

## Letter from State to COVID-19 Vaccinators

August 30, 2021

Dear COVID-19 Vaccination Provider,

The FDA granted full licensure for Pfizer's COVID-19 vaccine on August 23, 2021. The full licensure applies to the use of this vaccine in the 16+ population. The vaccine also continues to be available under emergency use authorization (EUA) for adolescents 12 through 15 years of age and for the administration of a third dose in certain (moderately or severely) immunocompromised individuals. This vaccine will now be marketed as Comirnaty (koe-mir'-na-tee). We encourage you to reach out to your patients who have not yet been vaccinated to let them know about this development and encourage them to get vaccinated as soon as possible.

Also on August 23, 2021 the FDA approved an amendment to the EUA for Pfizer-BioNTech extending the expiration dates of COVID-19 Vaccine from six to nine months. The extended expiration date is effective immediately for all currently available batches that have not yet expired and have been maintained in ultra-cold storage. Note: The expiration date extension does NOT apply to vials dated July 2021 and earlier.

Vaccination providers that have Pfizer vaccine in storage must:

1. Mark the appropriate carton and vials with the new expiration date **and**
2. Update the expiration date in the NYSIIS or CIR inventory module.

The extension of vaccine expiration applies to any vaccine that has been stored in a manner consistent with the storage guidelines that have been in place to this point. Specifically:

- Vaccine moved from ultra-cold storage to standard frozen storage and back once to ultra-cold storage
- Vaccine in a standard freezer for a total of up to 14 days
- Vaccine in a refrigerator for a total of up to 31 days, including vaccine that was previously in a standard freezer for 14 days

All of the above conditions are consistent with the existing storage guidance. **Vaccine stored under these conditions can be used until the correct beyond-use date, based on the vaccine storage conditions, or the updated expiration date, whichever occurs first.** Vaccine cannot be used after the new expiration date, even if the storage-determined beyond-use date would be after the updated expiration date.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as authorized storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. 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 a 3-month use extension.

Updated expiry dates for vaccine maintained in ultra-cold storage are shown below.

<b><u>Printed Expiry Date</u></b>	<b><u>Updated Expiry Date</u></b>
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

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 NDC. 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](#)

Thank you for your participation in the COVID-10 Vaccination Program.

The NYS COVID-19 Vaccine Team