Date: December 22, 2020

To: Orchard Woods Health Center Residents and Families

From: Minerva Dougan, Director of Nursing

Subject: COVID-19 Vaccination Information

THE VILLAGE AT
ORCHARD RIDGE
A National Lutheran Community

By now you have probably learned that two of the COVID-19 vaccinations have been approved by the FDA. Distribution has begun to frontline health care workers and residents in long-term care facilities. As shared in previous updates from Missy Sellers, associate administrator, through Operation Warp Speed's Pharmacy Partnership program, we are working with CVS to schedule a vaccine clinic for residents residing in Orchard Woods Health Center and all team members in early January. In the coming days, you will also receive an email from Docusign that will contain the necessary consent form required for all receiving the vaccine. Thank you in advance for quickly returning this consent form.

We 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. We want to assure 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. Two independent advisory committees of experts from academic institutions also monitor vaccines to ensure their safety.

Most of the COVID-19 vaccines require two separate doses given about three or 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. The COVID-19 vaccine cannot give you a COVID-19 infection. The vaccine works by helping the body create antibodies to fight off the virus. Feeling discomfort after getting the vaccine means that the vaccine is doing its job, and your body is making antibodies.

We have included two Frequently Asked Questions documents with this message for your review: one is regarding the Pfizer vaccine and the other was provided by CVS. While The Village at Orchard Ridge cannot require the vaccine, we do strongly recommend it and are confident in the work that has been done to get it to this stage.

CONTINUED

I encourage you 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. As we have been saying over the course of this difficult year, we are all in this together. Please know that the safety and wellbeing of our team members and residents have been and remain 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.

What is COVID-19?

COVID-19 is an infectious disease caused by a novel respiratory coronavirus. COVID-19 poses a serious public health risk and is highly contagious. For more information about the virus, please visit the CDC and/or WHO websites dedicated to this issue. Visit the CDC Traveler's Health website for travel notices and precautions.

How does COVID-19 spread?

Human coronaviruses are usually spread from an infected person to others through the air by coughing and sneezing and through close personal contact, such as touching or shaking hands.
It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose or possibly their eyes, but this is not thought to be the main way the virus spreads.
For more information about the transmission of COVID-19, please see the CDC website.

How would a COVID-19 vaccine work?

As with any vaccine, the goal of a COVID-19 vaccine is to expose the body to an antigen that won't cause disease but will provoke an immune response that can block or kill the virus if a person becomes infected. Vaccines contain either the whole virus or a component. After receiving a vaccine, a person develops immunity to that disease without having to get the disease. The immunity varies based on the type of vaccine you receive. Some vaccines last a year (like the flu vaccine) and others last longer (like the polio vaccine). Current science suggests that the COVID-19 vaccine will be more like the flu vaccine requiring annual dosing, but research will be required to fully answer this question.

What are the different technologies being used to develop a COVID-19 vaccine?

Manufacturers are taking different approaches toward developing a COVID-19 vaccine including using portions of the virus, genetic material or other vectors.

Traditional technology

A traditional vaccine technology is to use protein sub-units that can be injected into cells to stimulate a response. Such vaccines usually need adjuvants—or immune-stimulating molecules—delivered in conjunction with the vaccine and may also require multiple doses. Some of the candidates in development using this technique are from Novavax and Sanofi/GSK.

Novel technologies

Viral vector vaccines use another virus that has been engineered to express the S protein to generate an immune response. Some of the candidates in development using this category are from AstraZeneca/Oxford, Johnson & Johnson, Merck and Vaxart.

Nucleic acid vaccines deliver genetic material into the cell which is then translated into a protein – usually the S protein. However, this method – and the way the genetic material (RNA or DNA) is delivered into the cell – requires that these vaccines be stored and transported at ultracold temperatures of -20 to -70 degrees Celsius. Some candidates in development in this category are from BioNTech/Pfizer, Inovio and Moderna.

What is the FDA's Emergency Use Authorization and how does the process work?

In order to help make a vaccine available as soon as possible, the Food and Drug Administration (FDA) would need to authorize its distribution under an Emergency Use Authorization (EUA). The agency has issued guidance for the criteria that will be used to evaluate any EUA application. The FDA evaluates the following criteria when determining whether to issue an EUA:

- Safety: Whether the chemical, biological, radiological or nuclear (CBRN) agent can cause a serious or life-threatening disease or condition. The known and potential benefits of the product, when used to diagnose, prevent or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- Efficacy: If the product is determined to be effective in preventing SARS-CoV-2.
- There is no adequate, approved and available alternative to the product for diagnosing, preventing or treating the disease or condition.

Under the EUA, any investigational vaccines developed to prevent COVID-19 will be assessed on a case-by-case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product and the totality of the available scientific evidence relevant to the product. The final guidance specific to EUA for vaccines to prevent COVID-19 can be found here.

What are some of the clinical considerations or uncertainties concerning a potential vaccine?

Given each vaccine will have different clinical profiles, there are a number of important criteria to evaluate as part of overall planning efforts. Understanding these criteria will help the clinical community plan for safe and effective administration of the vaccine. Some of these considerations include:

- Efficacy, safety, age of vaccine recipient, duration of immunity and route of administration (e.g., intramuscular, intradermal injection, oral, other)
- Dosing frequency and tracking (e.g., single dose vs. multiple doses, time between doses)
- Shipping/storage requirements (e.g., room temperature, refrigerated, frozen, deep-frozen)
- Compounding requirements (e.g., reconstitution, ready-to-use)

Most COVID-19 vaccines under development are likely to require a second booster shot a month or so after the initial dose. Providers will need to ensure that individuals who got the first shot receive a second shot of the right vaccine at the right time. Educating the population about the importance of receiving the booster shot will be critical.

Is it safe to receive the vaccine?

CVS Health's COVID-19 vaccination services will be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines. CVS Health will only be administering vaccines that have been approved for emergency use by the FDA.

How is CVS Health working with the CDC to make the COVID-19 vaccine available?

As announced by the HHS and Department of Defense, CVS Health has entered into a contract with the CDC to be one of the official COVID-19 Vaccination Program Providers in the Pharmacy Partnership for Long-Term Care Program. As a result, once a COVID-19 vaccine is approved and available, the U.S. government will make a supply of the publicly funded vaccine available to CVS Health to provide on-site vaccination clinic services to residents and staff of long-term care facilities.

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 <u>NOT</u> 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
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Manufactured for
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55131 Mainz, Germany

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

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