



# Arkansas Department of Health

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Governor Asa Hutchinson  
José R. Romero, MD, Secretary of Health

August 24, 2021

Dear Arkansas Colleagues:

Thank you for your continued dedication to recommending and administering COVID-19 vaccinations to your patients and community members. In recent days, ADH has received various questions regarding “off-label use” of COVID-19 vaccines. We’d like to bring to your attention a communication CDC released on this topic, which also addresses other questions about FDA approval of Pfizer-BioNTech’s mRNA vaccine.

“Following recent regulatory actions and clinical recommendations, CDC is providing this update to remind providers, jurisdictions, and health systems of the requirements set forth in the [CDC COVID-19 Vaccination Program Provider Agreement](#), among other relevant updates. As a reminder, the Pfizer COVID-19 vaccine is recommended by CDC and ACIP for a two-dose series to vaccinate people 12 years of age and older and for an additional, third dose in certain immunocompromised individuals.

**Recent COVID-19 Vaccine Regulatory Updates:**

On Monday, August 23, 2021, [FDA approved COMIRNATY \(COVID-19 Vaccine, mRNA\) for use as a two-dose series for individuals 16 years of age and older](#). It can also be used under the EUA to prevent COVID-19 in individuals 12 through 15 years and provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

**Interchangeability of FDA authorized and FDA approved COVID-19 Products:** The FDA-approved Pfizer-BioNTech product COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under the EUA to administer the vaccination series for those seeking the approved vaccine. The Fact Sheet for Recipients provides additional information about both the approved and authorized vaccine. Providers should continue to use the vaccines on their shelves.

**CDC COVID-19 Vaccination Program Provider Agreements:** Providers are responsible for adhering to all requirements outlined in the agreement. Specifically, providers must administer COVID-19 vaccines in accordance with all [program requirements and recommendations](#) of CDC, the [Advisory Committee on Immunization Practices](#), and the U.S

Food and Drug Administration ([FDA](#)). This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (often referred to as “off-label use”) is not recommended. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.”

To clarify, let me add that “off-label use” means use in any age group that is not yet FDA or CDC approved or authorized to receive vaccine (such as children younger than 12 years of age), additional doses that are not approved or authorized, and dosage amounts not approved or authorized.

Thank you for your continued dedication to vaccinating all individuals in Arkansas.

Sincerely,

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