

## SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN 6 MONTHS THROUGH 4/5 YEARS OF AGE

June 18, 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 June 17, 2022, the FDA amended the Emergency Use Authorizations (EUAs) for the Pfizer-BioNTech and the Moderna COVID-19 vaccines to:

- authorize the use of a two-dose Moderna COVID-19 primary vaccine series for administration to children ages 6 months through 5 years, 6 years through 11 years, and 12 years through 17 years, as well as a third primary series dose at least one month following the second dose for individuals in these age groups who have been determined to have certain kinds of immunocompromise; and authorize the use of a three-dose Pfizer-BioNTech COVID-19 primary vaccine series for administration to children 6 months through 4 years.

On June 18, 2022, the Advisory Committee on Immunization Practices (ACIP), consistent with the parameters of the EUAs issued by FDA, recommended expanding eligibility for the pediatric population to receive the COVID-19 vaccine, as follows:

- a **two-dose** Moderna COVID-19 vaccine series (25µg each) is recommended for children ages **6 months - 5 years**,<sup>1</sup> under the EUA issued by FDA.
- a **three-dose** Pfizer-BioNTech COVID-19 vaccine series (3µg each) is recommended for children ages **6 months - 4 years**, under the EUA issued by FDA.

Based on CDC's review of the available data, and taking into account data and information that were presented to and considered by the ACIP, the Director of the CDC adopted these ACIP recommendations on June 18, 2022. In addition, the Director recommended that children ages 6 months through 5 years of age with moderate to severe immunocompromise who have received a two-dose Moderna COVID-19 primary series should receive a third primary series dose at least 28 days following the second primary series dose.

The Department of Health and Human Services (HHS) concurs with CDC's recommendations for use of a two-dose series of the Moderna COVID-19 vaccine for children ages 6 months

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<sup>1</sup> ACIP intends to consider recommendations for administration of the Moderna COVID-19 vaccine in children 6 years through 17 years of age at its June 22-23, 2022 meeting.

through 5 years, an additional Moderna dose for children in that age group who are immunocompromised, and a three-dose series of the Pfizer-BioNTech COVID-19 vaccine for children ages 6 months through 4 years in the U.S. population, 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 June 18, 2022, all authorized CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer, upon request:**

- **a two-dose series using the age-appropriate Moderna COVID-19 Vaccine product for children ages 6 months through 5 years.**
- **a third dose of age-appropriate Moderna COVID-19 Vaccine product for children ages 6 months through 5 years of age with moderate to severe immunocompromise who have received a two-dose Moderna COVID-19 primary series at least 28 days following the second primary series dose.**
- **a three-dose series using the age-appropriate Pfizer-BioNTech COVID-19 Vaccine product for children ages 6 months through 4 years.**

Healthcare providers enrolled in the CDC COVID-19 Vaccination Program who are authorized under state law to vaccinate people may administer these vaccines in accordance with the EUAs. In addition, I have previously authorized additional providers to administer COVID-19 vaccines as permitted by the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. §247d-6d(b),(i)(8). The PREP Act covers healthcare professionals administering vaccines in accordance with state law and allows me to authorize additional providers to administer vaccines regardless of state requirements. For example, I have authorized pharmacists, pharmacy interns, and pharmacy technicians under my PREP Act Declaration for COVID-19 countermeasures, as amended, to administer COVID-19 vaccine to children as young as three years old consistent with the applicable EUA and notwithstanding any state requirements that could effectively prevent them from administering COVID-19 vaccines to children beginning at age three. In addition, note that pharmacists, pharmacy interns, and pharmacy technicians who are authorized to administer COVID-19 vaccines to children under three years of age under their respective state laws may do so without regard to the age limitation of three years under my PREP Act declaration. For a full listing of providers authorized to administer COVID-19 vaccines under the PREP Act Declaration, see 87 FR 982-988 (January 7, 2022), [Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, section V](#).

All CDC COVID-19 Vaccination Program enrolled providers 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. As such, each applicable awardee jurisdiction shall submit orders for sufficient quantities of the pediatric COVID-19 vaccines covered under this Secretarial Directive to fulfill the needs of enrolled providers in their jurisdiction to administer these vaccines as requested by parents/guardians.

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