SECRETARIAL DIRECTIVE ON AVAILABILITY OF COVID-19 VACCINES

January 10, 2022

Effective January 10, 2022, the Secretarial Directives on Eligibility to Receive Particular COVID-19 Vaccine Boosters, dated September 25, 2021, October 22, 2021, November 21, 2021, and December 10, 2021, 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 January 3, 2022, FDA amended the Emergency Use Authorization (EUA)[1] for the Pfizer-BioNTech COVID-19 Vaccine to:

- Expand the use of a single booster dose to include use in individuals 12 through 15 years of age;
- Shorten the time between the completion of the primary vaccination series of the Pfizer-BioNTech COVID-19 Vaccine and receipt of a booster dose to at least five months; and
- Allow for a third primary series dose for certain immunocompromised children 5 through 11 years of age.

On January 7, 2022, FDA amended the EUA[2] for the Moderna COVID-19 Vaccine to shorten the time between completion of the primary vaccination series and receipt of a booster dose to at least five months.

On January 3, 2022, the Director of CDC recommended:

- that persons aged 18 years and older should receive a single homologous Pfizer-BioNTech COVID-19 vaccine booster dose (or heterologous as authorized for another COVID-19 vaccine for those 18 and older) five months after completion of a primary series of Pfizer-BioNTech COVID-19 Vaccine, six months after completion of a primary series of Moderna COVID-19 Vaccine, or two months after completion of a single dose primary series of Janssen COVID-19 Vaccine;
- that persons aged 16 through 17 years may receive a Pfizer-BioNTech COVID-19 Vaccine booster dose five months after completion of a primary series of Pfizer-BioNTech COVID-19 Vaccine; and

[1] *See* Updated Letter of Authorization for Pfizer-BioNTech COVID-19 Vaccine (https://www.fda.gov/media/150386/download)
[2] *See* Updated Letter of Authorization for Moderna COVID-19 Vaccine (https://www.fda.gov/media/144636/download)

- that moderately to severely immunocompromised children aged 5 through 11 years should receive an additional primary (i.e., third) Pfizer-BioNTech COVID-19 Vaccine dose at least 28 days after completion of doses one and two of the primary series.

On January 5, 2022, the Director of CDC adopted the Advisory Committee on Immunization Practices' (ACIP) January 5, 2022 recommendation: that children 12 through 17 years of age should receive a Pfizer-BioNTech COVID-19 Vaccine booster five months after completion of a primary series of the Pfizer-BioNTech COVID-19 Vaccine. On December 16, 2021, the CDC Director had adopted the ACIP's recommendation to preferentially recommend mRNA COVID-19 vaccines over the Janssen COVID-19 Vaccine for both primary series and booster doses; this recommendation has been retained.

In addition, on January 7, 2022, the Director of CDC revised her recommendation of January 3, 2022 to shorten the time interval between completion of a primary series of Moderna COVID-19 Vaccine and receipt of a booster dose to five months.

The Department of Health and Human Services (HHS) concurs with CDC's recommendations for the administration of COVID-19 vaccines.

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 January 10, 2022, all CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer, upon request:

- **to persons aged 12 years and older, a single homologous Pfizer-BioNTech COVID-19 Vaccine booster dose (or heterologous[3] as authorized for another COVID-19 vaccine for those 18 and older) five months after completion of a primary series of Pfizer-BioNTech COVID-19 Vaccine;**

- **to persons aged 18 years and older, a single homologous or heterologous[4] booster dose five months after completion of a primary series of Moderna COVID-19 Vaccine;**

- **to persons aged 18 years and older, a single homologous or heterologous[5] booster dose two months after completion of a single dose primary series of Janssen COVID-19 Vaccine; and**

- **to children aged 5 through 11 years who are moderately to severely immunocompromised, an additional primary (i.e., third) Pfizer-BioNTech COVID-19 Vaccine dose at least 28 days after completion of doses one and two of the primary series.**

[3] An mRNA booster dose is preferred to a Janssen booster.
[4] An mRNA booster dose is preferred to a Janssen booster.
[5] An mRNA booster dose is preferred to a Janssen booster.

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