

Vaccine Management

Lesson

Guidance on Vaccine Management

Note: Formalized training will be released after vaccine product approval to provide vaccine-specific storage and handling, vaccine administration, and operational guidelines.

Transfers

Vaccine shipments must be stored at the location identified and approved as part of the provider enrollment application. However, in the rare cases that an unplanned transfer of the vaccine is required, local health departments will be primarily responsible for this repositioning. Providers would need to request authorization from local health departments and indicate the reason for the repositioning, receiving location information, and vaccine inventory information. Upon approval, the receiving provider/location will have to accept the vaccine delivery and report received inventory within the system. Vaccine temperature documentation will be required to be provided upon request. Unauthorized redistribution of the COVID-19 vaccine will not be allowed.

Vaccine Transports

Ultra-cold vaccines may need to be transported in a thawed state following standard refrigerated transport guidelines. Vaccines may be sensitive to light and require additional protection using amber bags or transporting in cardboard vial trays. Vaccine transport requirements are determined by the manufacturer. Additional materials and transport guidance will be provided once vaccines are approved.

Managing Vaccine Expiration Dates

Vials may not be labeled with expiration dates. For ultra-cold vaccines, shelf life may be determined by storage method (e.g., thermal shipper, ULT freezer, or routine refrigerator). CDC is developing “beyond use date” (BUD) tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration. The label templates will be available on the CDC website.

Vial and Carton Labels under EUA

It is anticipated that COVID-19 vaccines will initially be authorized under an EUA. Vial and carton labels for vaccines *authorized* under an EUA will contain slight variations from labels typical of *approved* Food and Drug Administration (FDA) products, including:

- ✓ **Expiration Date:** The vaccine vials and cartons may not contain a printed expiration date. Expiration dates may be updated based on vaccine stability studies occurring simultaneously with COVID-19 vaccine distribution and administration. Additional information will be provided about how to access expiry information for individual vaccines. To ensure that information systems continue to work as expected, CDC has worked with FDA and the manufacturers to include a two-dimensional (2D) barcode on the vaccine vial (if possible) and carton (required) labels that includes a National Drug Code (NDC), lot number, and a placeholder expiration date of 12/31/2069 to be read by a scanner. The placeholder 12/31/2069 expiration date is not visible on the vaccine packaging nor found anywhere else; it is only to facilitate information system compatibility. CDC is developing “beyond use date” (BUD) tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration. The label templates will be available on the CDC website.
- ✓ **Manufactured Date:** A manufactured date will be on the packaging and should not be used as the expiration date when documenting vaccine administration. This date is provided to help with managing stock rotations; however, expiration dates should also be considered (see above) as using manufactured date alone could have some limitations.
- ✓ **2D Barcode:** The 2D barcode available on the vaccine carton (also on the vials for some vaccines) will include NDC, lot number, and a placeholder expiration date of 12/31/2069.
- ✓ **QR Code:** Each vaccine manufacturer will include a Quick Response (QR) code on the vaccine carton for accessing FDA-authorized, vaccine product-specific EUA fact sheets for COVID-19 vaccination providers and COVID-19 vaccine recipients.

A list of authorized COVID-19 vaccine products with corresponding EUA fact sheets for healthcare providers and vaccine recipients, and up-to-date expiration information by vaccine lot will be available on an HHS website.