

December 14, 2020

COM-2020-097

Dear provider of healthcare-related services,

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the first vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The EUA allows the Pfizer-BioNTech COVID-19 vaccine to be distributed in the United States (U.S.).

The use of Pfizer-BioNTech COVID-19 vaccine under this EUA is limited to **all** of the following requirements:

1. The vaccine is authorized for use in individuals 16 years of age and older.
2. The vaccination provider must communicate to the individual receiving the vaccine or their caregiver information consistent with the "[Fact Sheet for Recipients and Caregivers](#)" before receiving the vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or another designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
 - vaccine administration errors whether or not associated with an adverse event,
 - serious adverse events (irrespective of attribution to vaccination),
 - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
 - cases of COVID-19 that result in hospitalization or death.
5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 vaccine to recipients.

Please refer to the following sources for additional important details:

1. "[Letter of authorization](#)" – Includes details regarding the scope of authorization, product description, the specific conditions that must be met, among other important information.
2. "[Fact Sheet for Healthcare Providers Administering Vaccine](#)" – Contains instructions for healthcare providers, dosage and administration details, contraindications, warnings, reported

adverse reactions, information to provide to vaccine recipients/caregiver, mandatory requirements for the vaccine administration under EUA, how to report adverse events, information regarding the authority for issuance of the EUA, and the full EUA prescribing information.

3. "[COVID-19 Vaccination Program Operational Guidance](#)" – Serves as an interim playbook for state, territorial, tribal, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their jurisdictions.

As reported by the Centers for Disease and Control Prevention (CDC), below are eight things to know about U.S. COVID-19 Vaccination Program:

1. The safety of COVID-19 vaccines is a top priority.
2. COVID-19 vaccination will help to protect from getting COVID-19. Two doses are needed, with the second shot administered three weeks after the first one.
3. Because the current supply of the COVID-19 vaccine in the U.S. is limited, right now, the CDC recommends COVID-19 vaccine to be offered to healthcare personnel and residents of long-term care facilities.
4. Although the COVID-19 vaccine supply is currently limited, supply will increase in the weeks and months to come. Once the vaccine is widely available, the plan is to have several thousand vaccination providers offering COVID-19 vaccines in doctors' offices, retail pharmacies, hospitals, and federally qualified health centers.
5. COVID-19 vaccine recipients may have some side effects after vaccination, which is a normal sign that vaccine recipients' bodies are building protection.
6. Cost is not an obstacle to getting vaccinated against COVID-19. Doses purchased with U.S. taxpayer dollars will be provided to the American people at no cost. However, vaccination providers may be able to charge administration fees for giving the shot.
7. This first COVID-19 vaccine will be used under the EUA issued by the FDA, and other vaccines are still being developed and tested.
8. COVID-19 vaccines are one of many important tools to help us stop this pandemic. Everyone needs to continue using other preventative measures such as mouth and nose covering with a mask when around others, staying at least 6 feet away from others, avoiding crowds, and often hands washing.

Additional information can be found at the [FDA's COVID-19 Vaccines portal](#) and the CDC's website.

The situation with the COVID-19 pandemic is dynamic and continuously changing. We strongly encourage the frequent revision of updated information provided by the FDA and the CDC to assure that your practices are consistent with the most actualized information.



PharmPix is committed to our members' health and wellness. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. Also, you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

Regards,

Clinical Department

References:

1. COVID-19 Vaccines. U.S. Food and Drug Administration. (2020). Retrieved December 2020, from <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>.
2. FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. U.S. Food and Drug Administration. (2020). Retrieved December 2020, from <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>.
3. COVID-19 Vaccination Program Operational Guidance. Cdc.gov. (2020). Retrieved December 2020, from <https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html>.
4. COVID-19 and Your Health. Centers for Disease Control and Prevention. (2020). Retrieved December 2020, from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/8-things.html>.