SECRETARIAL DIRECTIVE ON AVAILABILITY OF COVID-19 VACCINES FOR CHILDREN AGES 5 THROUGH 11

November 3, 2021

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 October 29, 2021, FDA authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age.¹

Based on CDC's review of the available data, and taking into account data and information that were presented to and considered by the Advisory Committee on Immunization Practices (ACIP), the Director of the CDC recommended use of the Pfizer-BioNTech COVID-19 Vaccine (10µg) for children 5 years of age through 11 years of age in the U.S. population under the parameters of the Emergency Use Authorization (EUA) issued by FDA.

The Department of Health and Human Services (HHS) concurs with CDC's recommendation. 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 November 3, 2021, all CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer upon request Pfizer-BioNTech COVID-19 Vaccine doses to children 5 years of age through 11 years of age, pursuant to the EUA issued by FDA.

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

_

¹ Pfizer-BioNTech COVID-19 Vaccine EUA LOA reissued October 29 2021

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