

SECRETARIAL DIRECTIVE ON SIMPLIFIED AND EXPANDED USE OF BIVALENT mRNA COVID-19 VACCINES

April 24, 2023

Effective April 24, all prior Secretarial Directives on administration of monovalent Pfizer-BioNTech COVID-19 vaccine or monovalent Moderna COVID-19 vaccine in primary series doses for individuals ages 6 months and older are replaced with the following:

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 April 18, 2023, the U.S. Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals; specifically:

- **Most individuals, depending on age, previously vaccinated with a monovalent COVID-19 vaccine** who have not yet received a dose of a bivalent vaccine may receive a single dose of a bivalent vaccine.
- **Most individuals who have already received a single dose of a bivalent vaccine** are not currently eligible for another dose.
- **Individuals 65 years of age and older who have received a single dose of a bivalent vaccine** may receive one additional dose at least four months following their initial bivalent dose.
- **Most individuals with certain kinds of immunocompromise who have received a bivalent COVID-19 vaccine** may receive a single additional dose of a bivalent COVID-19 vaccine and subsequent additional doses may be administered at the discretion of their healthcare provider. However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.
- **Most unvaccinated individuals (those who have not previously received a COVID-19 vaccine)** may receive a single dose of a bivalent vaccine, rather than multiple doses of the original monovalent mRNA vaccines.
- **Children 6 months through 5 years of age who are unvaccinated** may receive a two-dose series of the Moderna bivalent vaccine (6 months through 5 years of age) OR a three-dose series of the Pfizer-BioNTech bivalent vaccine (6 months through 4 years of age). Children who are 5 years of age may receive two doses of the Moderna bivalent vaccine or a single dose of the Pfizer-BioNTech bivalent vaccine.
- **Children 6 months through 5 years of age who have received one, two, or three doses of a monovalent COVID-19 vaccine** may receive a bivalent vaccine dose; the

number of doses that they receive will depend on the vaccine and their vaccination history.

FDA also announced that the monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

Based on CDC's review of the available data, the Director of the CDC on April 19, 2023, recommended the following (with specific details regarding the scope of the CDC recommendations as noted below):

- Individuals ages 6 months and older receive a bivalent mRNA COVID-19 vaccine, within the parameters of the Emergency Use Authorization issued by FDA for the particular vaccine. Dose(s) varies by age, vaccine, and previous COVID-19 vaccines received.
- Individuals ages ≥ 65 years, and immunocompromised individuals ages ≥ 6 months, who previously received a bivalent mRNA vaccine dose may receive a second bivalent mRNA COVID-19 vaccine dose, within the parameters of the Emergency Use Authorization issued by FDA for the particular vaccine.

In addition, CDC repealed the previous recommendations for administration of monovalent Pfizer-BioNTech COVID-19 vaccine or monovalent Moderna COVID-19 vaccine in primary series doses for individuals ages 6 months and older.

The Department of Health and Human Services (HHS) concurs with CDC's recommendations for use of the authorized bivalent COVID-19 vaccines for individuals down to six months of age.

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 April 24, 2023, authorized CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer, upon request:

Ages 5/6 years and older:

- A single age-appropriate dose of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is recommended for individuals ages 6 years and older who are unvaccinated, or at least 2 months after receipt of any previously administered monovalent COVID-19 vaccine.
- A single age-appropriate dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is recommended for individuals ages 5 years and older who are unvaccinated, or at least 2 months after receipt of any previously administered monovalent COVID-19 vaccine.

Ages 6 months through 4/5 years:

- For children ages 6 months through 5 years of age: the following bivalent Moderna COVID-19 vaccine doses are recommended:

- For children who are unvaccinated, **two 25mcg** bivalent Moderna COVID-19 vaccine doses are recommended, separated by 1-2 months between doses.
- For children who have been previously vaccinated with one monovalent Moderna COVID-19 vaccine dose, a **single 25mcg** bivalent Moderna COVID-19 vaccine dose is recommended, 1-2 months after the first dose.
- For children who have been previously vaccinated with two monovalent Moderna COVID-19 vaccine doses, a **single 10mcg** bivalent Moderna COVID-19 vaccine dose is recommended, at least 2 months after the previous dose.
- For children ages 6 months through 4 years of age: the following bivalent Pfizer-BioNTech COVID-19 vaccine doses are recommended:
 - For children who are unvaccinated, **three 3mcg** bivalent Pfizer-BioNTech COVID-19 vaccines doses are recommended, with the second dose given 3-8 weeks after the first, and the third dose given at least 2 months after the second dose.
 - For children who have been previously vaccinated with one monovalent Pfizer-BioNTech COVID-19 vaccine dose, **two 3mcg** bivalent Pfizer-BioNTech COVID-19 vaccine doses are recommended, with the second dose given 3-8 weeks after the first, and the third dose given at least 2 months after the second dose.
 - For children who have been previously vaccinated with two monovalent Pfizer-BioNTech COVID-19 vaccine doses, a **single 3mcg** bivalent Pfizer-BioNTech COVID-19 vaccine dose is recommended, at least 2 months after the previous dose.
 - For children who have been previously vaccinated with three monovalent Pfizer-BioNTech COVID-19 vaccine doses, a **single 3mcg** bivalent Pfizer-BioNTech COVID-19 vaccine dose is recommended, at least 2 months after the previous dose.

Adults ages ≥ 65 years:

- For adults ages ≥ 65 years, a single additional dose of a bivalent mRNA COVID-19 vaccine (either bivalent Moderna COVID-19 vaccine or bivalent Pfizer-BioNTech COVID-19 vaccine) may be administered at least **4 months** following the first dose of a bivalent COVID-19 vaccine.

Individuals with immunocompromising conditions:

- For individuals with moderate to severely immunocompromising conditions, a single additional age-appropriate dose of a bivalent mRNA COVID-19 vaccine may be administered following the first dose of a bivalent COVID-19 vaccine for the following populations:
 - Ages ≥ 6 months may receive a bivalent Moderna COVID-19 vaccine dose.
 - Ages ≥ 5 years may receive a bivalent Pfizer-BioNTech COVID-19 vaccine dose.
 - Subsequent additional age-appropriate bivalent mRNA COVID-19 vaccine doses may be administered to immunocompromised persons at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
 - Clinical guidance for these additional doses will be provided in the CDC Interim Clinical Considerations.

All CDC COVID-19 Vaccination Program enrolled providers, within any age restrictions for the particular provider, must comply with this Directive as specified in updated CDC COVID-19 vaccination provider agreement 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