

SECRETARIAL DIRECTIVE ON AVAILABILITY OF BOOSTER DOSES OF COVID-19 VACCINES

November 21, 2021

Effective November 21, 2021, the Secretarial Directives on Eligibility to Receive Particular COVID-19 Vaccine Boosters, dated September 25, 2021 and October 22, 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 and safety 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 November 19, 2021, FDA amended the Emergency Use Authorizations (EUAs) for the two mRNA vaccines (the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine) to expand the population that is eligible to receive homologous or heterologous booster doses following primary vaccination.¹ Prior to those authorizations, individuals who have completed primary vaccination with an mRNA vaccine at least six months previously were authorized to receive a single booster dose if they fell into the following categories: individuals 65 years of age and older; individuals 18 through 64 years of age at high risk of severe COVID-19; and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. The November 19, 2021 amendments to the EUAs expand the population that is eligible to receive a booster dose to include all individuals 18 years of age and older, provided the booster dose is administered at least six months after completion of primary vaccination with an mRNA vaccine.

FDA also amended the EUA for the Janssen COVID-19 Vaccine to authorize use of the vaccine as a single heterologous booster dose for all adults 18 years of age and older who completed primary vaccination with an FDA authorized or approved mRNA COVID-19 vaccine.² Previously, individuals who received mRNA vaccines for primary vaccination were not eligible to receive the Janssen COVID-19 Vaccine as a heterologous booster unless they fell into the risk-based categories described above. Individuals aged 18 and older who received the Janssen COVID-19 Vaccine for primary vaccination remain eligible to receive a heterologous booster of the Pfizer-BioNTech COVID-19 Vaccine or the Moderna COVID-19 Vaccine two months after completing primary vaccination.

On November 19, 2021, 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 CDC recommended:

¹ See Updated Letter of Authorization for Pfizer-BioNTech COVID-19 Vaccine (<https://www.fda.gov/media/150386/download>) and Updated Letter of Authorization for Moderna COVID-19 Vaccine (<https://www.fda.gov/media/144636/download>).

² See Updated Letter of Authorization for Janssen COVID-19 Vaccine (<https://www.fda.gov/media/146303/download>).

- A single COVID-19 vaccine booster dose for persons aged 18 years and older³ who received an mRNA COVID-19 vaccine primary series (the Pfizer-BioNTech COVID-19 Vaccine or the Moderna COVID-19 Vaccine) based on individual benefit and risk, at least six months after the primary series, under the FDA’s EUA.
- A single COVID-19 vaccine booster dose for persons aged 50 years and older who received an mRNA COVID-19 vaccine (the Pfizer-BioNTech COVID-19 Vaccine or the Moderna COVID-19 Vaccine), at least six months after the primary series, under the FDA’s EUA.

The Department of Health and Human Services (HHS) concurs with CDC’s recommendations for the administration of COVID-19 vaccine booster doses.

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 21, 2021, all CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer, upon request:

- **A booster dose of the Pfizer-BioNTech COVID-19 Vaccine, the Moderna COVID-19 Vaccine, or the Janssen COVID-19 Vaccine to all people 18 years of age and older at least six months after completion of primary vaccination with an mRNA COVID-19 vaccine (the Pfizer-BioNTech COVID-19 Vaccine or the Moderna COVID-19 Vaccine), under the parameters of the EUAs issued by FDA.**
- **As previously recommended, a single COVID-19 vaccine booster dose of the Pfizer-BioNTech COVID-19 vaccine, the Moderna COVID-19 vaccine, or the Janssen COVID-19 vaccine to all people 18 years of age and older at least two months after receipt of the primary vaccination dose of the Janssen (Johnson & Johnson) COVID-19 vaccine, under the EUA issued by FDA.**

As previously recommended, individuals who are eligible to receive a homologous booster dose of any of the currently FDA authorized or approved COVID-19 vaccines may instead receive a single heterologous booster dose of the Pfizer-BioNTech COVID Vaccine, the Moderna COVID-19 Vaccine, or the Janssen COVID-19 Vaccine, under the parameters of the EUAs 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.

³ Individuals aged 18 years and older not otherwise already recommended to receive COVID-19 vaccine booster dose

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