

Date: August 25, 2021  
Topic: Regulatory Updates for COVID-19 Vaccines – U.S. Food and Drug Administration Approves Licensure of the Pfizer-BioNTech COVID-19 Vaccine  
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To: All Health Care Providers and Facilities

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## **Recent Regulatory Updates**

On Monday, August 23, 2021, the U.S. Food and Drug Administration ([FDA issued full approval to the Pfizer-BioNTech COVID-19 vaccine, which will now be marketed as COMIRNATY, for use as a two-dose series indicated for individuals 16 years of age and older.](#) COMIRNATY will remain available under the existing Emergency Use Authorization (EUA) to prevent COVID-19 in individuals ages 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to be moderately to severely immunocompromised.

FDA's full approval of the first COVID-19 vaccine, which required additional safety and efficacy data beyond what was provided for the EUA, is an important milestone that should reassure anyone who has concerns about getting vaccinated. On top of the rigorous testing and trials that went into Emergency Use Authorization of the Pfizer vaccine, the FDA has now completed additional analysis of the effectiveness and safety data from tens of thousands of clinical trial participants ages 16 years and older, as well as the analysis of real-world safety data.

## **Interchangeability of FDA Authorized and FDA Approved COVID-19 Vaccines**

[Comirnaty](#) is the new name for the Pfizer-BioNTech COVID-19 vaccine. It is the same vaccine formulation as the one that was first authorized for use in December 2020 and has been administered to millions of people in the United States and abroad.

The FDA-*approved* Pfizer-BioNTech COVID-19 vaccine, COMIRNATY (pictured below left), and the FDA-*authorized* Pfizer-BioNTech COVID-19 Vaccine under EUA (pictured below right) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Inventory of both types of vials will be distributed in the United States until Comirnaty receives full approval for those under age 16 years.



COVID-19 vaccine 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 they have in stock.

### **Booster Doses**

The Centers for Disease Control and Prevention (CDC) is developing a plan to begin offering a BOOSTER dose of the mRNA vaccine (Pfizer or Moderna), subject to FDA authorization and recommendation by CDC's Advisory Committee on Immunization Practices (ACIP). FDA is conducting an independent evaluation to determine the safety and effectiveness of a booster dose of the mRNA vaccines. The ACIP will decide whether to issue a booster dose recommendation based on a thorough review of the evidence. A BOOSTER dose (administered when the initial sufficient immune response to the primary vaccine series is likely to have waned over time in individuals with healthy immune systems) has not been approved at this time and if given would be considered an off-label use and a violation of the CDC COVID-19 Vaccination Program Provider Agreement.

### **CDC's COVID-19 Vaccination Program Provider Agreement Stipulations**

Providers enrolled through the Nevada State Immunization Program to receive and administer COVID-19 vaccines are responsible for adhering to all requirements outlined in the Agreement to Participate. 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 reasons 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 federally provided vaccines may be used. Providers administering doses in an off-label fashion would be in violation of the CDC Program Provider Agreement to Participate potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.

All of the COVID-19 vaccines authorized or approved in the U.S. are extremely safe and effective, based on extensive clinical trials, and nearly 200 million Americans have received at least one dose of a COVID-19 vaccine. Additional information will be provided as soon as it becomes available.

### **Resources**

- FDA approves (licenses) first COVID-19 vaccine: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>
- FDA information on Comirnaty: <https://www.fda.gov/vaccines-blood-biologics/comirnaty>
- Updated Pfizer-BioNTech COVID-19 Fact Sheet for Recipients: <https://www.fda.gov/media/144414/download>
- Information for COVID-19 Vaccine Providers in Nevada: [https://dpbh.nv.gov/Programs/Immunization/COVID/COVID\\_Vaccine/](https://dpbh.nv.gov/Programs/Immunization/COVID/COVID_Vaccine/)

- ACIP COVID-19 Vaccine Recommendations: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>
- Find COVID-19 Vaccines in Nevada at <https://www.immunizenevada.org/covid-19-vaccine-locator>
- Learn more about COVID-19 Vaccines at <https://www.NVCOVIDFighter.org/>

*Questions:*

*For updated guidance, please review the DPBH Technical Bulletin [website](#) and Nevada's health response [website](#) regularly. Email [dpbhcovid19vax@health.nv.gov](mailto:dpbhcovid19vax@health.nv.gov) with questions.*



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