



New York State COVID-19 Vaccination Provider Storage and Handling - Overview

A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. As part of the agreement for COVID-19 vaccination providers, providers are required to:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with EUA or vaccine package insert, manufacturer guidance, and CDC Guidance.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the [CDC Vaccine Storage and Handling Toolkit](#).
- Comply with [immunization program guidance](#) for handling temperature excursions (contact the manufacturer and also report to vaccinetempexcursion@health.ny.gov).
- Monitor and comply with COVID-19 vaccine expiration dates.
- Preserve all records related to COVID-19 vaccine management for a minimum of three years.
- Comply with federal instructions and timelines for disposing of COVID-19 vaccine and diluent, including unused doses.

COVID-19 vaccination providers must have proper storage and temperature monitoring equipment to meet the specific needs of the COVID-19 vaccine product(s) they have in their inventory. This includes the correct vaccine storage unit(s), whether a refrigerator, regular freezer, or ultra-cold freezer.

- Purpose-built, also referred to as “pharmaceutical-grade,” units are preferred and designed specifically for storage of biologics, including vaccines.
- Household-grade units can be an acceptable alternative in some situations.
- Most standard freezer units do not meet ultra-cold freezer requirements for storing vaccine between -60° C and -80° C. However, at this time, CDC does not recommend COVID-19 vaccination providers purchase ultra-cold storage units because vaccines requiring these storage conditions are expected to be shipped in containers that can maintain ultra-cold temperatures for an extended period.
- Dorm style refrigerators are NOT permitted for vaccine storage.
- Food and beverages should never be stored in the unit with vaccines.
- It is essential for each vaccine storage unit to have a temperature monitoring device (TMD) to ensure that vaccines are stored within the correct temperature range. CDC recommends a specific type of TMD called a “digital data logger” (DDL).
- Providers must notify New York State DOH regarding any compromised doses or suspected compromise doses at COVID19vaccine@health.ny.gov along with the required to reporting to the New York State Immunization Information System (NYSIIS) or Citywide Immunization Registry (CIR).
- Reach out to your regional hospital hub or local health department if doses are going to expire to see if they can be used.

Upon arrival, shipments of refrigerated and frozen vaccine must be immediately examined for signs of damage, for indication of a temperature excursion during transit, and to guarantee receipt of the appropriate vaccine types and quantities. Before opening ultra-cold vaccine shipments, make sure the vaccine can be quickly placed in an ultra-cold freezer or that dry ice is available for re-icing the shipping container to ensure vaccine remains at the appropriate ultra-

cold temperature. Vaccines and diluents must be carefully examined, stored at recommended temperatures, and documented using your facility's vaccine inventory management process immediately after they arrive.

As part of the COVID-19 Vaccination Program, a minimum order size of COVID-19 vaccine, diluent, and ancillary supplies will be shipped directly to enrolled COVID-19 vaccination providers. In most instances, vaccine will be delivered directly to the facility where it will be administered to maintain the vaccine cold chain. However, there may be circumstances where COVID-19 vaccine needs to be redistributed or transported. In these cases, approval must be requested and granted prior to any redistribution or transport of vaccine.

Providers must adhere to all CDC and NYS COVID-19 Vaccination Program requirements, including, but not limited to, all storage and handling requirements, and failure to adhere to such requirements can result in termination from the program as well as any other penalties available under federal or New York State law.