

December 7, 2021

Dear COVID-19 Vaccination Provider,

We have seen an increase in COVID-19 vaccine storage, handling, and administration errors, some of which have required vaccine recipients to be revaccinated. All COVID-19 vaccination providers should review product, storage and handling, and administration information for each COVID-19 vaccine they administer, ensure COVID-19 vaccination program staff are trained and receive updates, and implement continuous quality improvement strategies.

Errors reported to the NYC Department of Health and Mental Hygiene include:

- Failure to maintain required temperature ranges for storage units and not reviewing temperature logs to identify excursions resulting in administration of non-viable vaccine
- Use of vaccine beyond expiration dates
- Use of Pfizer adult vaccine for children ages 5 to 11 and administering the incorrect dose

Below are some important reminders and steps to implement to avoid these errors.

Training

- Ensure staff have read the FDA Fact Sheets for each COVID-19 vaccine.
- Require staff to complete updated trainings on all COVID-19 vaccines administered by your program. Keep training logs and certificates on file at your site.
- The CDC has COVID-19 vaccine <u>training modules</u>. COVID-19 vaccine manufacturers also conduct provider trainings. Training sessions for Pfizer vaccine can be found <u>here</u>.

Vaccine Storage & Handling

- Check vaccine expiration dates upon receipt; label vials with the expiration dates. The
 expiration date for some Moderna and Janssen vaccine lot numbers have been
 extended; check expiration dates on <u>Moderna's expiration date look-up website</u> and
 Janssen's expiry checker website.
- Label all vials with a **beyond use date** when moving vaccine to a new storage unit (e.g., moving vaccine from the freezer to the refrigerator).
- Store unpunctured vaccine vial in proper storage units for the allowable amount of time.
 Use continuous monitoring digital data loggers and check temperature recording at the beginning and end of vaccine operations daily. Refer to the <u>FDA Fact Sheets</u> for complete information.
 - Pfizer Vaccine for people ages 12 and older (purple cap) Pfizer will stop shipping this vaccine product in the next few weeks
 - Ultracold freezer: Store between -90°C and -60°C (-130°F to -76°F) until the expiration date
 - Freezer: Store between -25°C and -15 °C (-13°F to 5°F) for an additional 2 weeks (this temperature range is narrower than usual for freezer storage)
 - Refrigerator: Store between 2°C and 8°C (36°F to 46°F) for an additional 31 days.

- New Pfizer Comirnaty (Gray Cap) vaccine for people ages 12 and older (to replace the Purple Cap product later this month) and Pfizer vaccine for ages 5 to 11 (Orange Cap)
 - Ultracold: store between -90°C and -60°C (-130°F to -76°F) up to 6 months after manufacture date. The date listed on the vial is the manufacture date, not the expiration date.
 - Freezer: not allowed
 - Refrigerator: store between 2°C and 8°C (36°F to 46°F) for up to 10 weeks within 6-months after manufacture date.

Moderna Vaccine

- Ultracold: **not allowed**
- Freezer: store between -50°C and -15°C (-58°F to 5°F) until the expiration date
- Refrigerator: store between 2°C and 8°C (36°F to 46°F) for up to an additional 30 days

Johnson & Johnson vaccine

- Ultracold Freezer: not allowed
- Freezer: not allowed
- Refrigerator: store between 2°C and 8°C (36°F to 46°F) until the expiration date
- Once thawed COVID-19 vaccines are not allowed to be refrozen.
- If there is a storage and handling error or a temperature excursion, contact the NYC
 Department of Health immediately by emailing covidvax@health.nyc.gov. You will be prompted to complete a Temperature Excursion Incident Report and asked to contact the vaccine manufacturer to confirm vaccine viability, keep documentation received.

Vaccine Administration

- The Pfizer product for people ages 12 and older should **never** be given to a child younger than age 12. The vaccine for children ages 5 to 11 is a different vaccine product.
- The Moderna and Johnson & Johnson vaccines may only be administered to people ages 18 and older.
- Administration errors must be reported to the <u>Vaccine Adverse Event Reporting System</u>.
- Administration errors impacting five or more patients should be reported to the Bureau of Immunization immediately by emailing covidvax@health.nyc.gov.

Please email coviDVax@health.nyc.gov with questions. Thank you for protecting the health of New Yorkers.

Sincerely, fore 1. Trates

Jane R. Zucker, MD, MSc Assistant Commissioner Bureau of Immunization