

SECRETARIAL DIRECTIVE ON NOVAVAX COVID-19 VACCINE FOR PERSONS AGES 18 YEARS AND OLDER

July 21, 2022

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 July 13, 2022, the FDA issued an emergency use authorization (EUA) for the Novavax COVID-19 Vaccine, Adjuvanted for the prevention of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

On July 19, 2022, the Advisory Committee on Immunization Practices (ACIP), consistent with the parameters of the EUA issued by FDA, recommended a two-dose Novavax COVID-19 Vaccine, Adjuvanted primary series for persons ages 18 years and older.

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 July 19, 2022.

The Department of Health and Human Services (HHS) concurs with CDC's recommendations for use of a two-dose Novavax COVID-19 Vaccine, Adjuvanted primary series for persons ages 18 years and older, consistent with the parameters of the EUA issued by FDA.

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 July 25, 2022, CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer, to the extent the vaccine is available, upon request:

- **A two-dose Novavax COVID-19 Vaccine, Adjuvanted primary series for persons ages 18 years and older**
- **For those providers who do not have access to the Novavax COVID-19 Vaccine, Adjuvanted when a potential recipient requests it, the provider shall notify the person that providers with the vaccine can be located through the website: <https://www.vaccines.gov/>**

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