SECRETARIAL DIRECTIVE ON BIVALENT COVID-19 VACCINE BOOSTER DOSES FOR INDIVIDUALS AGES 12 YEARS AND OLDER

September 2, 2022

Effective September 2, the Secretarial Directive on Eligibility to Receive Particular COVID-19 Vaccine Boosters, dated January 10, 2022, and portions of the May 23, 2022[1] Secretarial Directive 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 August 31, 2022, the FDA amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination with FDA authorized or approved monovalent COVID-19 vaccines. The Moderna COVID-19 Vaccine, Bivalent(Original and Omicron BA.4/BA.5) (hereinafter, "Moderna COVID-19 Vaccine, Bivalent") is authorized for use as a single booster dose in individuals 18 years of age and older. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (hereinafter, "Pfizer-BioNTech COVID-19 Vaccine, Bivalent") is authorized for use as a single booster dose in individuals 12 years of age and older. With these amended EUAs, the Moderna COVID-19 and Pfizer-BioNTech COVID-19 monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals 12 years of age and older, but the monovalent Pfizer-BioNTech COVID-19 Vaccine remains authorized for boosters for individuals ages 5 through 11. In addition, the monovalent Pfizer-BioNTech COVID-19 Vaccine and the monovalent Moderna COVID-19 Vaccine remain authorized to provide the primary series in individuals 6 months and older.

On September 1, 2022, the Advisory Committee on Immunization Practices (ACIP) recommended:

- A single booster dose of bivalent Pfizer-BioNTech COVID-19 Vaccine for individuals ages 12 years and older at least two months after receipt of a primary series or prior monovalent booster dose, under the EUA issued by FDA;

[1] The portion of the Secretarial Directive on Pediatric and Second COVID-19 Vaccine Booster Doses dated May 23, 2022, requiring all CDC COVID-19 Vaccination Program enrolled providers to make immediately available and administer, upon request, a single booster dose of the age-appropriate Pfizer-BioNTech COVID-19 Vaccine to individuals 5 through 11 years of age at least five months after completion of a primary series with the Pfizer-BioNTech COVID-19 Vaccine remains in place. The portion of this Directive on second booster doses for individuals 50 years of age and older and individuals 12 years through 49 years of age with moderate to severe immunocompromise is rescinded as of September 2, 2022.

- Repealing its previous recommendations for administration of monovalent Pfizer-BioNTech COVID-19 Vaccine boosters for individuals ages 12 years and older;

or

- A single booster dose of bivalent Moderna COVID-19 Vaccine for individuals ages 18 years and older at least two months after receipt of a primary series or prior monovalent booster dose, under the EUA issued by FDA;
    - Repealing its previous recommendations for administration of monovalent Moderna COVID-19 Vaccine boosters for individuals ages 18 years and older.
- Bivalent booster recommendations are without regard to the number of previous monovalent booster doses received.

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 September 1, 2022.

The Department of Health and Human Services (HHS) concurs with CDC's recommendations for use of a single dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals ages 12 and older and a single dose of Moderna COVID-19 Vaccine, Bivalent for individuals ages 18 years and older, consistent with the parameters of the EUAs issued by FDA, and with repealing previous CDC recommendations for administration of monovalent mRNA COVID-19 boosters for individuals ages 12 years and older.

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 September 2, 2022, CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer, upon request, a single booster dose of:

- **Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals ages 12 and older at least two months after receipt of any monovalent primary series or monovalent booster dose of any COVID-19 vaccine, under the EUA issued by FDA; or**
- **Moderna COVID-19 Vaccine, Bivalent for individuals ages 18 years and older at least two months after receipt of any monovalent primary series or monovalent booster dose of any COVID-19 vaccine, under the EUA issued by FDA.**
- **Bivalent booster recommendations are without regard to the number of previous monovalent booster doses received.**

In addition, CDC COVID-19 Vaccination Program enrolled providers shall continue to make available the monovalent COVID-19 mRNA Vaccines to those 6 months and older for their primary series, and for boosters for ages 5-11. There shall be no disposal of the monovalent COVID-19 mRNA Vaccines at this time outside of the usual parameters.

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.

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