requested items and services, as well as for any requested items and services not covered by my insurance benefits. I understand that any payment for which I am financially responsible is due at the time of service or, if the applicable Provider invoices me after the time of service, upon receipt of such invoice. Walgreens may disclose your vaccination information from this visit for public health purposes and will send this information to the Medical Director or Administrator of the LTCF identified above. If you are an employee of the LTCF, Walgreens will send your vaccination information to your employer as required.

Print Name: _____ **Patient/Authorized Person signature:** _____ **Date:** _____

SECTION B-1 **SCREENING QUESTIONS.** The following questions will help us determine your eligibility to be vaccinated today.

1.	Do you feel sick today?	☐ Yes ☐ No ☐ Don't know
2.	Do you have any health conditions, such as heart disease, diabetes or asthma? If yes, please list: _____	☐ Yes ☐ No ☐ Don't know
3.	Do you have allergies to latex, medications, food or vaccines (examples: eggs, bovine protein, gelatin, gentamicin, polymyxin, neomycin, phenol, yeast or thimerosal)? If yes, please list: _____	☐ Yes ☐ No ☐ Don't know
4.	Have you ever had a reaction after receiving a vaccination, including fainting or feeling dizzy?	☐ Yes ☐ No ☐ Don't know
5.	Have you ever had a seizure disorder for which you are on seizure medication(s), a brain disorder, Guillain-Barré syndrome (a condition that causes paralysis) or other nervous system problem?	☐ Yes ☐ No ☐ Don't know
6.	**For women:** Are you pregnant or considering becoming pregnant in the next month?	☐ Yes ☐ No ☐ Don't know

SECTION B-2 I certify that I am: (a) the patient and at least 18 years of age; (b) the legal guardian of the patient or representative of; or (c) a representative of the LTCF and, based upon clinical observation, have sufficient knowledge of the patient's condition to answer the Screening Questions. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction.

Patient/LTCF Representative:_____ **Date:** _____

SECTION C INSURANCE – PATIENT TO COMPLETE IF APPLICABLE

Please ensure to record BOTH pharmacy AND medical insurance information since there are multiple ways immunizations can be billed at Walgreens.

Non-Medicare:	Pharmacy Card	Medical Card
Insurance Plan/Plan ID:		
Member/Recipient ID #:		
RX BIN:		N/A
RX PCN:		N/A
Group Number:		

Medicare:	Medicare Part B
Medicare Number*:	

*Medicare Claim Number for cards distributed earlier than 2018.

Is the patient the cardholder? ☐ Yes ☐ No

If no, please provide cardholders name, date of birth (MM/DD/YYY) and relationship: _____

SECTION D HEALTHCARE PROVIDER ONLY

Complete BEFORE vaccine administration

1. I have reviewed the **Patient Information** and **Screening Questions.** Initial here: _____
2. I have verified that this is the **vaccine requested** by the patient. Initial here: _____
3. This vaccine is appropriate for this patient based on the **Age Guidelines and Other Guidelines** provided by federal and/or state regulations and company policies. Initial here: _____

   3a. Does this patient have a high-risk medical condition? ☐ Yes ☐ No

   If yes, please list medical condition(s): _____
4. The **Vaccine NDC matches** the NDC on the bottom of this VAR form and the NDC on the patient leaflet. (Perform **3-way NDC match**.) Initial here: _____
5. I have verified the **Expiration Date** is greater than today's date and have entered the **Lot # and Expiration Date** in the field below. Initial here: _____

SECTION E Complete DURING the patient interaction

1. I confirm(ed) the patient's **Name, DOB and Requested Vaccine** and verified it matches the information on the VAR form. Initial here: _____
2. I have reviewed the **Screening Questions** and answers. Initial here: _____
3. I provided a **EUA Fact Sheet** to the patient or the LTCF representative. Initial here: _____

SECTION F

Complete AFTER vaccine administration

Vaccine	NDC	Manufacturer	Dosage	☐ Dose 1	Site of administration	EUA Fact Sheet published date
				☐ Dose 2		

Clinician's name (print):_____ **Clinician's signature:**_____ **Title:**_____

If applicable, intern/tech name (print):_____ **Administration date:** _____ **Date EUA Fact Sheet given to patient:** _____

COVID-19 VACCINE LOT# _____ **COVID-19 VACCINE EXPIRATION DATE** _____

1. Update the patient's record with any new allergy, health condition or primary care provider information.
2. Enter vaccine lot #, expiration date and site of administration, then scan the VAR form into the patient's record.

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE?

WHAT IS COVID-19?

COVID-19 disease 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 PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 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 PFIZER-BIONTECH COVID-19 VACCINE?

Tell the 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 PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech 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 PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?

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

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?
The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine. 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 Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech 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 "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?
It is your choice to receive or not receive the Pfizer-BioNTech 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 PFIZER-BIONTECH COVID-19 VACCINE?
Currently, there is no approved alternative vaccine available for prevention of COVID-19. FDA may allow the emergency use of other vaccines to prevent COVID-19.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Pfizer-BioNTech 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 PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?
No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech 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.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

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 local or state 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 Pfizer-BioNTech 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 Pfizer-BioNTech 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, available alternatives. In addition, the FDA decision is based on the totality of 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 in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech 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).

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-0.7

Revised: December 2020

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

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.

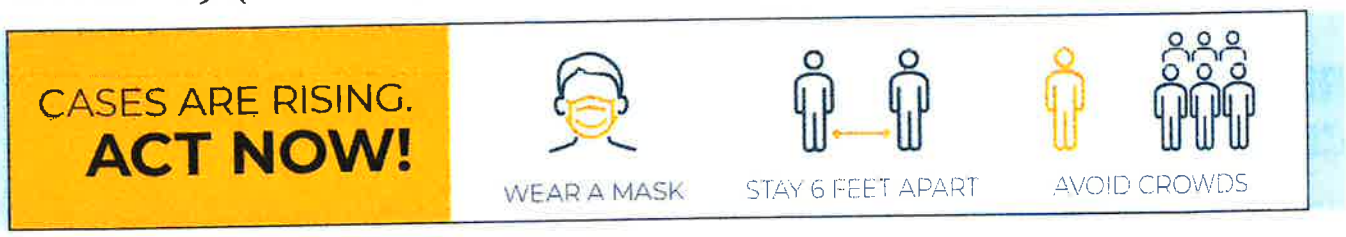
The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of 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).

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

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020



Importance of COVID-19 Vaccination for Residents of Long-term Care Facilities

Updated Dec. 13, 2020 Print

Based on recommendations from the Advisory Committee on Immunization Practices (ACIP), an independent panel of medical and public health experts, CDC recommends residents of long-term care facilities be included among those offered the first supply of COVID-19 vaccines.

Vaccinating LTCF residents will save lives

Making sure LTCF residents can receive COVID-19 vaccination as soon as vaccines are available will help save the lives of those who are most at risk of dying from COVID-19. According to ACIP's recommendations, long-term care facility residents include adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently. The communal nature of LTCFs and the population served (generally older adults often with underlying medical conditions) puts facility residents at increased risk of infection and severe illness from COVID-19. By November 6, 2020, approximately 569,000–616,000 COVID-19 cases and 91,500 deaths were reported among LTCF residents and staff members in the United States, accounting for 39% of deaths nationwide.

Benefits of vaccination believed to outweigh possible risks

All COVID-19 vaccines were tested in clinical trials involving tens of thousands of people to make sure they meet safety standards and protect adults of different races, ethnicities, and ages, including adults over the age of 65. There were no serious safety concerns. The most common side effects were pain at the injection site and signs and symptoms like fever and chills. After a review of all the available information, ACIP and CDC agreed the lifesaving benefits of COVID-19 vaccination for LTCF residents outweigh the risks of possible side effects.

The safety of COVID-19 vaccines is a top priority

To help make important unapproved medical products, including vaccines, available quickly during the COVID-19 pandemic, the US Food and Drug Administration (FDA) can use what is known as an Emergency Use Authorization (EUA). Before any vaccine can be authorized for use under an EUA, FDA must determine that the vaccine's benefits outweigh possible risks.

Once people begin receiving COVID-19 vaccinations, CDC and FDA will monitor vaccine safety closely. The United States will use existing robust systems and data sources to conduct ongoing safety monitoring. An additional layer of safety monitoring has also been added that allows CDC and FDA to evaluate COVID-19 vaccine safety almost immediately. Learn more about COVID-19 vaccine safety monitoring.

For LTCFs in particular, CDC will work with pharmacies and other partners to report possible side effects (called adverse events) to the Vaccine Adverse Event Reporting System (VAERS). Facility staff and residents' families are encouraged to also report any adverse events immediately.

CDC will work with pharmacies and other partners to provide communication materials to help LTCFs educate residents and their families about the vaccine, answer their questions about vaccine safety and other issues, and prepare them for vaccination clinics. For some COVID-19 vaccines, two shots are needed to provide the best protection, and the shots are given several weeks apart. Each recipient or caregiver will receive a vaccination record card to ensure they receive the correct vaccine for the second dose.

Risks and benefits will be explained to everyone offered a COVID-19 vaccination

Explaining the risks and benefits of any treatments to a patient in a way that they understand is the standard of care. In LTCFs, consent or assent for vaccination should be obtained from residents (or the person appointed to make medical decisions on their behalf) and documented in the resident's chart per standard practice.

For LTCFs participating in the Federal Pharmacy Partnership for Long-term Care Program, pharmacies will work directly with LTCFs to ensure staff and residents who receive the vaccine also receive an EUA fact sheet before vaccination. The EUA fact sheet explains the risks and benefits of the COVID-19 vaccine they are receiving and what to expect. Each LTCF resident's medical chart must note that this information was provided to the resident. If a resident is unable to make medical decisions due to decreased mental capacity or illness, the EUA fact sheet will be provided to the person appointed to make medical decisions on their behalf (the medical proxy or power of attorney).

Last Updated Dec. 13, 2020