

SECRETARIAL DIRECTIVE ON BIVALENT COVID-19 VACCINES FOR INDIVIDUALS DOWN TO SIX MONTHS OF AGE

December 09, 2022

The Centers for Disease Control and Prevention (CDC) has determined that, as part of the broad range of prevention and mitigation strategies, vaccines are an important tool to help stop the COVID-19 pandemic. To that end, CDC has continued to consider available science, including SARS-CoV-2 epidemiology, evidence related to the effectiveness of currently available Food and Drug Administration (FDA) approved or authorized COVID-19 vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

On December 08, 2022, the FDA amended the emergency use authorizations (EUAs) for the updated (bivalent) Moderna and Pfizer-BioNTech COVID-19 vaccines to include use in individuals down to 6 months of age. Specifically,

- Children 6 months through 5 years of age who received the original (monovalent) Moderna COVID-19 Vaccine are now eligible to receive a single booster dose of the updated (bivalent) Moderna COVID-19 Vaccine two months after completing a primary series with the monovalent Moderna COVID-19 Vaccine.
- Children 6 months through 4 years of age who have not yet begun their three-dose primary series of the Pfizer-BioNTech COVID-19 Vaccine or have not yet received the third dose of their primary series will now receive the updated (bivalent) Pfizer-BioNTech COVID-19 vaccine as the third dose in their primary series following two doses of the original (monovalent) Pfizer-BioNTech COVID-19 Vaccine.

Based on CDC's review of the available data, the Director of the CDC endorsed the following within the parameters of EUAs issued by the FDA on December 08, 2022:

- A single booster dose of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is recommended for children ages 6 months through 5 years at least 2 months after completion of a Moderna COVID-19 vaccine primary series.
- A third primary series dose of Pfizer-BioNTech Vaccine COVID-19, Bivalent (Original and Omicron BA.4/BA.5) is recommended for children ages 6 months through 4 years at least 8 weeks after receipt of a second primary series dose of monovalent Pfizer-BioNTech COVID-19 vaccine.

In addition, CDC repealed its previous recommendation for administration of monovalent Pfizer-BioNTech COVID-19 Vaccine as a third primary series dose for children ages 6 months through 4 years.

The Department of Health and Human Services (HHS) concurs with CDC's recommendations for use of bivalent COVID-19 vaccines for individuals down to six months of age, consistent with the parameters of the EUAs issued by FDA.

Accordingly, pursuant to Section 319 of the Public Health Service Act (42 U.S.C. §247d), the Secretary of HHS hereby **DIRECTS** as follows:

As of December 09, 2022, authorized CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer, upon request:

- **A single booster dose of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) for children 6 months through 5 years of age at least 2 months after completion of the monovalent Moderna COVID-19 Vaccine primary series.**
- **A third primary series dose of Pfizer-BioNTech Vaccine COVID-19, Bivalent (Original and Omicron BA.4/BA.5) for children 6 months through 4 years of age at least 8 weeks after receipt of the second primary series dose of monovalent Pfizer-BioNTech COVID-19 Vaccine.**

CDC COVID-19 Vaccination Program enrolled providers authorized to administer COVID-19 vaccine to covered children must comply with this Directive as specified in updated CDC COVID-19 vaccination provider requirements posted at:

<https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>.

This Directive also applies to all awardees and recipients of HHS grant and cooperative agreement funds, including grants to states and U.S. territories that have been awarded to support, implement, and expand COVID-19 vaccination programs nationwide.

This Directive should be read and implemented consistent with other existing direction from HHS and CDC, including the *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations (Playbook)* guidance document; prior directives from the HHS Secretary and supplements and addenda to vaccine distribution and vaccine prioritization; the CDC Provider Agreement and related guidance; and any workplan, application, jurisdiction vaccination plan, or other submission from an awardee or recipient of CDC grants or cooperative agreements related to COVID-19 vaccine activities. To the extent that this Directive directly conflicts with those documents, this Directive shall be read to replace and supersede those documents.

I thank you for your attention to this matter, as well as for your efforts in the COVID-19 response.

/s/

Xavier Becerra
Secretary