SECRETARIAL DIRECTIVE ON BIVALENT COVID-19 VACCINE BOOSTER DOSES FOR INDIVIDUALS AGES 5 YEARS AND OLDER

October 13, 2022

This Secretarial Directive supplements the September 2, 2022 Secretarial Directive on Bivalent COVID-19 Vaccine Booster Doses for Individuals Ages 12 Years and Older:

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") was authorized for use as a single booster dose in individuals 18 years of age and older. And, the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (hereinafter, "Pfizer-BioNTech COVID-19 Vaccine, Bivalent") was authorized for use as a single booster dose in individuals 12 years of age and older. Further, on October 12, 2022, these EUAs were revised by FDA to expand booster use of Pfizer-BioNTech COVID-19 Vaccine, Bivalent to children 5 – 11 years of age and Moderna COVID-19 Vaccine, Bivalent to children 6 – 17 years of age. 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 5 years of age and older. The monovalent Pfizer-BioNTech COVID-19 Vaccine and the monovalent Moderna COVID-19 Vaccine remain authorized/approved to provide the primary series in individuals 6 months and older.

On September 1, 2022, the Advisory Committee on Immunization Practices (ACIP) recommended use of these COVID-19 vaccines as authorized by FDA on August 31, 2022.

Following the revision of the EUAs on October 12, 2022, the Director of CDC has recommended expanded booster use of these bivalent COVID-19 vaccines as authorized by the FDA and repealed CDC's previous recommendations for administration of monovalent Pfizer-BioNTech COVID-19 boosters for individuals ages 5–11 years.

The Department of Health and Human Services (HHS) concurs with CDC's recommendations for use of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals ages 5 years and older and a single booster dose of Moderna COVID-19 Vaccine, Bivalent for individuals ages 6 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 vaccine boosters for individuals ages 5 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:

In addition to the Directive of September 2, 2022, as of October 12, 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 5 – 11 years 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 6 - 17 years 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.**

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