



FAQs About Medical Consent & Pfizer-BioNTech Booster Doses for Long-term Care Residents

A Resource for Providers Participating in the CDC COVID-19 Vaccination Program, Long-term Care Residents & Their Families

In response to inquiries about medical consent surrounding the administration of a booster shot of Pfizer-BioNTech COVID-19 vaccine to residents in long-term care (LTC) settings at least six months after their Pfizer-BioNTech primary series¹, the Centers for Disease Control and Prevention (CDC) has developed the following responses to frequently asked questions (FAQs).

These FAQs are intended to clarify that medical consent is not required by federal law for COVID-19 vaccination in the United States.

Providers enrolled in the [CDC COVID-19 Vaccination Program](#), including those administering vaccine to residents in LTC settings, are required by the CDC Provider Agreement to follow applicable state and territorial laws on medical consent. Providers should consult their legal counsel on such requirements.

Frequently Asked Questions

Is medical consent required for LTC residents to receive a booster shot of Pfizer-BioNTech COVID-19 vaccine?

Medical consent is not required by federal law for COVID-19 vaccination in the United States.

COVID-19 vaccine providers should consult with their own legal counsel for state or territorial requirements related to consent; compliance with all applicable state and territorial laws is required under the CDC Provider Agreement.

The COVID-19 Provider Agreement contains the following requirements:

- Before administering a COVID-19 vaccine with Emergency Use Authorization (EUA), the provider must provide the approved EUA fact sheet (or Vaccine Information Sheet, as applicable) to each vaccine recipient, the adult caregiver accompanying the recipient (as applicable), or other legal representative (as applicable). The fact sheet/information sheet explains risks and benefits of the particular COVID-19 vaccine and what to expect but is not a consent

document.

Is consent required for the booster shot if consent was previously given for the Pfizer-BioNTech primary series?

Explaining the risks and benefits of any treatment to a patient – in a way that they understand – is the standard of care.

Providers should consult with their legal counsel to determine whether previous medical consent obtained from a resident or their representative is legally sufficient under the applicable laws of the state or territory for purposes of administration of a booster dose of Pfizer-BioNTech COVID-19 vaccine.

Is consent for a booster shot of Pfizer-BioNTech COVID-19 vaccine required if the vaccine is being administered by a different provider?

Providers should consult with their legal counsel to determine whether consent for the Pfizer-BioNTech primary series previously obtained from an LTC resident or their guardian by a different provider is sufficient, or if consent should be obtained prior to administration of the booster shot of Pfizer-BioNTech vaccine, in accordance with any applicable laws of the state or territory.

Does CDC have a consent form that should be used to receive a COVID-19 vaccine?

No. Since applicable medical consent laws are a matter of state, tribal, or territorial law, providers are advised to consult with their legal counsel to assure compliance with the scope of those consent laws.

A written form is not needed if a state law allows for oral consent and the organization/provider does not otherwise require it.

Reference

1. On September 24, 2021, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations, including residents in LTC settings, and also recommended a booster dose for those in high risk occupational and institutional settings. <https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html>

Related Links:

- [COVID-19 Vaccine Access in Long-term Care Settings](#)
- [Long-term Care Administrators and Managers: Options for Coordinating Access to COVID-19 Vaccines](#)
- [COVID-19 Vaccines for Long-term Care Facility Residents](#)
- [About mRNA Vaccines: Background Information for Healthcare Providers](#)

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