COVID-19 VACCINE SCREENING AND CONSENT FORM

Administration Facility Name/Facility ID: _____

SECTION 1: INFORMATION ABOUT PATIENT (PLEASE PRINT)

Name: Last:	First:		Middle Initial:	
Date of Birth: Month Day Year	**Mobile Phone Number (Patient or Guardian):** ( )			
Address:	**Apt/Room #:**			
City:	**State:**		**Zip:**	
Name of Legal Guardian: Last:	First:		Middle Initial:	
Sex (Gender assigned at birth) ☐ Female ☐ Male	**Race** ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American	☐ Native Hawaiian or other ☐ Pacific Islander ☐ White	☐ Other Asian ☐ Other Nonwhite ☐ Other Pacific Islander	☐ Unknown
				Ethnicity ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

Primary Insurance Carrier ID #:_____ Grp #: _____
Insurance Company :_____ Insurance Company Phone #_____
Insured's Name:_____ Relationship:_____ Insured's Date of Birth_____
Secondary Insurance Carrier ID #:_____ Grp #: _____
Insurance Company :_____ Insurance Company Phone #_____
Insured's Name:_____ Relationship:_____ Insured's Date of Birth_____

Is this the patient's first or second dose of the COVID-19 vaccination? ☐ First Dose ☐ Second Dose

SECTION 2: COVID-19 SCREENING QUESTIONS

Please check YES or No for each question.	**Yes**	**No**
1. Do you have today or have you had at any time in the last 10 days a fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea, vomiting, or diarrhea?		
2. Have you tested positive for and/or been diagnosed with COVID-19 infection within the last 10 days?		
3. Have you had a severe allergic reaction (e.g. needed epinephrine or hospital care) to a previous dose of this vaccine or to any of the ingredients of this vaccine?		
4. Have you had any other vaccinations in the last 14 days (e.g. influenza vaccine, etc.)?		
5. Have you had any COVID-19 Antibody therapy within the last 90 days (e.g. Regeneron, COVID Convalescent Plasma, etc.)		

SECTION 3: IMMUNIZATION SCREENING GUIDANCE FOR COVID-19 VACCINE

Please check YES or No for each question.	**Yes**	**No**
6. Do you carry an Epi-pen for emergency treatment of anaphylaxis and/or have allergies or reactions to any medications, foods, vaccines or latex?		
7. For women, are you pregnant or is there a chance you could become pregnant?		
8. For women, are you currently breastfeeding?		
9. Are you immunocompromised or on a medication that affects your immune system?		
10. Do you have a bleeding disorder or are you on a blood thinner/blood-thinning medication?		
11. Are you a female age 18 to 49 years old receiving the Janssen (Johnson and Johnson) COVID-19 vaccine?		
12. If you are under the age of 18 are you and/or your guardian aware that you are only eligible to receive the Pfizer vaccine?		
13. Have you received a previous dose of any COVID-19 vaccine? If yes, which manufacturer's vaccine did you receive:		

- I certify that I am: (a) the patient and at least 18 years of age; (b) the legal guardian of the patient and confirm that the patient is at least 12 years age (for Pfizer vaccine consent only); or (c) legally authorized to consent for vaccination for the patient named above. Further, I hereby give my cons

to the Florida Department of Health (DOH) or its agents to administer the COVID-19 vaccine.

- I understand that this product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals either 12 years of age or older (Pfizer only) or 18 years of age and older (Pfizer, Moderna and Johnson and Johnson) ; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.
- 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 and have received, read and/or had explained to me the Emergency Use Authorization Fact Sheet on the COVID-19 vaccine 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.
- I acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes (or more in specific cases) after administration for observation. If I experience a severe reaction, I will call 9-1-1 or go to the nearest hospital.
- On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless the State of Florida, the Florida Department of Health (DOH), the Florida Division of Emergency Management (FDEM) and their 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 listed above.
- I acknowledge that: (a) I understand the purposes/benefits of Florida SHOTS, Florida's immunization registry and (b) DOH will include my personal immunization information in Florida SHOTS and my personal immunization information will be shared with the Centers for Disease Control (CDC) or other federal agencies.
- I further authorize DOH, FDEM, or its agents to submit a claim to my insurance provider or Medicare Part B without supplemental coverage payment for me for the above requested items and services. I assign and request payment of authorized benefits be made on my behalf to DOH, FDEM, or its agents with respect to the above requested items and services. I understand that any payment for which I am financially responsible is due at the time of service or if DOH invoices me after the time of service, upon receipt of such invoice.
- I acknowledge receipt of the DOH Notice of Privacy Practices.

Signature of Patient or Authorized Representative_____ **Date:** _____

Print Name of Representative and Relationship to Person Receiving Vaccine: _____

Site (LD/RD)	Route	Manufacturer (MVX)	Lot # Unit of Use/ Unit of Sale	Expiration Date	Date of EUA Fact Sheet
	IM				

Administered at location: facility name/ID	
Administered at location: Type	
Administration Address:	
CVX (product)	
Sending organization:	

Vaccinator Print Name: _____ **Signature:** _____ **Date:** _____

Vaccine administering provider suffix: _____

FORMULARIO DE SELECCIÓN Y CONSENTIMIENTO PARA LA VACUNA PARA LA COVID-19

Nombre de la institución de administración/identificación de la institución: _____

SECCIÓN 1: INFORMACIÓN ACERCA DEL PACIENTE (EN LETRA DE IMPRENTA)

Nombre: Apellido:	Primer nombre:	Inicial del 2.º nombre:
Fecha de nacimiento: Mes Día Año	**N.º de teléfono (paciente o tutor):** ( )	
Dirección:		**N.º de apartamento/habitación:**
Ciudad:	**Estado:**	**Código postal:**
Nombre del tutor legal: Apellido:	Primer nombre:	Inicial del 2.º nombre:

Sexo (Sexo asignado al nacer)	Raza				Origen étnico
☐ Mujer	☐ Indio americano/Nativo de Alaska	☐ Nativo hawaiano u otro	☐ Otro asiático	☐ Desconocido	☐ Hispano o latino
☐ Hombre	☐ Asiático	☐ Isleño del Pacífico	☐ Otro no blanco		☐ No hispano ni latino
	☐ Negro o afroamericano	☐ Blanco	☐ Otro isleño del Pacífico		☐ Desconocido

N.º de identificación de la **compañía de seguros principal**: _____ N.º de lote: _____
Compañía de seguros: _____ N.º de teléfono de la compañía de seguros _____
Nombre del asegurado: _____ Relación: _____ Fecha de nacimiento del asegurado _____
N.º de identificación de la **compañía de seguros secundaria**: _____ N.º de lote: _____
Compañía de seguros: _____ N.º de teléfono de la compañía de seguros _____
Nombre del asegurado: _____ Relación: _____ Fecha de nacimiento del asegurado _____

¿Es esta la primera o segunda dosis de la vacuna para la COVID-19 del paciente? ☐ Primera dosis ☐ Segunda dosis

SECCIÓN 2: PREGUNTAS DE DETECCIÓN DE LA COVID-19

Marque SÍ o No para cada pregunta.	**Sí**	**No**
1. ¿Tiene hoy o ha tenido en algún momento de los últimos 10 días fiebre, escalofríos, tos, falta de aliento, dificultad para respirar, fatiga, dolores musculares o corporales, dolor de cabeza, pérdida repentina del sentido del olfato o del gusto, dolor de garganta, congestión (nariz tapada) o secreción nasal (moqueo), náuseas, vómitos o diarrea?		
2. ¿Ha tenido un resultado positivo en una prueba de detección de infección con la COVID-19 o se la han diagnosticado esta en los últimos 10 días?		
3. ¿Ha tenido una reacción alérgica grave (p. ej., necesitó epinefrina o atención en un hospital) a una dosis previa de esta vacuna o a alguno de los ingredientes de esta vacuna?		
4. ¿Ha recibido alguna otra vacuna en los últimos 14 días (p. ej., vacuna contra la influenza, etc.)?		
5. ¿Ha recibido alguna terapia de anticuerpos contra la COVID-19 en los últimos 90 días (p. ej., Regeneron, plasma de convalecientes de COVID, etc.?		

SECCIÓN 3: GUÍA DE SELECCIÓN PARA LA INMUNIZACIÓN CON LA VACUNA PARA LA COVID-19

Marque SÍ o No para cada pregunta.	**Sí**	**No**
6. ¿Lleva con usted un Epi-pen para el tratamiento de emergencia de la anafilaxia y/o tiene alergias o reacciones a algún medicamento, alimento, vacuna o al látex?		
7. En el caso de las mujeres, ¿está embarazada o existe la posibilidad de que quede embarazada?		
8. En el caso de las mujeres, ¿está amamantando actualmente?		
9. ¿Está inmunodeprimido/a o está recibiendo un medicamento que afecta al sistema inmunitario?		
10. ¿Tiene un trastorno hemorrágico o está tomando un anticoagulante?		
11. ¿Es una mujer de 18 a 49 años de edad que recibe la vacuna de Janssen (Johnson and Johnson) contra la COVID-19?		
12. Si es menor de 18 años, ¿sabe usted y/o su tutor que usted solo es elegible para recibir la vacuna de Pfizer?		

13. ¿Ha recibido una dosis previa de alguna vacuna para la COVID-19? En caso afirmativo, ¿de qué fabricante era la vacuna que recibió?		

- Certifico que: (a) soy el paciente y tengo al menos 18 años de edad; (b) soy el tutor legal del paciente y confirmo que el paciente tiene al menos 12 años de edad (para el consentimiento para la vacuna de Pfizer únicamente); o (c) estoy legalmente autorizado para otorgar el consentimiento para la vacunación del paciente mencionado anteriormente. Además, otorgo mi consentimiento para que el Departamento de Salud de Florida (Florida Department of Health, DOH) o sus agentes administren la vacuna para la COVID-19.
- Entiendo que este medicamento no ha sido aprobado ni autorizado por la FDA, pero ha sido autorizado por la FDA para su uso de emergencia, en virtud de una Autorización para uso de emergencia (Emergency Use Authorization, EUA) para prevenir la enfermedad por el coronavirus 2019 (COVID-19), para su uso en personas de 12 años de edad o mayores (Pfizer únicamente), o bien, de 18 años de edad o mayores (Pfizer, Moderna y Johnson and Johnson); y el uso de emergencia de este medicamento solo está autorizado durante la vigencia de la declaración de que existen circunstancias que justifican la autorización de dicho uso de urgencia del medicamento en virtud de la Sección 564(b)(1) de la Ley Federal de Alimentos, Medicamentos y Cosméticos (Food, Drug, and Cosmetic Act, FD&C Act), a menos que se termine la declaración o se revoque antes.
- Entiendo que no es posible predecir todos los posibles efectos secundarios o complicaciones asociadas a la administración de vacunas. Entiendo los riesgos y beneficios asociados a la vacuna mencionada anteriormente y he recibido, leído y/o me han explicado la Hoja informativa de uso de emergencia sobre la vacuna para la COVID-19 que he elegido recibir. Reconozco que he tenido la oportunidad de hacer preguntas y que me respondieron dichas preguntas de forma satisfactoria.
- Reconozco que se me ha aconsejado que permanezca cerca del centro de la vacunación durante aproximadamente 15 minutos (o más, en casos específicos) para estar en observación después de la administración de la vacuna. Si experimento una reacción grave, llamaré al 9-1-1 o iré al hospital más cercano.
- En mi nombre, en el de mis herederos y representantes personales, por la presente libero y eximo de responsabilidad al Estado de Florida, al Departamento de Salud (Department of Health, DOH) de Florida, a la División de Manejo de Emergencias de Florida (Florida Division of Emergency Management, FDEM) y a su personal, agentes, sucesores, divisiones, filiales, subsidiarias, funcionarios, directores, contratistas y empleados de cualquier responsabilidad o reclamación, ya sea conocida o desconocida, que surja de la administración de la vacuna mencionada anteriormente, o que esté relacionada con ella de cualquier manera.
- Doy fe de que: (a) entiendo los propósitos/beneficios de Florida SHOTS, el registro de vacunación de Florida; y que (b) el DOH incluirá mi información personal de vacunación en Florida SHOTS y que esta será compartida con los Centros para el Control de Enfermedades (Centers for Disease Control, CDC) u otras agencias federales.
- Además, autorizo al DOH, a la FDEM o a sus agentes a presentar una reclamación a mi proveedor de seguros o a la Parte B de Medicare sin que se me pague una cobertura suplementaria por los artículos y servicios solicitados anteriormente. Asigno y solicito que el pago de los beneficios autorizados se haga en mi nombre al DOH, la FDEM o a sus agentes con respecto a los artículos y servicios solicitados anteriormente. Entiendo que cualquier pago del cual soy financieramente responsable se deberá realizar al momento del servicio, o si el DOH me factura después del momento del servicio, al recibir dicha factura.
- Confirmo la recepción del Aviso de Prácticas de Privacidad del DOH.

Firma del paciente o representante autorizado_____ **Fecha:** _____

Nombre del representante, en letra de imprenta, y relación con la persona que recibe la vacuna:

_____

Centro (LD/RD)	Ruta	Fabricante (MVX)	N.° de lote unidad de uso/unidad de venta	Fecha de vencimiento	Fecha de la Hoja informativa de la EUA
	i.m.				

Administrada en la ubicación: nombre/identificación de la institución	
Administrada en la ubicación: tipo	
Dirección de la administración:	

CVX (producto)	
Organización de envío:	

Nombre del vacunador, en letra de imprenta: _____ **Firma** _____ **Fecha:** _____

Sufijo del proveedor que administra la vacuna: _____

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 12 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 12 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
- have ever fainted in association with an injection

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 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 23,000 individuals 12 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?

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. 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

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

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- diarrhea
- vomiting
- arm pain

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

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 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. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

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.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

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).

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

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

LAB-1451-4.2a
Revised: 10 May 2021

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

Barcode Date: 05/2021