



December 15, 2020

**Re: COVID-19 Vaccine**

Dear Resident / Family,

As the Chief Medical Officer for Signature HealthCARE, I routinely consult with the leadership at Signature facilities, including each facility's Medical Director, about the clinical care delivery to their patients. You or your loved one are not my patient, but I do care about all of our patients, and am writing out of care and concern for them and our staff.

By now, you have probably heard that the COVID-19 vaccines will soon be approved and ready for distribution to residents and staff at our facility. We have long awaited this exciting news!

I understand that some of you may be concerned about the safety of these new vaccines, as they have been developed and tested far more quickly than those in the past. Based on clinical information I've seen, I want to share with you that the speed with which these vaccines were developed is not due to skipping important safety steps, but rather the result of focused, collaborative work performed by experts across the globe.

Vaccines approved for use by the U.S. Food and Drug Administration have undergone the same level of rigorous testing for safety and efficacy as other vaccines and have been tested in tens of thousands of people, including older adults. Furthermore, two independent advisory committees of experts from academic institutions consistently monitor vaccines to ensure their safety.

Most of the COVID-19 vaccines require two separate doses given about three to four weeks apart, depending on the vaccine. Participants of clinical trials have reported experiencing short-term side effects after being vaccinated, with more pronounced discomfort after the second dose. These possible side effects include headache, muscle pains, fatigue, chills, fever and pain at the injection site. Sometimes there is misunderstanding about the cause of these reactions, as you may have heard someone say a vaccine has "made them sick" or given them the disease that the vaccine was intended to prevent. I want to be clear; this is not the case.

The COVID-19 vaccine cannot give you / your loved one a COVID-19 infection. The vaccine works by helping the body create antibodies to fight the virus. Feeling discomfort after getting the vaccine means that the vaccine is doing its job and your body is making antibodies.

This facility, along with thousands of other long-term care facilities, is participating in a program with the Centers for Disease Control to help efficiently distribute the COVID-19 vaccines to our residents free of charge, once they are available. We have partnered with Walgreens, CVS, Omnicare, Pharmerica and local health departments who will deliver and administer the vaccine here.

Please do not hesitate to reach out to us if you have any questions about the COVID-19 vaccine, its possible side effects, and what to expect after you or a loved one receives it. We are all in this together, and the safety and wellbeing of our staff and residents has always been and remains our top priority.

We are confident that the worldwide, unprecedented scientific achievement of these COVID-19 vaccines will eventually enable to us enjoy life with our loved ones again. We look forward to doing our part in this effort by getting the COVID-19 vaccine and hope you will join us.

Sincerely,

A handwritten signature in black ink, appearing to read 'Arif Nazir', with a stylized flourish at the end.

Dr. Arif Nazir  
**Chief Medical Officer**  
Signature HealthCARE and affiliates

## COVID-19 Vaccine

### The COVID-19 Vaccine is coming!!

**OUR RESIDENTS WILL BE THE FIRST PRIORITY TO RECEIVE IT.**

#### What Should You Know?

*The following information was obtained from official government sources.  
We encourage you to discuss with your physician and contact us with any questions.*

#### Vaccine Distribution

- There will be a 3 phased approach to distribution of the COVID-19 vaccination, as described by Centers for Disease Control and Prevention (CDC)'s official plan.
  - Phase 1 – Limited doses available:
    - 1 A – Frontline healthcare industry workers
    - 1 B – Other essential workers and persons at higher risk of contracting and suffering serious complications from COVID-19, including people 65 years of age and older.
  - Phase 2 – Large number of doses available:
    - Remainder of Phase 1 populations
    - Critical populations
    - General population
  - Phase 3 – Continued Vaccination, shift to routine strategy:
    - Remainder of Phase 1 populations
    - Critical populations
    - General population

#### Vaccine Information

- The federal government purchased the vaccines and are expected to be **free of charge**.
- The vaccine requires 2 separate doses. The second vaccine dose must be received, as part of the complete vaccination against COVID-19.
- ***The initial vaccine supply will be far short of demand, so it will be extremely important to receive the vaccine when provided and available to you.***
- Even if a person has previously tested positive for COVID-19, it is still highly recommended that **all** persons receive a COVID-19 vaccination due to the potential for reinfection.
- None of the COVID-19 vaccines currently in development in the United States use the live virus that causes COVID-19.
- Vaccines may have some side effects, such as fever, body aches, and malaise, which are normal and signs that the body is building immunity. These reaction symptoms are normal and expected, and should not deter persons from receiving the second dose.

- Vaccines typically take a few weeks to build immunity after complete vaccination.
- Vaccines will not cause a positive result on viral (PCR/Antibody) tests.
- It is currently unknown how long the vaccine's protection from COVID-19 will last, or if vaccination will have to be repeated annually, etc.
- Health officials recommend that even after a vaccine is widely available, additional measures like masks and social distancing are still necessary until the public health threat has subsided.
  
- **Pfizer vaccine –**
  - Emergency Use Authorization (EUA) was approved by the FDA on December 10, 2020
  - **2 Doses required:** 21 days between doses
  - Intramuscular (IM) administration
  - The vaccine is shown to be 95% effective in preventing symptomatic COVID infections (to put it in perspective, flu vaccines are roughly 60% effective against flu).
  - No serious safety concerns were reported in the trial.
  - The most commonly reported side effects from the Pfizer vaccine in the clinical trials (which are Normal and expected) were pain at the injection site, fatigue, chills and fever.
    - Prior to receiving the vaccine, you will be provided with a vaccine information sheet from the pharmacy.
  - Approved for use in individuals 16 years and older.
  - People with **severe** allergic reactions to any ingredient in the vaccine or had a severe allergic reaction to a previous dose of this vaccine should **NOT** get this vaccine
  
- **Moderna vaccine –**
  - Moderna submitted to the FDA for Emergency Use Authorization on November 30, 2020. The FDA is set to meet on Thursday December 17, 2020 to review and hopefully grant EUA authorization for the use of this vaccine.
  - Current reports show the effective rate is 94.5%
  - **2 Doses required:** 28 days (4 weeks) between doses
  - Intramuscular (IM) administration
  - No serious safety concerns were reported in the trial
  - Normal and expected side effects noted are pain at injection site, muscle aches and headaches.

## **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](http://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
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	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
<p data-bbox="315 415 618 445"><a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a></p> 	<p data-bbox="954 464 1214 533">1-877-829-2619 (1-877-VAX-CO19)</p>

## 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/](http://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  
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**BIONTECH**

Manufactured for  
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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