Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

August 25, 2021

Dear Colleague:

On Monday, August 23, 2021, the Food and Drug Administration (FDA) approved Comirnaty (COVID-19 Vaccine, mRNA) for use as a two-dose series for individuals 16 years of age and older. Comirnaty has been known as the Pfizer-BioNTech COVID-19 vaccine that was available for use under FDA Emergency Use Authorization (EUA). This vaccine may still be used under the EUA to prevent COVID-19 in individuals aged 12 through 15 years, and for the administration of a third dose in certain immunocompromised individuals.

Comirnaty (the fully approved vaccine) and the 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 efficacy 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 health care providers administering provides additional information about both the approved and authorized vaccine. Providers should continue to use the vaccines on their shelves.

Providers are responsible for adhering to all requirements outlined in the CDC COVID-19 Vaccination Program Provider Agreement. The Centers for Disease Control & Prevention (CDC) has notified Maryland that providers must administer COVID-19 vaccines in accordance with all program requirements and recommendations of the CDC, the Advisory Committee on Immunization Practices, and the FDA. This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, “off-label use” (including administration to children under 12 years old) of these products is not recommended. Off-label use would violate the provider agreement and could expose providers to the following risks:

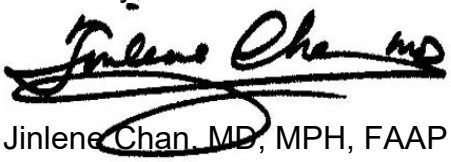
- Administration of the product off-label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after 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.

Based on CDC Vaccine Confidence data, approximately 10% of the unvaccinated Maryland population reports that they probably will get vaccinated or are unsure. With the full licensure of the Pfizer vaccine, confidence in the vaccine may rise and cause an increase in demand for the vaccine. We encourage you to reach out to your unvaccinated patients, address any lingering hesitancy issues, and recommend vaccination.

The Advisory Committee on Immunization Practices will be meeting on August 30 to discuss their recommendations for the use of Comirnaty. We will keep you informed of any changes in recommendations.

Sincerely,



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Deputy Secretary for Public Health Services