ST. PAUL'S
SENIOR LIVING COMMUNITY

January 18, 2021

Dear Volunteer:

We at St. Paul's are excited that in January we began to offer the COVID-19 vaccines. On February 2nd, we will host another vaccination clinic at The Villas at St. Paul's in which we are including all of *our volunteers who are 18 years and older*. This clinic will provide the first of two vaccinations. The second vaccination will be given on February 23rd. You must receive both vaccinations. We are hopeful to accommodate all of our volunteers however, it will ultimately depend on the number of vaccines available that day the number of responses we get.

Attached, please find the Emergency Use Authorization (EUA) Fact Sheet for the Pfizer vaccine.

IF you have an interest in receiving the vaccine, we would ask that you complete the attached consent and sent it back to us by January 27th along with a copy of your insurance card (front and back).

To return a consent form and a copy of insurance cards, options include:
- Email to covid19consent@sp1867.org
- Fax the completed form to Attention: Robyn Weaver at 724-588-1135
- Drop the completed form off at The Villas receptionist's desk, Attention: Robyn Weaver.

Please complete the following sections of the form:
- Patient Information
- Mark that you are an employee/staff member (category identified for volunteers too)
- Leave the first of second dose of COVID blank – that will be completed on vaccine day
- Insurance information – complete which ever applies to your situation, prescription insurance, Medicare or Medical insurance. If you do not have any medical insurance, please check the uninsured box
- For those with prescription insurance, Medicare or medical insurance, please make a copy of the front and back of your insurance card and return it with the consent form.
- If you do not have any medical insurance – please complete the section asking for either your social security number, state ID, or driver's license number.

- Please answer all the potential contra-indications questions except question number 1. That one question will be completed on vaccine day.
- Read the consent for services disclaimer.
- Sign and date the form.

If by any chance you have tested positive within the last 30 days, please consult your physician as to whether or not you should get vaccinated.

Individuals may have some side effects, which are normal signs that their bodies are building protection. The most common side effects are pain at the injection site, fever, and chills. These side effects tend to be mild to moderate and go away on their own within 1–2 days.

Please feel free to call me with any questions at (724) 588-9613 ext. 1135.

Sincerely,

Wendy Vaughn
Director of Volunteer Services

Enc. (2)

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.

Revised: December 2020

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.

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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.

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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

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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).

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

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

LAB-1451-0.7

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

Barcode Date: 12/2020

COVID Vaccine Intake Consent Form

CVS pharmacy

Clinic Information

Clinic ID	Clinic Name		Telephone	Store Number

Address		City	State	Zip

Patient Information

Last Name	First Name	Date of Birth	Gender

Address	City	State	Zip

Primary Care Provider (PCP) Name	PCP Phone Number	PCP Fax Number

PCP Address	City	State	Zip

Are you a resident ○ of a Long Term Care facility or an employee/staff member ○ ?

Is this the patient's first ○ or second ○ dose of the COVID-19 vaccination?

Insurance Information: (For onsite clinics, please ensure a copy of the patient's insurance card(s) was collected)

* INDICATES REQUIRED FIELDS

Prescription Insurance: _____ ○ Yes ○ No

*Are you the primary cardholder?   ***If no**, include the primary cardholder's DOB

*Prescription Benefit Plan Name	*Cardholder ID #	*RX Group ID	*BIN	*PCN

Medicare Fields:

○ Yes ○ No

*Is the Patient age 65 or older
or Medicare Eligible?   *Medicare Part A/B ID Number (MBI) **Note:** *MBI is required for all patients age 65 and older, or Medicare eligible. Refer to your Medicare Red, White, and Blue card*

Medical Insurance: _____

*Medical Insurance Provider	*Cardholder ID #	*Group ID	*Payer ID

○ Yes ○ No

*Is the patient the primary cardholder?   ***If no**, include primary cardholder's DOB

*If uninsured, you must check the box below to attest that the following information is true and accurate:

○ I I do not have any insurance, including but not limited to Medicare, Medicaid or any other private or government-funded health benefit plan.

In order to have your vaccine administration fee paid for by the United States Health Resources & Services Administration's COVID-19 Program for Uninsured Patients, please provide either (a) a valid Social Security number, (b) state identification number and state of issuance, OR (c) a driver's license number and the state of issuance.

*Social Security Number	or State Identification Number & State	or Driver's License Number & State

Potential Contraindications	YES	NO	DON'T KNOW
1. Are you feeling sick today?	○	○	○
2. Have you ever received a dose of COVID-19 vaccine? **If yes**, which vaccine product? ○ Pfizer ○ Moderna ○ Another product: _____	○	○	○
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) in the past? *Example: a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?*	○	○	○
Was the severe allergic reaction after receiving a COVID-19 vaccine?	○	○	○
Was the severe allergic reaction after receiving another vaccine or injectable medication?	○	○	○
Was the severe allergic reaction related to receiving Polyethylene Glycol?	○	○	○
4. Have you received any vaccines in the past 14 days?	○	○	○

Last Name	First Name	Date of Birth

Potential Contraindications continued	YES	NO	DON'T KNOW
5. Have you received monoclonal antibodies or convalescent plasma as part of a COVID-19 treatment in the past 90 days?	○	○	○

Potential Considerations	YES	NO	DON'T KNOW
1. Do you have a bleeding disorder or are you taking a blood thinner?	○	○	○
2. Do you have a weakened immune system or currently take medications that can diminish your immune response (i.e., HIV medications, steroids, anticancer drugs, or radiation treatment, etc.?)	○	○	○
3. For women, are you currently pregnant or breastfeeding?	○	○	○

CONSENT FOR SERVICES: I have been provided with the Vaccine Information Sheet(s) or patient fact sheet corresponding to the vaccine(s) that I am receiving. I have read the information provided about the vaccine I am to receive. I have had the chance to ask questions that were answered to my satisfaction. I understand the benefits and risks of vaccination and I voluntarily assume full responsibility for any reactions that may result. I understand that I should remain in the vaccine administration area for 15 minutes after the vaccination to be monitored for any potential adverse reactions. I understand if I experience side effects that I should do the following: call pharmacy, contact doctor, call 911. I request that the vaccine be given to me or to the person named above for whom I am authorized to make this request. State of Georgia only: I verify a pharmacist asked for my health history and whether I have had a physical exam within the past year. Health care providers did not identify condition(s) that would mean I should not receive vaccine(s).

AUTHORIZATION TO REQUEST PAYMENT: I do hereby authorize CVS Pharmacy® ("CVS®") to release information and request payment. I certify that the information given by me in applying for payment under Medicare or Medicaid, or the HRSA COVID-19 Program for Uninsured Patients, is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

DISCLOSURE OF RECORDS: I understand that CVS® may be required to or may voluntarily disclose my health information to the physician responsible for this protocol of specific health information of people vaccinated at CVS (if applicable), my Primary Care Physician (if I have one), my insurance plan, health systems and hospitals, and/or state or federal registries, for purposes of treatment, payment or other health care operations (such as administration or quality assurance). I also understand that CVS will use and disclose my health information as set forth in the CVS Notice of Privacy Practices (copy is available in-store, online or by requesting a paper copy from the pharmacy). State of California only: I agree to have CAIR share my immunization data with Health Care Providers, agencies or schools. Vaccine Clinics: If I am receiving a vaccine through a vaccine clinic, I understand that my name, vaccine appointment date and time will be provided to the clinic coordinator.

X
_____
Signature of patient to receive vaccine (or parent, guardian, or authorized representative)   Date
If signing on behalf of the patient, you are stating that you are authorized to provide the required consents on behalf of the patient.

_____
Name of parent, guardian, or authorized representative   Phone Number   Relationship

Vaccine Administration Information for Immunizer/Pharmacist use only

Administration Date	Vaccine	VIS Date	Manufacturer	Volume (mL)
			○ L ○ R	

Lot #	Exp. Date	Route	Site	**Patient Temperature**

Administering Immunizer Name & Title	Administering Immunizer Signature

To be filled out by immunizer, as required for state immunization registry reporting. Only for states listed.

MS: Check all fields for patients 18 years of age and younger
OK: Check Race and Ethnicity for all patients. Select Next of Kin for patients 18 years of age and younger.

Race: ○ **1** - American Indian or Alaska Native   ○ **2** - Asian   ○ **3** - Native Hawaiian/Other Pacific Islander
○ **4** - Black or African American   ○ **5** - White   ○ **6** - Other Race

Ethnicity: ○ **1** - Hispanic   ○ **2** - Not Hispanic or Latino   ○ **3** - Unknown

Next of Kin (18 or younger)

Name	Phone Number	Relationship

Address

State of NJ only

Prescriber Name	Prescriber Address

For CA, MA, MT, NJ, NM, NY, TX (For CA, this indicator means the registry will not share with Universities, Schools or other agencies) **Registry Sharing Indicator:** ○ Yes   ○ No