

To: CAHAN San Diego Participants

Date: December 15, 2022 From: Public Health Services

Health Advisory Update #59: Coronavirus Disease 2019 (COVID-19) Vaccine Update: COVID-19 Bivalent Booster

Eligibility Expanded Down to Six Months of Age

# **Key Messages**

- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have authorized the Pfizer-BioNTech (Pfizer) and Moderna COVID-19 bivalent boosters for children down to 6 months of age.
- Children ages 6 months to 4 years who have started, but not yet completed, the 3-dose Pfizer primary series are eligible to have a bivalent booster substitute for the 3<sup>rd</sup> dose of the Pfizer primary series.
- Children ages 6 months to 5 years who have completed the 2-dose Moderna primary series are eligible to receive a bivalent booster two months after completion of the series.
- COVID-19 vaccines can be co-administered with routine child and adolescent vaccines.

#### Situation

Following thorough evaluation and analysis of the safety and effectiveness data, federal agencies have granted both Pfizer-BioNTech (Pfizer) and Moderna COVID-19 bivalent boosters Emergency Use Authorization (EUA) and recommendations for use in children down to 6 months of age.

### **Approval Process**

### Federal

On December 8, 2022, the Food and Drug Administration (FDA) expanded the eligibility for the Pfizer bivalent booster to include children 6 months to 4 years of age, provided they had not already completed the Pfizer 3-dose primary series. The FDA also expanded the eligibility for the Moderna bivalent booster to include children 6 months to 5 years of age. The FDA determined that the known and potential benefits of the Pfizer and Moderna bivalent boosters outweigh the known and potential risks of the boosters in these pediatric populations.

On December 9, the Centers for Disease Control and Prevention (CDC) updated its <u>COVID-19 Vaccine Interim Clinical</u> Considerations as follows:

- Children ages 6 months to 4 years who have started, but not yet completed, the 3-dose Pfizer primary series are eligible for substitution of a bivalent booster for the 3<sup>rd</sup> dose of the Pfizer primary series.
- Children who have completed the 3-dose Pfizer primary series are not eligible for a bivalent booster at this time.
- Children ages 6 months to 4 years who have completed the 2-dose Moderna primary series are eligible to receive a Moderna bivalent booster two months after completion of the Moderna series.
- Children 5 years of age who have received the 2-dose Moderna primary series are eligible to receive either a Moderna or Pfizer bivalent booster, two months after completion of the Moderna series.

A CDC Clinical Outreach and Communication Activity (COCA) on updates to the COVID-19 vaccine recommendations, including bivalent boosters for children down to 6 months of age, was held on December 13, 2022. A recording of the webinar and the slides are available here.

The American Academy of Pediatrics (AAP) supports co-administration of COVID-19 vaccines with routine childhood and adolescent immunizations to get pediatric patients caught up and remain up-to-date on recommended vaccines.

## **Scheduling**

MyTurn.ca.gov is currently being updated to reflect the expanded eligibility. Parents and guardians are encouraged to check with their child's healthcare provider to schedule their vaccine appointments.

# **Actions Requested**

- 1. If not already enrolled, providers can **listen** to the recorded webinar on <u>how to enroll in the California COVID-19</u> <u>vaccination program</u> and **participate** in COVID-19 vaccination efforts.
- 2. Remain up-to-date on COVID-19 vaccine clinical considerations, including contraindications and precautions.
- 3. **Provide** bivalent boosters to eligible children down to 6 months of age using either the Moderna or Pfizer vaccine as follows:
  - a) Moderna bivalent booster can be given beginning 2 months after completion of the Moderna primary series in children 6 month to 4 years of age.
  - b) Either the Moderna or Pfizer bivalent booster can be given to children 5 years of age, 2 months after completing the Moderna primary series.
  - c) Pfizer bivalent booster can only be given as a substitute for the 3<sup>rd</sup> dose in the 3-dose Pfizer primary series in children 6 months to 4 years of age.
- 4. **Co-administer** routine childhood and adolescent vaccines with COVID-19 vaccine to avoid missed opportunities to keep children up-to-date will all recommended vaccine.
- 5. **Report** vaccine-related adverse events and deaths, as well as vaccine administration errors to the <u>Vaccine Adverse Event Reporting System (VAERS)</u> and to the County Immunization Program at IZINFO.HHSA@sdcounty.ca.gov or Fax: (619) 692-5677.

#### Resources

- Fact Sheet for Recipients and Caregivers, Pfizer COVID-19 bivalent booster, 6-months- to 4-year-olds | FDA
- Fact Sheet for Healthcare Providers, Pfizer COVID-19 bivalent booster, 6-months- to 4-year-olds | FDA
- Fact Sheet for Recipients and Caregivers, Moderna COVID-19 bivalent booster, 6-months- to 5-year-olds | FDA
- Fact Sheet for Healthcare Providers, Moderna COVID-19 bivalent booster, 6-months- to 5-year-olds | FDA
- Safety of COVID-19 Vaccines | CDC
- Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit | CDC
- Vaccine Resources and Guidance (SanDiegoCounty.gov)

Thank you for your participation.

### **CAHAN San Diego**

County of San Diego Health & Human Services Agency Epidemiology and Immunization Services Branch Phone: (619) 692-8499; Fax: (858) 715-6458

Urgent Phone for pm/weekends/holidays: (858) 565-5255

E-mail: cahan@sdcounty.ca.gov

Secure Website: <a href="https://member.everbridge.net">https://member.everbridge.net</a>
Public Website: <a href="http://www.cahansandiego.com">https://member.everbridge.net</a>