



EXPIRATION EXTENSION: PFIZER-BIONTECH COVID-19 VACCINE

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Background

On August 30, 2021, we received additional information and clarity from CDC regarding the expiration extension of Pfizer-BioNTech COVID-19 vaccine. This update includes helpful scenarios that you will likely encounter at your practice specific to Beyond Use Date (BUD) timeframes. We appreciate your patience as we have worked to obtain the most accurate and complete data. Below you will also find the previous emails sent regarding this topic for your reference; however, this most recent message provides the most comprehensive and updated information for your support.

The FDA has approved an amendment to the EUA 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.

Printed Expiry Date	Updated Expiry Date
May 2021	August 2021
June 2021	September 2021
July 2021	October 2021
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.

No changes have been made to the vaccine itself to enable extension of expiry dating. This 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.

Currently available vaccine will not have an updated NCD. Please refer to the [MDHHS EUA Fact Sheet](#) for additional information. You can also locate information on Pfizer storage and handling may at [Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC](#).

BUD Case Scenarios: Pfizer-BioNTech COVID-19 Vaccine Expiration Extension

With the Pfizer-BioNTech COVID-19 Vaccine expiration date extension, there have been a number of questions about how this might impact beyond-use date. Below are a few case scenarios you might encounter.

To prevent vaccine from inadvertently being discarded, providers should ensure the new expiration date is indicated, i.e., label the tray or post on the unit.

- Case scenario #1: You move a vial of Pfizer vaccine from freezer storage to the refrigerator on August 15. It is marked with the expiration date of August 2021 (August 31, 2021). Can you store this vaccine for the full 31 days allowed for refrigeration storage, or do you need to administer it by August 31, 2021?
 - **Yes, you can store this vaccine vial for the full 31 days (i.e., through September 15, 2021). The recent expiration date extension changes the expiration date to November 2021. The BUD replaces the manufacturer's expiration date (now November/2021) and should be noted on the label along with the initials of the person making the calculation.**
- Case scenario #2: You move a vial of Pfizer vaccine from ultracold storage to the freezer on August 23. It is marked with the expiration date of August 2021 (August 31, 2021). Can you store this vaccine for the full 2 weeks allowed in the freezer? After that time, can you still move it to the refrigerator and store for an additional 31 days?
 - **Yes, you can store this vaccine vial for the full 2 weeks in the freezer (through September 6, 2021), move it to the refrigerator, and store for an additional 31 days (October 7, 2021). The recent expiration date extension changes the expiration date to November 2021. The BUD replaces the manufacturer's expiration date (now November 2021) and should be noted on the label along with the initials of the person making the calculation.**

- Case scenario #3: You move a vial of Pfizer-BioNTech COVID-19 vaccine from the freezer to the refrigerator on August 1, 2021. Since the expiration date has been extended, can you store this vial in the refrigerator through November 31, 2021?
 - **No, you cannot store this vial through the extended expiration date. A vial can be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days) regardless of the expiration date extension.**

Clinical guidance and resources for storing, preparing and administering the vaccine, including labels to assist with tracking the BUD can be found here: www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

Tracking Expiration Dates – we strongly encourage utilization of this CDC resource:

For organizations accessing and using the CDC COVID-19 Vaccine Lot Number and Expiration Date Report to track vaccine expiration dates, it is strongly recommended that the report files are downloaded on a routine basis. Updates are received from each manufacturer (as indicated in the "Date Last Updated" column in the report file) and CDC lot files are updated and published daily by 12:00 pm ET. The Pfizer-BioNTech expiration extensions are available as of August 27, 2021. Visit [CDC's Vaccine Lot Number and Expiration Date webpage](#) and complete registration to request access to the report files. Contact IISInfo@cdc.gov if you have any questions.

Additional information on Pfizer-BioNTech storage and handling can be found on [CDC's Pfizer-BioNTech COVID-19 Vaccine webpage](#).

If you have any questions regarding COVID-19 vaccination, please contact CHECCimms@michigan.gov