

From: CTDPHHealth_Alert_Network@ct.gov <noreply@everbridge.net>

Sent: Tuesday, August 24, 2021 6:05 PM

Subject: Pfizer Vaccine Expiration is Extended and Message from the CDC About Off-Label Usage of COVID-19 Vaccines



DEPARTMENT OF PUBLIC HEALTH

August 24, 2021

Pfizer Vaccine Expiration is Extended and Message from the CDC About Off-Label Usage of COVID-19 Vaccines

Dear Connecticut COVID-19 Vaccine and Connecticut Vaccine Program Providers,

This communication is being sent to all key contacts at provider organizations administering COVID-19 vaccine. Please feel free to share it with others in your organization who may benefit from the update. Note that all of our communications are archived on our [web site](#).

Pfizer Vaccine Expiration has been Extended by the Food and Drug Administration (FDA)

The FDA has approved an amendment to the Emergency Use Authorization for Pfizer-BioNTech, extending the expiration dates of COVID-19 vaccine from six to nine months.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine may remain in use for 3 months beyond the expiry date printed on the label as long as authorized storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Please note: the ultra-cold temperature range has been broadened to include -90° C (-130°F). **Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are NOT eligible for extension.**

For vials with expiration dates in the future, updated expiry dates for vaccine maintained in ultra-cold storage are shown below. **Please continue to administer your supply of Pfizer vaccines maintained in ultra-cold storage according to the updated expiry date below, rather than the printed date on the vial.**

<u>Printed Expiry Date</u>	<u>Updated Expiry Date</u>
August 2021	November 2021
September 2021	December 2021
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022

In addition, per FDA's concurrence letter to Pfizer-BioNTech, the shelf-life extension from 6 months to 9 months when stored at -90°C to -60°C is also applicable to batches that might have expired prior to the issuance of this concurrence letter provided they have been stored at -90°C to -60°C.

The change is based on stability data generated on batches manufactured over approximately the past nine months of COVID-19 vaccine development, from the batches that supplied early clinical trials through the commercial scale batches currently in production. No changes have been made to the vaccine itself.

Currently available vaccine will not have an updated NCD. Please refer to the current [EUA Fact Sheet for information](#).

Additional information on Pfizer storage and handling may be found at: [Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC](#)

Message from Centers for Disease Control and Prevention (CDC) About Off-Label Usage of COVID-19 Vaccines

Providers are responsible for adhering to all requirements outlined in the CDC's COVID-19 Provider Agreement. Specifically, providers must administer COVID-19 vaccines in accordance with all [program requirements and recommendations](#) of CDC, the [Advisory Committee on Immunization Practices](#), and the U.S Food and Drug Administration ([FDA](#)). This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (often referred to as "off-label use") is not recommended. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.

Reminder COVID-19 Vaccine Provider Call Wednesday

We will be hosting a COVID-19 Vaccine Provider call to discuss booster dose planning this coming Wednesday, August 25 from 9:00am-10:00am. Join: [CoVP Office Hours](#).

Thank you.

CT DPH Immunization Program

Main P: (860) 509-7929 | Fax: (860) 706-5429 | Email: dph.immunizations@ct.gov

Website: [CT Immunization Program](#) | [COVID-19 Vaccine Program](#)