Clinicians who administer COVID-19 vaccines off-label to children under 12 years would be violating their provider agreement, risking liability for adverse events and potentially forfeiting payment.

Health officials laid out the possible consequences after the Food and Drug Administration (FDA) granted licensure to the Pfizer-BioNTech vaccine Comirnaty on Monday.

“Ordinarily … when a medical product is approved, physicians often do use off-label prescribing. However, this is a different situation,” Acting FDA Commissioner Janet Woodcock, M.D., said at a press conference. “The vaccine is being distributed under a provider agreement by the U.S. government through the CDC (Centers for Disease Control and Prevention), and there are many considerations that would pertain to off-label prescribing for the recipient and so forth.”

Vaccine providers must adhere to requirements of the CDC, its vaccine committee and the FDA. The FDA licensed the vaccine as a two-dose series for people ages 16 years and older. It also can be used for adolescents as young as 12 years under emergency use authorization (EUA). Some people ages 12 years and older who are immunocompromised are eligible for a third dose.

If vaccine providers use the vaccine off-label, the CDC said they could lose

- immunity from claims,
- a patient's eligibility for federal compensation after an adverse event,
- eligibility to provide COVID-19 vaccines and
- payment.
The AAP also is discouraging off-label use of the vaccine as clinical trials are still underway in children under 12 years.

"We do not want individual physicians to be calculating doses and dosing schedules one-by-one for younger children based on the experience with the vaccine in older patients," Yvonne A. Maldonado, M.D., FAAP, chair of the AAP Committee on Infectious Diseases, said in a statement. "We should do this based on all of the evidence for each age group, and for that we need the trials to be completed. I know parents are anxious to protect their children, but we want to make sure children have the full benefit of ongoing clinical trials."

**FDA extends expiration for COVID-19 vaccine**

Vaccine providers can use the Pfizer-BioNTech vaccine distributed under the EUA and the fully licensed version interchangeably as they use the same formulation, according to the FDA.

The FDA also has extended the expiration date of the vaccine from six months to nine months. The three-month extension applies to batches with an expiration date between August 2021 and February 2022 that are stored consistently between -90 degrees Celsius and -60 degrees Celsius.

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**Resources**

- [Prescribing information for Comirnaty](#)
- [CDC COVID-19 vaccine provider requirements](#)
- [CDC Advisory Committee on Immunization Practices COVID-19 vaccine recommendations](#)
- [Information from the CDC on clinical considerations for COVID-19 vaccines](#)
- [CDC COVID vaccination toolkit for pediatricians](#)
- [AAP guidance on providing COVID-19 vaccines to adolescents](#)
- [Information for parents from HealthyChildren.org on preparing children and adolescents for COVID-19 vaccination](#)