



**TO:** West Virginia Healthcare Providers, Hospitals and Other Healthcare Facilities

**FROM:** Ayne Amjad, MD, MPH, Commissioner and State Health Officer  
Bureau for Public Health, West Virginia Department of Health and Human Resources

**DATE:** December 23, 2020

**LOCAL HEALTH DEPARTMENTS:** Please distribute to community health providers, hospital-based physicians, infection control preventionists, laboratory directors, and other applicable partners.

**OTHER RECIPIENTS:** Please distribute to association members, staff, etc.

The U.S. Food and Drug Administration (FDA) has issued emergency use authorization (EUA) for two vaccines for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The Pfizer-BioNTech mRNA COVID-19 vaccine received FDA authorization December 11, 2020 for individuals ages 16 and older. It is a 2-dose vaccination series, given intramuscularly, recommended at least 3 weeks apart.

The Moderna mRNA COVID-19 vaccine received FDA authorization December 18, 2020 for individuals 18 and older. It is a 2-dose vaccination series, given intramuscularly, recommended at least 1 month apart.

**Priority Groups**

After receiving FDA authorization for use in the U.S., Pfizer and Moderna vaccines began arriving in West Virginia mid-December. The State of West Virginia is dedicated to ensuring that all West Virginians have access to a COVID-19 vaccination as soon as possible. Following recommendations by the Centers for Disease Control and Prevention (CDC), the guiding principles in decision making for allocating limited supplies in West Virginia include reducing hospitalizations, reducing morbidity and mortality, protecting the most vulnerable West Virginians, and ensuring state and local communities can maintain critical services.

The early focus of vaccine distribution is to protect the most vulnerable West Virginians. Because vaccines will be in limited supply initially, the first phase targets individuals in high-risk settings such as healthcare, emergency response, long-term care facilities, and critical infrastructure. This approach is imperative to preserve critical infrastructure, to ensure West Virginia's healthcare system can meet the state's healthcare needs and to save lives.

As West Virginia receives more vaccine and has vaccinated those identified for Phase 1, vaccinations will be made available to the general public. Decisions on moving to the next phase are made at a state/local level. Phases may overlap. It is not necessary to fully complete vaccination in one phase before beginning the next phase.

To view the state's phased allocation plan, visit <https://dhhr.wv.gov/COVID-19/Pages/Vaccine.aspx>.

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## **Common Side Effects**

**Short-Term:** The majority of short-term side effects reported in clinical trials were mild to moderate and occurred within the first few days of receiving a COVID-19 vaccine. Examples of common mild to moderate immune responses include pain at the injection site and arm, redness at injection site, headache, fatigue, fever, or chills. The occurrence of such physical responses is typically higher after the second dose of a COVID-19 vaccine.

**Long-Term:** Historically, long-term side effects from vaccines have been rare and most side effects have been seen within the first 60 days of receiving vaccines.

Before vaccination, COVID-19 vaccine recipients should be counseled about expected local (e.g., pain, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms.

## **Reporting Adverse Reactions**

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under EUA:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at <https://vaers.hhs.govexternal/icon> or by calling 1-800-822-7967.

In addition, the CDC has developed a new, voluntary smartphone-based tool, [v-safe](#). This tool uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. Reports to v-safe indicating a medically significant health impact are followed up by the CDC/v-safe call center to collect additional information to complete a VAERS report.

## **Contraindications**

All individuals should be screened for allergies, and individuals with allergy questions or concerns should consult a healthcare provider. Contraindications are conditions or factors that would be a reason to not get vaccination due to harm. The only current contraindication to receiving the COVID-19 vaccine is anaphylaxis to any components of the COVID-19 vaccine. The vaccines are still being studied in pediatric populations and those under 16 years of age (Pfizer) or 18 years of age (Moderna) are not currently eligible for vaccination.

## **Ingredients Included in mRNA COVID-19 Vaccine**

<b>Description</b>	<b>Pfizer-BioNTech</b>	<b>Moderna</b>
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	Polyethylene glycol (PEG) 2000
	1,2-distearoyl-sn-glycero-3-phosphocholine	dimyristoylglycerol (DMG)
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102
Salt, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

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The following fact sheets contain additional information about who should not receive the vaccine.

**Pfizer-BioNTech Fact Sheet for Vaccine Recipients and Caregivers:**

<https://www.fda.gov/media/144414/download>

**Moderna Fact Sheet for Vaccine Recipients and Caregivers:**

<https://www.fda.gov/media/144638/download>

**Precautions**

Precautions are conditions or factors that would be a reason to consult with a healthcare provider before proceeding with vaccination. Vaccine providers should observe patients with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination. All other persons should be observed for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions. The CDC considers a history of severe allergic reaction (e.g., anaphylaxis) to *any other* vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a **precaution** but not a contraindication to vaccination. These persons may still receive vaccination but should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination.

**No Contraindication or Precaution**

There are allergies that do not constitute a contraindication or precaution to vaccination, including:

- History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies
- History of allergy to oral medications (including the oral equivalent of an injectable medication)
- Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis)
- Family history of anaphylaxis
- Any other history of anaphylaxis that is not related to a vaccine or injectable therapy

For the rare instances when individuals experience immediate allergic reactions, appropriate medical treatments are available (and are mandatory on-site) to manage the symptoms. Clinical considerations are available here: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>.

**Enrollment in Vaccination Program**

COVID-19 vaccination providers must be credentialed and licensed, sign and agree to the CDC COVID-19 Vaccination Provider Agreement and complete the CDC COVID-19 Vaccination Provider Profile. At this time, vaccine providers are being enrolled by provider type, as high priority populations are identified. Additional communications regarding provider enrollment will be forthcoming as more vaccines become available within the State of West Virginia.

**Personal Protective Equipment Requirements (PPE)**

Minimum PPE requirement for use during COVID-19 vaccine administration should include facemask or N95; goggles or face shield; and hand washing/hand sanitizer use and glove change with each dose administered.

**COVID-19 Vaccine Product Use Set to Expire**

**Vaccine product set to expire within 48 hours in the following sequence:**

- Identify current phase structure qualified individuals to administer the vaccine to.
- Contact vaccine lead to determine if any unopened packages set to expire can be used by another location within 24 hours. Utilization of vaccine doses must be based on the current phase structure for qualified individuals.

**Vaccine product set to expire within 6 hours in the following sequence:**

- Administer vaccine to site team members that are eligible based on current phase structure for qualified individuals.
- Administer vaccine to site team members aged 65 years and older.
- Administer vaccine to site team members aged 60-64 years old.
- Administer vaccine to other site team members not identified above.

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To view the state's phased structure, visit <https://dhhr.wv.gov/COVID-19/Pages/Vaccine.aspx>.

Site team members that receive a first dose of the vaccine will qualify for the second dose.

**Additional Resources**

DHHR Vaccine Website (Emergency Use Authorization Fact Sheet, Immunization Screening and Consent Form, DHHR FAQ)

<https://dhhr.wv.gov/COVID-19/Pages/Vaccine.aspx>

COVID-19 Vaccination Communication Toolkit for Medical Centers, Clinics, and Clinicians

<https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>

CDC's COVID-19 Vaccine Information for General Public

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

CDC's COVID-19 Vaccine Information for Healthcare Personnel

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html>

For questions about this alert, contact the Office of Epidemiology and Prevention Services (OEPS) at 1-800-423-1271, ext. 1; 304-558-5358, ext. 2; or the 24/7 answering service at 304-342-5151.

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