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Technical Bulletin

Date: **October 19, 2022**
Topic: **Bivalent COVID-19 Booster Vaccine Recommended for 5 Years and Older**
Contact: **Jessica Lamb, RN, Nevada State Immunization Program**
To: **All Health Care Providers and Facilities; Pharmacists; Local Health Authorities**

Background:
On October 12, 2022, the U.S. Food and Drug Administration (FDA) issued amended Emergency Use Authorizations (EUAs) to both Moderna and Pfizer-BioNTech to authorize their bivalent formulations of the COVID-19 vaccine for pediatric use as a single booster dose, at least two months following primary or booster vaccination. The bivalent vaccines contain two messenger RNA (mRNA) components of SARS-CoV-2 virus; one from the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2. The Moderna COVID-19 Vaccine, Bivalent has received authorization for pediatric individuals 6-11 years of age and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent has received authorization for pediatric individuals 5-11 years of age. In addition to these pediatric authorizations, Moderna's current COVID-19 bivalent booster now has extended authorization to those individuals 12 years of age and older (it was previously only authorized for individuals 18+ years).

In addition, on October 12, 2022, **Pfizer-BioNTech's monovalent mRNA COVID-19 vaccine is no longer authorized by the FDA to be administered as a booster dose for pediatric individuals 5-11 years of age.** This now means that the recently approved bivalent booster vaccines are the only authorized booster formulations available for administration. *All COVID-19 monovalent formulation vaccines may ONLY be administered as a primary series, NOT as booster dose to any individuals, regardless of their age.* Administration of any monovalent booster vaccines for individuals 5+ years are now considered vaccine administration errors and must be reported to the Vaccine Adverse Event Reporting System (VAERS).

At the most recent Advisory Committee on Immunization Practices (ACIP) meeting and Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting, evidence and data was presented and discussed on this matter. This technical bulletin summarizes the recent Pfizer-BioNTech and Moderna bivalent COVID-19 booster vaccine eligibility. At this time, the single dose, COVID-19 bivalent booster vaccines are not authorized to be used as a primary series and are only available to individuals 5+ years who have completed an FDA authorized COVID-19 primary vaccine series, regardless of the number or type of booster doses received/administered prior.

Persons eligible to receive the recommended **Pfizer-BioNTech COVID-19, pediatric bivalent formulation booster vaccine** include:

- **Any pediatric individual ages 5-11 years who has completed a COVID-19 primary vaccine series**
  - *Dose interval: a single booster dose administered at least two months following completion of any age appropriate, FDA authorized COVID-19 vaccine primary series and/or previous booster dose*
  - *Dose amount: 0.2mL each dose (*10 µg/dose*), to be administered intramuscularly (*Please note that this product **requires diluent**.)

Persons eligible to receive the recommended **Moderna COVID-19, pediatric bivalent formulation booster vaccine** include:

- **Any pediatric individual ages 6-11 years who has completed a COVID-19 primary vaccine series**
  - *Dose interval: a single booster dose administered at least two months following completion of any age appropriate, FDA authorized COVID-19 vaccine primary series and/or previous booster dose*
  - *Dose amount: 0.25mL each dose (*25 µg/dose*), to be administered intramuscularly*

UPDATED AGE RECOMMENDATION FOR ADULT DOSING OF MODERNA BIVALENT BOOSTER:
Those now eligible to receive the recommended **Moderna COVID-19, bivalent booster vaccine** include:

- **Any individual 12 years of age or older who has completed a COVID-19 primary vaccine series**
  - *Dose interval: a single booster dose administered at least two months following completion of any age appropriate, FDA authorized COVID-19 vaccine primary series and/or previous booster dose*
  - *Dose amount: 0.5mL each dose (*50 µg/dose*), to be administered intramuscularly*

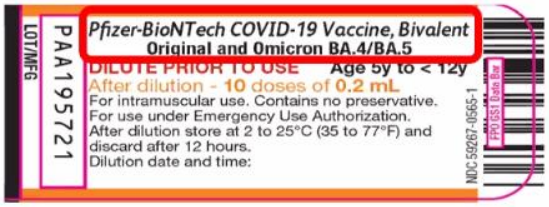
Both Pfizer-BioNTech and Moderna's COVID-19 Bivalent booster vaccines will have the same storage and handling parameters as their original/other bivalent vaccine products. Pfizer-BioNTech Pediatric COVID-19 Bivalent booster vaccine (ages 5-11years) is expected to be packaged in 10-dose vials in cartons of 10 vials each (100 doses total) and will require diluent. Moderna's Pediatric COVID-19 Bivalent booster vaccine (ages 6-11 years) will use the same vial formulation as the 12+ vials, except the 6-11year dose (.25mL) will be half the amount of the 12+ dose (0.5mL). Moderna's COVID-19 Bivalent booster vaccine will continue to be packaged in 5-dose vials in cartons of 10 vials each (50 doses total for 12+ use, 100 doses total for 6-11 use). Once punctured, both Pfizer and Moderna's bivalent booster vials, must be used within **12 hours**. Similar to existing Moderna and Pfizer-BioNTech (grey cap) products, vials must be discarded ≤12 hours after the first puncture. Additional storage and handling parameters are outlined in the chart on page 3.

It is important to note the primary goal of the COVID-19 vaccine response should continue to be COVID-19 vaccine administration to the unvaccinated. The Nevada Department of Health and Human Services is encouraging individuals to speak with a health care provider about vaccination and COVID-19 vaccines. Individuals may be referred to NVCOVIDFighter.org or 1-800-401-0946 for more information on vaccine access and other COVID-19 resources.

For more information and/or additional resources, the Centers for Disease Control and Prevention (CDC) has published updated COVID-19 vaccine interim clinical considerations, COVID-19 Vaccination Clinical and Professional Resources and COVID-19 vaccine schedules for non-immunocompromised individuals and immunocompromised individuals.

Pfizer-BioNTech's Vaccine Information Fact Sheets for Recipients and/or Caregivers and Healthcare Providers have also been updated by the FDA for reference.

Moderna's Vaccine Information Fact Sheets for Recipients and/or Caregivers and Healthcare Providers are available for reference, in addition to a Letter to Healthcare Providers.

[Pfizer-BioNTech COVID-19 Vaccine Storage and Handling]	[Moderna COVID-19 Vaccine Storage and Handling]
Requires diluent (1.3mL diluent/per vial)	Does ***not*** require diluent
Ultra-cold freezer storage (-90°C to -60°C) until expiry	***No ultra-cold freezer storage***
No freezer storage	Freezer storage (-25°C to -15°C) until expiry
Refrigerate (2°C to 8°C) up to 10 weeks without puncturing	Refrigerate (2°C to 8°C) up to 30 days without puncturing
Pediatric Bivalent Booster Vial (5-11 years):  **Bivalent Booster Label:**  	**Pediatric (6-11 years) & 12+ Bivalent Booster Vial:**  **Bivalent Booster Label:** 

Questions:

For updated guidance, please review the DPBH Technical Bulletin web page and the Nevada Health Response website regularly. Email questions to dpbhcovid19vax@health.nv.gov.

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