

SECRETARIAL DIRECTIVE ON ELIGIBILITY TO RECEIVE PARTICULAR COVID-19 VACCINE BOOSTERS

September 25, 2021

The Centers for Disease Control and Prevention (CDC) has determined that, as part of the broad range of prevention and mitigation strategies, “[v]accines are an important tool to help stop the COVID-19 pandemic.¹” 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 September 22, 2021, FDA amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to allow for use of a single booster dose, to be administered at least six months after completion of the Pfizer-BioNTech COVID-19 vaccine primary series in: individuals 65 and older; individuals 18 through 64 years of age at high risk of severe COVID-19; and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

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 CDC² recommended that: people 65 years and older and residents in long-term care settings 18 years or older should receive a booster shot of Pfizer-BioNTech COVID-19 vaccine at least six months after their Pfizer-BioNTech COVID-19 vaccine primary series; people aged 50–64 years with underlying medical conditions should receive a booster shot of Pfizer-BioNTech COVID-19 vaccine at least six months after their Pfizer-BioNTech COVID-19 vaccine primary series; people aged 18–49 years with underlying medical conditions may receive a booster shot of Pfizer-BioNTech COVID-19 vaccine at least six months after their Pfizer-BioNTech COVID-19 vaccine primary series, based on their individual benefits and risks; and people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot of Pfizer-BioNTech COVID-19 vaccine at least six months after their Pfizer-BioNTech COVID-19 vaccine primary series, based on their individual benefits and risks.

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:

¹ See CDC, *Operational Strategy for K-12 Schools through Phased Mitigation* (<https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/operation-strategy.html#vaccination>.)

² A forthcoming technical amendment to the current COVID-19 Public Readiness and Emergency Preparedness (PREP) Act declaration will clarify that liability immunity extends to persons deemed qualified or authorized to order and administer COVID-19 vaccines, including in such cases where vaccines are authorized, approved or licensed by FDA and recommended by CDC (including those adopted from ACIP recommendations), such as recommendations for the booster doses referenced herein.

As of September 25, 2021, all CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer a booster dose of Pfizer-BioNTech COVID-19 vaccine to any and all individuals seeking such a dose who have completed their primary series of Pfizer-BioNTech COVID-19 vaccine at least six months ago and (1) who are 65 years or older; (2) who are 18 years or older and are residents in long term care settings; (3) who are 18 years or older with underlying medical conditions as described in CDC clinical guidance and in accordance with the CDCs recommendation³; or (4) who are 18 years or older with increased risk of getting COVID-19 disease due to occupational or institutional exposure, such as frontline essential workers and healthcare workers⁴ as described in and in accordance with CDC's recommendation.

All enrolled providers in the CDC COVID-19 Vaccination Program 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>. CDC COVID-19 Vaccination Program enrolled providers and state, territorial, local, or tribal authorities are advised not to use or authorize uses of this booster dose beyond what is set forth in this Directive.

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 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

³ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>