



DATE:	2/28/2021
TO:	Health Alert Network
FROM:	Allison V. Beam, JD, Acting Secretary of Health
SUBJECT:	Change in Pfizer-BioNTech COVID-19 Vaccine Transportation and Storage Conditions
DISTRIBUTION:	Statewide
LOCATION:	n/a
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a Health Advisory: Provides important information for a specific incident or situation; may require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PHARMACY, PEDIATRIC, NURSING, PATIENT SAFETY OFFICER, COUIRER AND LABORATORY STAFF IN YOUR HOSPITAL; **EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

The Pennsylvania Department of Health is providing updated guidance for providers on the Pfizer-BioNTech COVID-19 vaccine storage and transportation conditions. The information in this HAN should be used to supplement other relevant guidance documents and guide the implementation of public health expectations for vaccine providers.

Key messages included in the guidance:

- Undiluted frozen vials of the Pfizer-BioNTech COVID-19 vaccine may now be transported using proper transport and temperature monitoring devices and stored at -25°C to -15°C (-13°F to 5°F).
- Total cumulative time that the vials are stored at -25°C to -15°C (-13°F to 5°F) should not exceed 2 weeks.

1. The Pfizer-BioNTech COVID-19 Vaccine:

The Pfizer-BioNTech vaccine was approved by the FDA through an Emergency Use Authorization (EUA) on December 11, 2020. One of the challenges to the distribution and storage of the Pfizer-BioNTech vaccine was the ultra-cold temperature range of -80°C to -60°C (-112°F to -76° F) under which it had to be stored and transported. On February 25, 2021 the FDA approved a revised transportation and storage temperatures recommendation to allow for storage and transportation of the vaccine in a traditional vaccine storage freezer at -25°C to -15°C (-13°F to 5°F), instead of the ultra-cold storage for a period of up to 2 weeks.

2. Storage and Handling of the Pfizer-BioNTech Vaccine:

- Frozen vials prior to use:
 - Vials must be kept frozen and protected from the light.
 - Vials should be stored in an ultra-low temperature freezer at -80°C to -60°C (-112°F to -76° F) until the expiration date on the vial.
 - Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for a period up to 2 weeks.
 - Vials stored at the -25°C to -15°C (-13°F to 5°F) may be returned one time to the ultra-low temperature storage conditions of -80°C to -60°C (-112°F to -76° F).
 - Total cumulative time that the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks
 - For example:
 - A vial can be removed from an ultra-low temperature freezer and placed in traditional vaccine freezer for 10 days. It then can be placed back in an ultra-low temperature freezer and stored. It then can be removed and placed in a traditional vaccine freezer for up to an additional 4 days prior to administration. The total time duration allowable is 14 days at -25°C to -15°C (-13°F to 5°F).
 - The vaccine cannot be utilized past its expiration date on the vial.
- Transportation of frozen vials:
 - The Pfizer-BioNTech vaccine will be transported from its manufacturing facility under ultra-cold conditions of -80°C to -60°C (-112°F to -76° F).
 - If local transportation of the vials is needed, the vials may be transported at the -25°C to -15°C (-13°F to 5°F) temperature using proper transport and temperature monitoring devices.
 - Any hours used for local transport should count against the 2-week storage limit at -25°C to -15°C (-13°F to 5°F).
- Temperature monitoring of the freezer must occur according to [PA DOH guidance](#).

Any additional information regarding the Pfizer-BioNTech COVID-19 Vaccine can be found at www.fda.gov

If you have questions about this guidance, please contact DOH at 1-877-PA-HEALTH (1- 877-724-3258) or your local health department.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of February 28, 2021 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.
