MEMORANDUM

Date: January 31, 2022

To: Directors, Local Departments of Social Services
Assistant Directors, Local Departments of Social Services

Through: Michelle L. Farr, LICSW, LCSW-C MLF
Executive Director, Social Services Administration

From: Richard Lichenstein, MD RL
Child Welfare Medical Director, Social Services Administration

Re: Guidance on COVID-19 Vaccine for Youth in Out-of-Home Placement

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The use of vaccines is a time-tested public health intervention to control infectious diseases in populations and to protect the health of individuals, particularly those most vulnerable to serious disease. However, as with any intervention, vaccines are not without risk; informed decision making for vaccination, based on current, accurate information and health provider counsel is best practice to maximize both health measure acceptance and safety. Generally, local departments of social services (LDSS) are responsible for making safety and risk decisions regarding out-of-home youth, however collaborations with family and youth ensure that all possibilities are explored, and end results supported. In the context of the COVID-19 vaccine, a LDSS may only consent with specific court authorization or if the agency has been awarded full guardianship following TPR. For youth under 18 years of age, parents and certain others may consent. Unless disabled, youth 18 years of age and older and certain youth under 18 years of age may consent.

Vaccines to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2 are recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). ACIP does not state a product preference; persons may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them. At the time of this guidance, there are 2 COVID-19 vaccines available for use under U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA): Pfizer (5-15 years of age); Moderna is available for those 18 years of age and older under the EUA. A standard immunization series for Pfizer is 2 shots separated by 21 days and for Moderna 28 days. Pfizer has full approval for those 16 years of age and older.

In addition, all children aged 12 years and older should receive a COVID-19 booster shot. These boosters should be delivered at least 5 months after completing the primary COVID- 19 vaccination series. Similarly, the Moderna booster should be delivered at least 5 months after completing the primary COVID- 19 vaccination series. Vaccination guidance during the pandemic changes rapidly. The following website: cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html offers practical guidance regarding COVID-19 vaccine for children and teens.

Given the current emergency use (**not yet fully FDA approved**) status of the COVID-19 vaccines, it is particularly important to ensure the appropriate input of involved families of origin, as well as that of the consenting out-of-home youth, in the process of deciding whether or not an out-of-home youth receives one of the authorized biological products.

The following guidance, informed by the DHS Office of the Attorney General, is for local departments of social services in preparation for youth vaccination appointments; there will be additional information and documentation to be obtained and completed during the vaccination visit. The guidance will be modified in accordance with any changes in federal regulatory decisions regarding the availability and usage of COVID-19 vaccines in the United States. In this guidance, "youth" is any individual in out-of-home care that is of an appropriate age to receive an FDA authorized COVID-19 vaccine.

Guidance

1. Consent
    a. Consent for COVID-19 vaccine administration shall be required prior to any youth's appointment for such vaccination.
    b. Youth should be included in the decision-making process regarding the administration of the COVID-19 vaccine.
    c. According to the Minor Consent Law [Md. Code Ann., Health-Gen. II § 20-102(a)], youth under the age of 18 years may only consent for medical treatment, including vaccination, if they are a parent, married, or living separately from their parent/guardian and self-supporting.
        i. Minor youth, including pregnant minors, who are unable to consent for vaccination and not under full guardianship after termination of parental rights need to have parental consent for COVID-19 vaccine administration.
            1. When a youth is not able to consent for self (is not a parent, married, or living separately from their parent/guardian and self-supporting), LDSS staff shall attempt to contact the parent/guardian for written or verbal consent prior to vaccinating the youth using the *COVID-19 Immunization Consent Form for Parent/Guardian* (**APPENDIX A**).
            2. If the parent/guardian gives verbal consent, LDSS staff signs and completes the bottom section of the *COVID-19 Immunization Consent Form for Parent/Guardian*.
            3. If the parent/guardian has designated a proxy to provide consent, the LDSS staff will attempt to contact that individual for written or verbal consent prior to vaccinating the youth. That proxy must sign an *Affidavit for Person Other than the Parent Consenting to the COVID-19 Vaccination of an Out-of-Home Minor* (**APPENDIX D.1**)
            4. If the parent/guardian is not responding to attempts to reach them after seven days or refuses to consent and the youth is unable to consent for self, then the LDSS may ask the court for authority to provide consent.
                a. The court must grant authority to the LDSS before it consents.
                b. The LDSS director or their authorized designee will document consent on the *COVID-19 Immunization Consent Form for LDSS* (**APPENDIX B**).
        ii. Minor youth who are unable to consent for vaccination and under full guardianship after termination of parental rights need to have their jurisdiction's LDSS director provide consent for COVID-19 vaccine administration, utilizing the *COVID-19 Immunization Consent Form for LDSS*.
            1. Pregnant minors should be consulted by the LDSS director or their authorized designee prior to any consent being given.
    d. Youth who are 18 years and older may consent for medical treatment, including immunizations, unless they have a disability and lack the capacity to consent.

i. If the youth 18 years or older has a disability and lacks the capacity to consent, then LDSS should attempt to contact the youth's parent/guardian.
    1. Prior to providing the COVID-19 vaccine, the attending physician and a second physician or a nurse practitioner, one of whom shall have examined the patient within two hours before making the certification, shall certify in writing that the youth is incapable of making an informed decision regarding the vaccine. The certification shall be based on a personal examination of the patient.

ii. The parent/guardian needs to sign an *Affidavit for Person Other than Self Consenting to the COVID-19 Vaccination of an Out-of-Home Incapable Adult* (**APPENDIX D.2**).
    1. If a parent is unavailable, LDSS staff should attempt to contact an adult sibling, aunt, uncle, or other relative, for consent by signing an *Affidavit for Person Other than Self Consenting to the COVID-19 Vaccination of an Out-of-Home Incapable Adult*.
    2. If no such person is available, the LDSS may ask the court for authority to provide consent, utilizing the *COVID-19 Immunization Consent Form for LDSS* as indicated above.

iii. All youth able to consent for vaccination, due to age or conditions outlined in the Minor Consent Law, can make decisions about receiving the COVID-19 vaccine.
    1. When a youth is consenting for self, LDSS staff will obtain written consent prior to vaccinating the youth using the *COVID-19 Immunization Consent Form for Youth* (**APPENDIX C**).

2. Information requirements
    a. A youth's medical history should be reviewed to ensure immunization is not contraindicated by a history of severe allergic reaction (anaphylaxis) or immediate allergic reaction to vaccinations or the components of the COVID-19 vaccines.
    b. A consultation with a youth's medical provider prior to any appointment for COVID-19 vaccination is required if there is a question about the youth's past medical history (e.g., the consenting party is uncertain or unaware of the history) or the youth is medically fragile.
        i. The medical provider is to be consulted once consent is given for COVID-19 vaccination.
        ii. The youth's medical provider is to complete the *COVID-19 Vaccine Risk Assessment for Youth in Out-of-Home Placement* (**APPENDIX E**) prior to any vaccination appointment.
    c. The party that is providing consent for a youth's COVID-19 vaccination is to be presented with the *FDA COVID-19 Fact Sheets* (**APPENDIX F**) for review prior to decision making and completion of the appropriate Consent Form.
        i. At the time of the dissemination of this guidance, only the Pfizer COVID-19 vaccine is authorized for individuals 5 years of age and older. The Pfizer Fact Sheet (**APPENDIX F.1 and Appendix F.2**) should be distributed for youth 5 to 17 years of age.
        ii. All Fact Sheets can be distributed for youth 18 years of age and older, as they can receive any FDA authorized COVID-19 vaccine.
        iii. Where necessary, assistance in reading the Fact Sheets should be rendered.
3. Documentation requirements
    a. Vaccinations must be documented in the "Health" tab of the youth's CJAMS record
        i. The documenting LDSS staff must use the "Examination" section of the "Health" tab
        ii. All completed forms must be scanned into the vaccination record at the time of "Health" tab documentation.

APPENDIX A

COVID-19 Immunization Consent Form for Parent/Guardian

Youth Name: _____ **Date of Birth:** _____ **Jurisdiction:** _____

The COVID-19 vaccine is recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). ACIP does not state a product preference; persons may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them.

Has this youth ever had an allergic reaction to a vaccine? ❑ **Yes** ❑ **No** ❑ **Unknown**

If yes, describe: _____

Parent/Guardian or Proxy Instructions to Consent: Check the statement that is correct about your consent for COVID-19 vaccination.

❑ I have read or have had read to me and understand the COVID-19 Vaccine FACT SHEET FOR RECIPIENTS AND CAREGIVERS and **I give consent** for my child to receive the COVID-19 vaccine.

❑ I have read or have had read to me and understand the COVID-19 Vaccine FACT SHEET FOR RECIPIENTS AND CAREGIVERS and **I DO NOT consent** for my child to receive the COVID-19 vaccine.

Name of Parent/Guardian or Proxy: _____ Telephone: _____

Signature of Parent/Guardian: _____ Date: _____

Instructions for LDSS Staff: Complete this section if verbal consent or refusal is obtained from the parent/guardian over the telephone. Check the statement that is correct about the parent/guardian's consent for COVID-19 vaccination.

I have reviewed the COVID-19 Vaccine FACT SHEET FOR RECIPIENTS AND CAREGIVERS with the youth's parent/guardian or their proxy, named above.

The parent/guardian or their proxy of the youth: ❑ **Consented to the vaccine**. ❑ **Refused the vaccine**.

Staff Name:_____ Signature:_____ Date:_____

Witness Name:_____Signature:_____Date:_____

APPENDIX B

COVID-19 Immunization Consent Form for LDSS

Youth Name: _____ **Date of Birth:** _____ **Jurisdiction:** _____

The COVID-19 vaccine is recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). ACIP does not state a product preference; persons may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them.

The local department of social services (LDSS) is consenting because the court gave the LDSS express authority or the youth is under full TPR (termination of parental rights) guardianship.

Has the youth ever had an allergic reaction to a vaccine? ❑ **Yes** ❑ **No** ❑ **Unknown**

If yes, describe: _____

LDSS Instructions to Consent: Check the statement that is correct about the consent for COVID-19 vaccination.

❑ I have read and understand the COVID-19 Vaccine FACT SHEET FOR RECIPIENTS AND CAREGIVERS, and **I give consent** for this youth to receive the COVID-19 vaccine.

❑ I have read and understand the COVID-19 Vaccine FACT SHEET FOR RECIPIENTS AND CAREGIVERS, and **I DO NOT consent** for this youth to receive the COVID-19 vaccine for the following reason:_____

LDSS authorized representative: _____ Telephone: _____

Signature of LDSS: _____ Date: _____

Witness Name: _____

Witness Signature: _____ Date:_____

APPENDIX C

COVID-19 Immunization Consent Form for Youth

Youth Name: _____ **Date of Birth:** _____ **Jurisdiction:** _____

The COVID-19 vaccine is recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). ACIP does not state a product preference; persons may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them.

You are able to consent for the vaccine because you are:

❑ 18 years of age or older

❑ A parent

Have you ever had an allergic reaction to a vaccine? ❑ Yes ❑ No ❑ Unknown

If yes, describe: _____

Youth Instructions to Consent: Check the statement that is correct about your consent for COVID-19 vaccination.

❑ I have read or have had read to me and understand the COVID-19 Vaccine FACT SHEET FOR RECIPIENTS AND CAREGIVERS and **I give consent** to receive the COVID-19 vaccine.

❑ I have read or have had read to me and understand the COVID-19 Vaccine FACT SHEET FOR RECIPIENTS AND CAREGIVERS and **I DO NOT consent** to receive the COVID-19 vaccine.

Name of Youth: _____ Telephone: _____

Signature of Youth: _____ Date: _____

Witness/Staff Name: _____

Witness/Staff Signature: _____ Date:_____

APPENDIX D.1

Affidavit for Person Other than the Parent Consenting to the COVID-19 Vaccination of an Out-of-Home Minor

I, _____, affirm under the penalties of perjury that I am
print name

- ❑ A grandparent
- ❑ An adult brother or sister
- ❑ An adult aunt or uncle
- ❑ A stepparent
- ❑ Another adult who has care and control
- ❑ An adult who has care and control of the minor named below under an order of a court or by commitment by a court to the care of an agency of the state or county and reasonably believe the minor needs immunization.

of _____, a minor/incapable adult whose (*check one)*
print name of minor

❑ natural or adoptive parent, ❑ guardian, ❑ person who, under court order, is authorized to give consent for the minor is_____ and for whom I am
print name of parent
giving consent for COVID-19 vaccination.

The following describes the situation of alternate consent:

- ❑ The parent has verbally delegated the authority to me to consent for immunization of the above-named minor and I have sufficient information about the minor and the minor's family to enable me to consent.
- ❑ I have no knowledge that the parent has expressly refused to give consent to the immunization or told me that I may not consent. The parent is not reasonably available because:
  - ❑ the location of the person is unknown.
  - ❑ I have made a reasonable effort within the past 90 days to locate and communicate with the parent for the purpose of obtaining consent and that attempt has failed.
  - ❑ I have contacted the parent and requested that the parent consent to the immunization and no action has been taken on the request.

_____ _____
Signature of Person Giving Consent Witness

_____ _____
Date Date

*"Parent" is defined as the natural or adoptive parent, the guardian, or a person who, under court order, is authorized to give consent for the minor

APPENDIX D.2

Affidavit for Person Other than Self Consenting to the COVID-19 Vaccination of an Out-of-Home Incapable Adult

In accordance with Md. Code, Health-Gen. § 5-605, the following individuals or groups, in the specified order of priority, may make decisions about health care for a person who has been certified to be incapable of making an informed decision and who has not appointed a health care agent in accordance with this subtitle or whose health care agent is unavailable. Individuals in a particular class may be consulted to make a decision only if all individuals in the next higher class are unavailable:
(i) A guardian for the patient, if one has been appointed;
(ii) The patient's spouse or domestic partner;
(iii) An adult child of the patient;
(iv) A parent of the patient;
(v) An adult brother or sister of the patient; or
(vi) A competent friend or other relative of the patient.

I, _____, affirm under the penalties of perjury
print name
that I am

❑ An appointed guardian
❑ A parent
❑ An adult brother or sister
❑ An adult aunt or uncle who has maintained regular contact with the patient sufficient to be familiar with the patient's activities, health, and personal beliefs.
❑ A grandparent who has maintained regular contact with the patient sufficient to be familiar with the patient's activities, health, and personal beliefs.
❑ Another adult relative/close friend who has maintained regular contact with the patient sufficient to be familiar with the patient's activities, health, and personal beliefs.

of _____, an incapable adult for whom I am
print name of Out-of-Home adult

giving consent for COVID-19 vaccination.

_____ _____
Signature of Person Giving Consent Witness

_____ _____
Date Date

APPENDIX E

COVID-19 VACCINE RISK ASSESSMENT FOR YOUTH IN OUT-OF-HOME PLACEMENT

Patient Name: _____

Patient Date of Birth: _____

To be completed by medical provider:

Is there a documented history of severe reaction to prior vaccines or injectable medications?

- ❑ No history of severe or immediate reaction.
- ❑ History of severe or immediate reaction: [Explain]

Are there allergies or other contraindications that would prevent the patient from receiving the COVID-19 vaccine or any specific risks involved with administering the COVID-19 vaccine to the identified patient?

- ❑ No allergies or other contraindications
- ❑ Allergies/Contraindications include: [Explain]

_____

Other specific risks involved with administering COVID-19 vaccine to the patient:

- ❑ No other specific risks.
- ❑ Other specific risks include: [Explain]

_____

Medical Provider Name: _____

Medical Provider Signature: _____

Date: _____

Name of LDSS Staff Consulting Medical Provider: _____

LDSS Staff Signature: _____

APPENDIX F.1

VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 5 THROUGH 11 YEARS OF AGE

FOR 5 THROUGH 11 YEARS OF AGE

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine for use in individuals 5 through 11 years of age.[1]

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide a two-dose primary series to individuals 5 through 11 years of age.

The Pfizer-BioNTech COVID-19 Vaccine has also received EUA from FDA to provide a third primary series dose to individuals 5 through 11 years of age who have been determined to have certain kinds of immunocompromise.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

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

WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. 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 leading to death. 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.

[1] You may receive this Vaccine Information Fact Sheet even if your child is 12 years old. Children who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 through 11 years of age; or (2) COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer BioNTech COVID-19 Vaccine authorized for use in individuals 12 years of age and older.

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 CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

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

The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 28 days after the second dose to individuals who are determined to have certain kinds of immunocompromise.

The vaccine may not protect everyone.

WHO SHOULD <u>NOT</u> GET THE VACCINE?

Your child should not get the vaccine if your child:

- 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 VACCINE?

The 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), tromethamine, tromethamine hydrochloride, sucrose, and sodium chloride.

HAS THE VACCINE BEEN USED BEFORE?

Millions of individuals 12 years of age and older have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020. In a clinical trial, approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. In other clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. The vaccine that is authorized for use in children 5 through 11 years of age

includes the same mRNA and lipids but different inactive ingredients compared to the vaccine that has been used under EUA in individuals 12 years of age and older and that has been studied in clinical trials. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be readily prepared to deliver appropriate doses to the 5 through 11 year-old population.

WHAT ARE THE BENEFITS OF THE VACCINE?
The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?
There is a remote chance that the 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 vaccine. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face • myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain

- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child 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 HAVE MY CHILD GET THE PFIZER-BIONTECH COVID 19 VACCINE?

Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will not change your child's standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?

For children 5 through 11 years of age, there are no other COVID-19 vaccines available under Emergency Use Authorization and there are no approved COVID-19 vaccines.

CAN MY CHILD RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering to have your child receive the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child's healthcare provider.

WHAT IF MY CHILD IS IMMUNOCOMPROMISED?

If your child is immunocompromised, you may be given the option to have your child receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to have your child maintain physical precautions to help prevent COVID-19. In addition, your child's close contacts should be vaccinated as appropriate.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?

If your child is pregnant or breastfeeding, discuss the options with your healthcare provider.

WILL THE VACCINE GIVE MY CHILD COVID-19?

No. The vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.

KEEP YOUR CHILD'S VACCINATION CARD

When your child gets the first dose, you will get a vaccination card to show when to return for your child's next dose(s) of the vaccine. Remember to bring the card when your child returns.

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 CHILD'S VACCINATION INFORMATION BE RECORDED? The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that your child receives the same vaccine when your child returns 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)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An 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 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.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

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

LAB-1486-2.1

Revised: 03 January 2022

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

GDTI: 0886983000424

APPENDIX F.2

VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND OLDER

FOR 12 YEARS OF AGE AND OLDER

You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 12 years of age and older.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.[1]

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:

- a 2-dose primary series to individuals 12 through 15 years of age; • a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; • a single booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA); and
- a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series.

[1] When prepared according to their respective instructions for use, the FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

1 Revised: 03 January 2022

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- a 2-dose primary series to individuals 12 years of age and older; • a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; • a single booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA); and
- a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

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. 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 leading to death. 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 COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, when prepared according to their respective instructions for use, can be used interchangeably.

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 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- 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

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

- A single booster dose of the vaccine may be administered at least 5 months after completion of a primary series of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) to individuals 12 years of age and older.
- A single booster dose of the vaccine may be administered to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding timing of the booster dose.

The vaccine may not protect everyone.

WHO SHOULD <u>NOT</u> GET THE VACCINE?

You should not get the 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 VACCINES?

COMIRNATY (COVID-19 Vaccine, mRNA) and the authorized formulations of the vaccine include the following ingredients:

- mRNA and 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).

Pfizer-BioNTech COVID-19 vaccines for individuals 12 years of age and older contain 1 of the following sets of additional ingredients; ask the vaccination provider which version is being administered:

- potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

OR

- tromethamine, tromethamine hydrochloride, and sucrose

COMIRNATY (COVID-19 Vaccine, mRNA) contains 1 of the following sets of additional ingredients; ask the vaccination provider which version is being administered: • potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

OR

- tromethamine, tromethamine hydrochloride, and sucrose

HAS THE VACCINE BEEN USED BEFORE?

Yes. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccines and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020. The vaccine that is authorized for use in individuals 12 years of age and older includes two formulations; one that was studied in clinical trials and used under EUA, and one with the same mRNA and lipids but different inactive ingredients. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be administered without dilution.

WHAT ARE THE BENEFITS OF THE VACCINE?

The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the 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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine, more commonly in males under 40 years of age than among females and older males.

In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face • myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are 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 either "COMIRNATY (COVID-19 Vaccine, mRNA)" or "Pfizer-BioNTech COVID-19 Vaccine EUA", as appropriate, 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 COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?

Under the EUA, it is your choice to receive or not receive the 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 COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?

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

CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?

If you are immunocompromised, you may receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE VACCINE GIVE ME COVID-19?
No. The 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 next dose(s) of the 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)?
An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An 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 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.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY (COVID-19 Vaccine, mRNA) will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

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

LAB-1451-15.1

Revised: 03 January 2022

APPENDIX F.3

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.

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 has received EUA from FDA to provide:
- a two-dose primary series to individuals 18 years of age and older;
- a third primary series dose to individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise;
- a single booster dose to the individuals 18 years of age and older who have completed a primary series with the Moderna COVID-19 Vaccine; and
- a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine.

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.

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 had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- 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 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 <u>NOT</u> 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 trihydrate, 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.

<u>Primary Series:</u> The Moderna COVID-19 Vaccine is administered as a 2-dose series, one month apart. A third primary series dose may be administered at least one month after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

- A single booster dose of the Moderna COVID-19 Vaccine may be administered at least 5 months after completion of a primary series of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.
- A single booster dose of the Moderna COVID-19 Vaccine may be administered to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. Please check with your healthcare provider regarding timing of the booster dose.

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. Millions of individuals have received the vaccine under EUA since December 18, 2020.

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 *?* 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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Moderna COVID-19 Vaccine, more commonly in males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of the Moderna COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the Moderna COVID-19 Vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported in clinical trials 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, fever, and rash

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

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?
Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of Moderna COVID-19 Vaccine at the same time as other vaccines. If you are considering receiving Moderna COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third primary series dose of the Moderna COVID-19 Vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

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.

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, 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 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 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).

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Moderna US, Inc.
Cambridge, MA 02139

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