Storage & Handling

California Bridge Access Program (BAP)

for uninsured & underinsured adults

For Existing COVID-19 Providers ★

Summary of new storage & handling requirements:

- No new requirements

Look for the gold stars in [Requirements at a Glance](#) that identify new requirements.

Providers will be notified when [COVID-19 Vaccine Product Guide](#) has been updated and posted after any FDA authorizations.

Click NEXT to review this lesson content.

Welcome

Proper storage and handling protect vaccine viability, which is necessary to stimulate a healthy immune response after vaccination.

This lesson prepares you to store and handle COVID-19 vaccines in your practice. By the end of this lesson, you'll be able to

- list vaccine storage units that meet program requirements,

- monitor temperatures and report excursions,

- manage expiration and beyond-use dates, and

- identify key factors in proper vaccine preparation.

Review Time: about 15 minutes (there is no audio – click Next)

What You'll Learn

1

Storage Units
&
Data Loggers

2

Temperature
Monitoring

3

Expiration &
Beyond-Use
Dates

4

Vaccine
Preparation

Storage Units & Data Loggers

Overview

Providers agree to use proper storage units and temperature monitoring devices, and follow protocols outlined in CDC's Vaccine Storage & Handling Toolkit.

A COVID-19 Addendum addresses storage & handling, preparation & administration, and transport for Moderna, Novavax, and Pfizer-BioNTech vaccine products.

Resources: Bookmark CDC's Vaccine Storage & Handling Toolkit.

Storage Units

Overview

Purpose-built or pharmaceutical-grade are the gold standard. They are designed for biologics, including vaccines. Storage units can be large or compact, under-the-counter. They

- offer reliable and uniform temperature,
- are designed to reduce cold air loss with door openings, and
- recover quickly after doors are closed.

Commercial or household standalone units are acceptable. If necessary, combination units may be used—but frozen vaccines must be stored in a separate standalone freezer.

Never store vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit.

Resources: See Requirements at a Glance, Storage Equipment.

Pharmacy-Grade

Bookmark Key Resources

- Vaccine Storage & Handling Toolkit

- Requirements at a Glance

Placement

Storage Units

Leave space along sides and top, and from any wall.

Don't block the cover of the motor compartment.

Make sure door opens and closes smoothly.
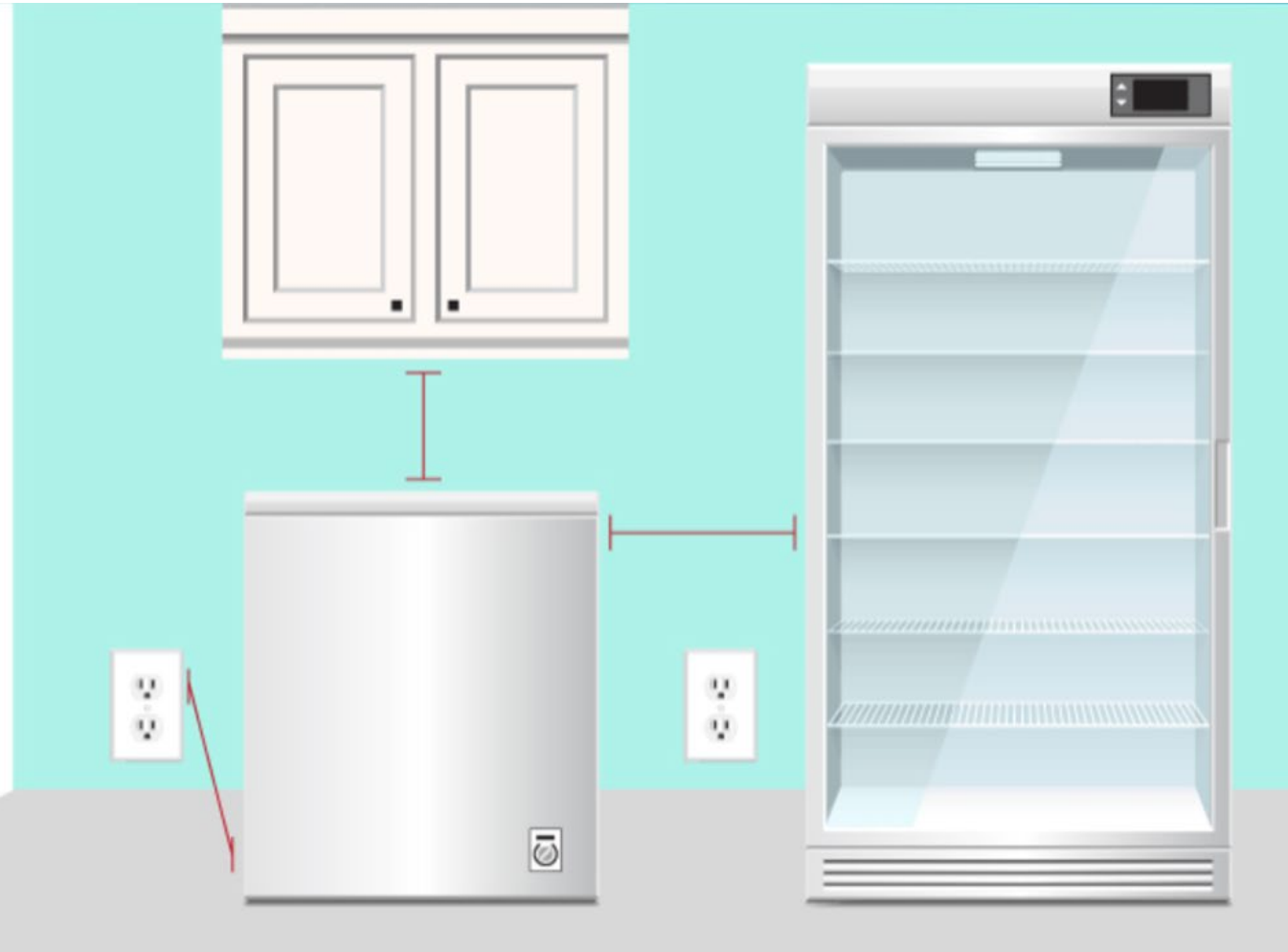
Getting Ready for Use: Key Points

Storage Units

Store vaccines in original packaging (trays)

Store biologics on separate shelf; no food or drinks to minimize door openings

Avoid outlets with **RESET** button, outlets controlled by wall switch, and power strips

Use "Do Not Disconnect" labels; use outlet covers
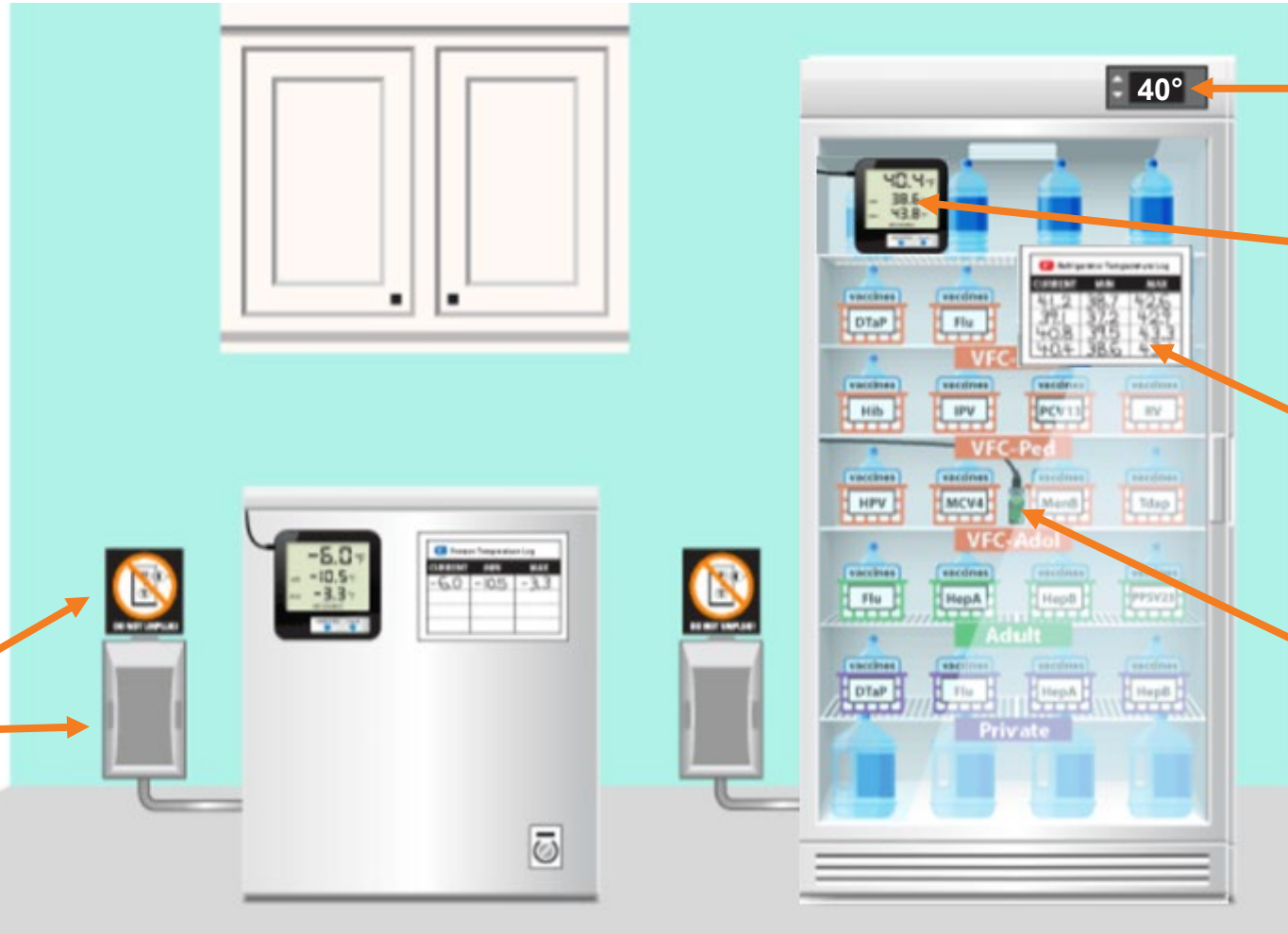
Set thermostat within required range

Ensure digital display is easily visible

Post temperature logs on corresponding unit

Position data logger probe in the center near vaccines

Setup
Storage Units

Never borrow BAP-supplied vaccines to supplement private stock, or vice versa

Organize your storage unit to avoid administration errors

Recommended Temperatures
Storage Units

Vaccines must be stored under manufacturer-recommended storage temperatures defined in EUA Fact Sheets for HCPs and CDC's Vaccine Storage & Handling Toolkit & COVID-19 Addendum.

Resources: See COVID-19 Vaccine Product Guide for summary chart.

Bookmark Key Resources

- Vaccine Storage & Handling Toolkit

- Requirements at a Glance

- **COVID-19 Vaccine Product Guide**

Data Loggers
Overview

Storage units must be equipped with a digital data logger; devices with buffered probes provide more accurate readings. For ultra-cold storage, devices must use an air-probe, or probe designed for vaccine temperatures.

Keep a backup device on hand for transports and should primary devices fail. Devices must have a current and valid Certificates of Calibration Testing.

Resources: See Requirements at a Glance, Storage Equipment.
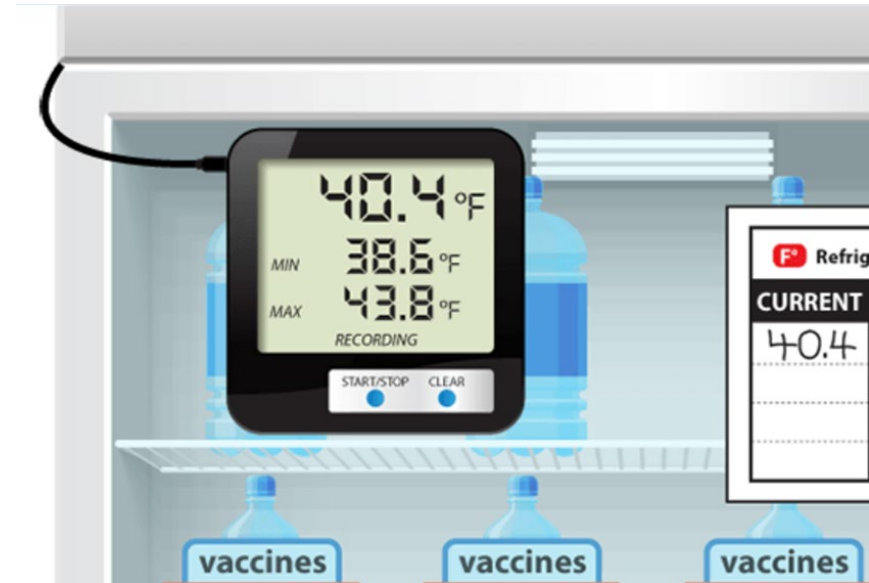
Features

Data Loggers

CDC recommends devices with the following features:

- Current, minimum, and maximum temperatures
- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- Alarm for out-of-range temperatures
- Reset button
- Accuracy within +/-.5°C accuracy (+/-1°F)
- Low-battery indicator

Resources: See CDC's Vaccine Storage & Handling Toolkit.
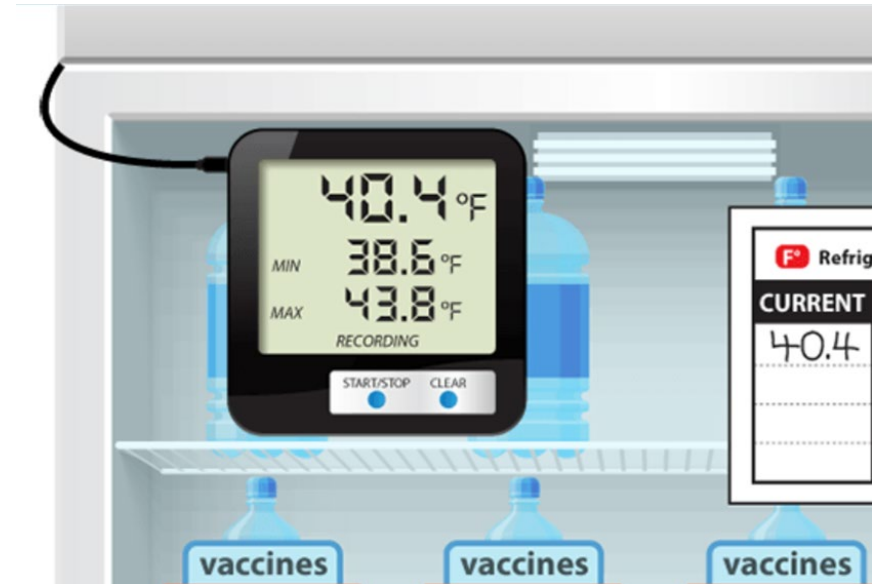
Setup
Data Loggers

To ensure you are notified if temperatures drift outside recommended ranges, configure device settings carefully.

- Set HI & LO alarm limits to reflect recommended product temperatures.

- Select the temperature scale that matches your temperature range.

- Record every 30 minutes (or less) so you can respond promptly to alerts.

Resources: See Requirements at a Glance, Storage Equipment.
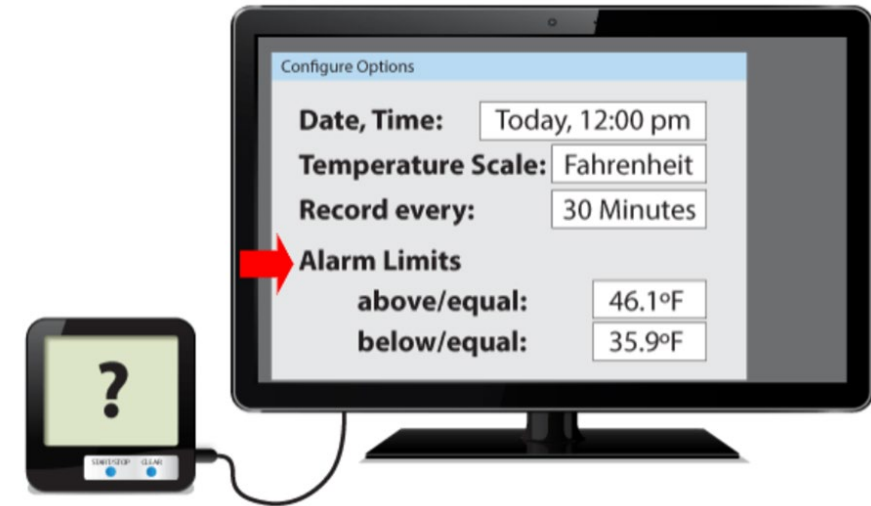
What You'll Learn

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Storage Units
&
Data Loggers

2
Temperature Monitoring

3
Expiration & Beyond-Use Dates

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Vaccine Preparation

Temperature Monitoring
Overview

Temperature monitoring is a critical step to protect vaccines.

Monitor and record your data logger's current, MIN, and MAX readings **twice daily** on your temperature logs for refrigerated, frozen, or ultra-cold vaccines, or use this COVID-19 Temperature Log.

Post refrigerated and frozen temperature logs on corresponding storage units to prevent recording errors.

Resources: See Requirements at a Glance, Temperature Monitoring.

Temperature Monitoring (Cont.)
Overview

Take these steps to prepare for your initial vaccine shipment:

- Ensure staff are trained to operate your data loggers and download any temperature data file in the event of an excursion; refer to device's product guide.

- Some devices must be cleared (MIN/MAX temperatures and alarm symbol) after each recording to ensure staff don't record previous readings again (see image); check your device's product guide.

- Train staff not to ignore alarm alerts; if temperature alarms go off repeatedly, do not disconnect the alarm until it has been confirmed as a false alarm.

- Supervisors should plan to review logs to ensure staff understand how to record temperatures, record twice daily, and respond to all out-of-range temperatures.

Temperature Monitoring (Cont.)

Overview

[Record storage unit temperatures](#) following the instructions on the [COVID-19 Temperature Log](#).

1 Record the time and your initials next to the day of the month:

a.m. temperatures **before** opening the refrigerator or freezer.

p.m. temperatures about an hour before the office closes to allow time for corrective actions.

2 Record a check mark if you see or hear an alarm.

If the alarm did not go off, leave blank.

3 Record CURRENT, MIN, and MAX temperatures neatly, accurately, and in the correct columns.

Day	Time	Initials	Alarm	CURRENT	MIN	MAX
16	8:00 am	CS	✓	2.4 C	0.6 C	4.1 C
	pm					

2.4 °C
MIN 0.6 °C
MAX 4.1 °C
RECORDING

START/STOP   CLEAR

Temperature Monitoring (Cont.)

Overview

Record storage unit temperatures following the instructions on the COVID-19 Temperature Log.

IF NO ALARM:

4 **Clear MIN and MAX.**
(Skip this step if your data logger resets automatically.)

Confirm MIN and MAX now match the CURRENT temperature.

5 **Ensure data logger is in place and recording.**

(Some devices need to be reconnected and restarted.)

Refer to the device's product guide.

Reporting Temperature Excursions

Temperature Monitoring

Any temperature outside recommended ranges is considered a temperature excursion and may spoil vaccines.

A temperature excursion triggers a **visual or audible alarm** or alert depending on the data logger. Staff will need to confirm when the excursion occurred and its duration. There may be multiple temperature excursions overnight or weekend.

Your device may have a **temperature data file** that must be downloaded to get the data manufacturers will need to determine whether vaccines can be administered. The manufacturer's determination is only as accurate as the data you provide.

Sample Data File

	Limit	First Event	Events	Time	Pass/Fail
High	8.1°C	1/16/2018 2:34 PM	5	25 Mins	**FAIL**
Low	1.9°C	None	0		PASS

Bookmark Key Resources

- Requirements at a Glance

Reporting Temperature Excursions
Temperature Monitoring

If an alarm goes off, take action immediately and report the temperature excursion (instructions provided on the COVID-19 Temperature Log):

- Clear the alarm symbol to ensure staff don't respond to previous alerts.

- Label exposed vaccines DO NOT USE so vaccines are not administered.

- Alert the Vaccine Coordinator on duty or your supervisor.

- Download the temperature data file (if any) and locate the excursion details.

- Complete the Temperature Excursion Worksheet to gather data manufacturers will need to determine viability, then contact the manufacturer.

- Report temperature excursions daily in myCAvax under **Vaccine Inventory**. For technical questions, look for the Knowledge Center link in myCAvax.

- Do not administer vaccines until the manufacturer resolution is determined.

Resources: See Requirements at a Glance, Reporting Temperature Excursions.

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Expiration Dates

Overview

Determining vaccine and diluent expiration dates is critical for proper storage and handling. Do not administer expired vaccine. Expiration dates may be extended as more data come in. To determine expiration dates:

- *Moderna:* <mark>Waiting to hear from the manufacturer</mark>.
- *Novavax:* <mark>Waiting to hear from the manufacturer</mark>.
- *Pfizer-BioNTech:* <mark>Waiting to hear from the manufacturer</mark>.

Resources: See Requirements at a Glance, Managing Expiration & Beyond-Use Dates.

Bookmark Key Resources

- Requirements at a Glance

Beyond-Use Dates
Overview

Vaccines may have a shortened beyond-use date (BUD) as specified in the EUA Fact Sheet for HCPs and documented in CDC's Toolkit & COVID-19 Addendum.

The BUD replaces the manufacturer's expiration date. If the vaccine has no beyond-use date, use the expiration date.

Discard vaccine after the earlier of the expiration or beyond-use date.

Label vaccines (date, time and staff initials) and track carefully to ensure vaccines aren't used past the beyond-use date.

Resources: Complete CDC's product training for vaccines your location will order to ensure staff are trained on storage and handling including beyond-use dates and labels.

Bookmark Key Resources

- Requirements at a Glance

Before Puncture

Beyond-Use Dates

Manufacturer-shortened expiration dates may apply if storing unpunctured vials under conditions other than coldest recommended temperatures.

Apply CDC's vaccine-specific BUD tracking labels so vaccines aren't used past these reduced limits. (Select the vaccine product, click Storage & Handling, and look for the "Labels and Guidance.")

Resources: See Requirements at a Glance, Managing Expiration & Beyond-Use Dates.

Sample BUD Label

FORMULATION: 5 Through 11 Years of Age
Pfizer-BioNTech COVID-19 Vaccine

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

Lot number(s): _123456A_

Today's date: _06_/_01_/_2021_ Time: _2:30 PM_

USE BY*

Date: _08_/_10_/_2021_ Time: _2:30 PM_

*As the 10 week deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Name: _Amy Nurse RN_

CDC

After Puncture

Beyond-Use Dates

Multidose vials have a shortened use-by date/time after the first puncture. Once vial is punctured, label vial with puncture date/time. Do not administer after the use-by date/time.

Pfizer-BioNTech
Up to 12 hours (including thaw time) at 8ºC to 25ºC (46ºF to 77ºF) Discard unused vaccine after this timeframe.

9 AM

**Label Vial
Use-By & Initials**

11/12/23
9 PM TP

Resources: See COVID-19 Vaccine Product Guide for summary chart.

Bookmark Key Resources

- Requirements at a Glance

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Vaccine Preparation

Overview

Use this administration checklist (to be updated after FDA authorization) to ensure your patients receive sufficient protection after vaccination and to minimize revaccination efforts due to administration errors.

- Always check expiration & beyond-use dates before preparation and administration.

- Prepare vaccine according to the manufacturer fact sheet.

- Don't exceed the number of doses in the fact sheet.

- Never use partial doses (pool) from two or more vials to obtain a dose of vaccine.

- Administer COVID-19 vaccines in the correct site and route.

Resources: See Requirements at a Glance, Vaccine Preparation.

Bookmark Key Resources

- Requirements at a Glance

Summary

You have now completed the lesson. You should now be able to:

- **list vaccine storage units that meet program requirements,**
  Ranked in order: purpose-built or pharmaceutical; commercial or household standalone; combination units (frozen vaccines stored in standalone freezer)

- **monitor temperatures and report excursions**
  Record temperatures twice daily; for excursions, quarantine vaccines, contact manufacturer for guidance, and report excursions in myCAvax.

- **manage expiration and beyond use dates**
  [Requirements at a Glance](#), Managing Expiration & Beyond-Use Dates

- **identify key factors in proper vaccine preparation**
  [Requirements at a Glance](#), Vaccine Preparation

Go to [eziz.org/vfa-317/bap/](#) for provider alerts, job aids, Provider Call Center contact details, and more!

Looking for myCAvax Training Resources?

The Knowledge Center houses key job aids and videos that are updated every release to include enhancements across vaccine programs.

You can access the Knowledge Center from the myCAvax homepage (or at various places throughout the system) using the links as shown below.

Need help? View our jobs aids in the Knowledge Center, or contact us.

Done!

You have completed the **Storage & Handling** lesson.

Click "EXIT" at the top of page.