Washington State Department of Social & Health Services
Transforming lives

DEVELOPMENTAL DISABILITIES ADMINISTRATION
RESIDENTIAL HABILITATION CENTER
STANDARD OPERATING PROCEDURE

TITLE:	VACCINE STORAGE AND HANDLING	105.5

PURPOSE

The purpose of this procedure is to establish requirements for Residential Habilitation Center (RHC) vaccine storage and handling procedures that protect clients and staff from vaccine-preventable diseases.

SCOPE

This procedure applies to all Residential Habilitation Center employees involved in ordering, receiving, storing, dispensing, or transferring vaccines. All staff handling vaccines must read, sign, and adhere to the protocols described in this document.

PROCEDURE

A. All RHCs must maintain a vaccine management plan that addresses routine and emergency situations, ensures accountability, and maintains efficacy of vaccines.

B. The RHC will follow the requirements of Washington State Department of Health immunization program for any vaccines received from the program. (See State Program User Manual.)

C. Ordering, Receiving, and Inventory

1. Vaccines must be ordered based on historical or projected use. Excess quantities must not be ordered.

2. Upon arrival at the facility, vaccines must be checked and transferred to appropriate temperature storage in a timely fashion. See “Storage Temperatures” in Attachment A for appropriate temperatures.

3. Vaccines must be delivered in thermal protective shippers and staff must check for damage and check quantities against packing lists for errors upon delivery.

4. Vaccines must be released only in response to one of the following valid requests:

   a. A medical order for administration to clients; or

   b. A written request to transfer stock from employee health for staff immunization.

5. Vaccine inventory must be routinely monitored.

   a. Inventory must be:

      i. Electronically monitored; or
      ii. Manually checked at least monthly.

   b. Any significant quantity discrepancies must be investigated and documented.

6. Any unused or expired vaccines must be disposed of or returned to vendor for credit, as applicable.

D. Storage and Handling

1. Vaccine storage units must be pharmaceutical-grade, laboratory-grade, or stand-alone style (only a freezer portion or only a refrigerator portion). Dormitory style units must not be used for vaccine storage.

2. Unless otherwise indicated on Attachment A for a specific vaccine, vaccine storage units must be maintained within the following ranges:

   a. Refrigerator temperatures must be kept between 2°C and 8°C (36°F and 46°F).

   b. Freezer temperatures must be kept between -25°C and -15°C (-13°F and 5°F).

E. Temperature monitoring

1. Temperatures must be monitored using a calibrated digital data logger (DDL) with a buffered temperature probe that continuously tracks temperature.

   a. If the DDL has a built in system to trigger an alarm or send an alert, it may be checked monthly or bimonthly based on memory capabilities by downloading and saving data to a computer.

   b. If the DDL does not have a built in system to trigger an alarm or send an alert, but does track minimum and maximum temperatures, temperatures must be checked and recorded at the beginning of each workday.

   c. If the DDL doesn't alarm, send alerts, or track minimum and maximum temperatures, temperatures must be checked and recorded at the beginning and end of each workday.

2. Any digital data logger discrepancies or errors must be investigated and resolved for accuracy.

3. Out-of-range temperatures (excursions) must be identified, investigated, and resolved according to Attachment B, *Handling a Temperature Excursion in Your Vaccine Storage Unit*.

F. Transporting vaccines

1. RHCs must not transport vaccines from the original receiving facility.

2. If vaccines must be transported, the RHC must follow CDC vaccine transportation guidance and obtain approval for that transport from pharmacy personnel. All appropriate packaging, temperature control devices, inventory and invoice records and any other documentation or process must comply with CDC or internal procedures.

G. Emergencies

1. Pharmacy vaccine freezers and refrigerators must be kept in buildings connected to a backup generator in case of power outage.

2. If a backup generator fails, staff must not open the freezer or refrigerator as long as temperature remains within range (opening will disrupt insulation).

3. If the temperature in a freezer goes out of range, remove the vaccines and initiate emergency transfers into hard-sided insulated containers with coolant and calibrated thermometer.

   a. Coolant may be frozen conditioned water bottles or pre-identified phase change materials at that change phase at 2-8°C.

   b. To protect from freezing, vaccines must not be touching coolants. Layers of cardboard, Styrofoam, or bubble wrap may be used as insulation for even temperatures.

   c. This is considered a temperature excursion and the processes in Attachment B must be followed.

   d. If a vaccine thaws, do not refreeze the vaccine.

4. If there are issues for vaccines stored in a refrigerator, move to insulated storage as described in subsection (G)(3) above. If the temperature is monitored with a DDL and temperatures are within range, this is not considered a temperature excursion.

5. RHCs must designate an employee responsible for refrigerator or freezer repair and document the employee's name and include contact information for resolving issues.

H. Training

1. Staff involved in ordering, receiving, storing, dispensing, or transferring vaccines must:

   a. Complete the CDC's You Call the Shots - Vaccine Storage and Handling training annually; and

   b. Review this procedure and related forms annually.

2. Training activities must be documented according to the RHC's process.

AUTHORITY

Chapter 71A.20 RCW *Residential Habilitation Centers*

REFERENCES

Immunization Information System Training Portal (DOH)
Vaccine Storage and Handling (DOH)
Vaccine Storage and Handling Resources (CDC)
You Call the Shots (CDC Training)

DEFINITIONS

Buffered temperature probe means a temperature probe designed to prevent false readings by protecting the thermometer from sudden changes in temperature that can occur when opening a refrigerator door. A probe is "buffered" by immersing it in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon®, aluminum).

Conditioned water bottles means frozen water bottles that have been submerged under lukewarm water until the ice block inside can spin freely.

Digital data logger (DDL) means an electronic device that records data digitally over time or in relation to location with either a built-in or external instrument or sensor.

Dormitory-style (bar-style) storage unit means a combination refrigerator-freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

Phase change materials (PCMs) means engineered packing supplies that help control container temperatures during vaccine transport or shipping. Vaccine appropriate PCMs change phases 4°C-5°C (39°F-41°F)

Temperature excursion means a temperature reading that is outside the recommended range for vaccine storage as defined by the manufacturer's package insert.

SUPERSESSION

None.

Approved: /s/: Shannon Manion Date: June 15, 2021
Interim Deputy Assistant Secretary
Developmental Disabilities Administration

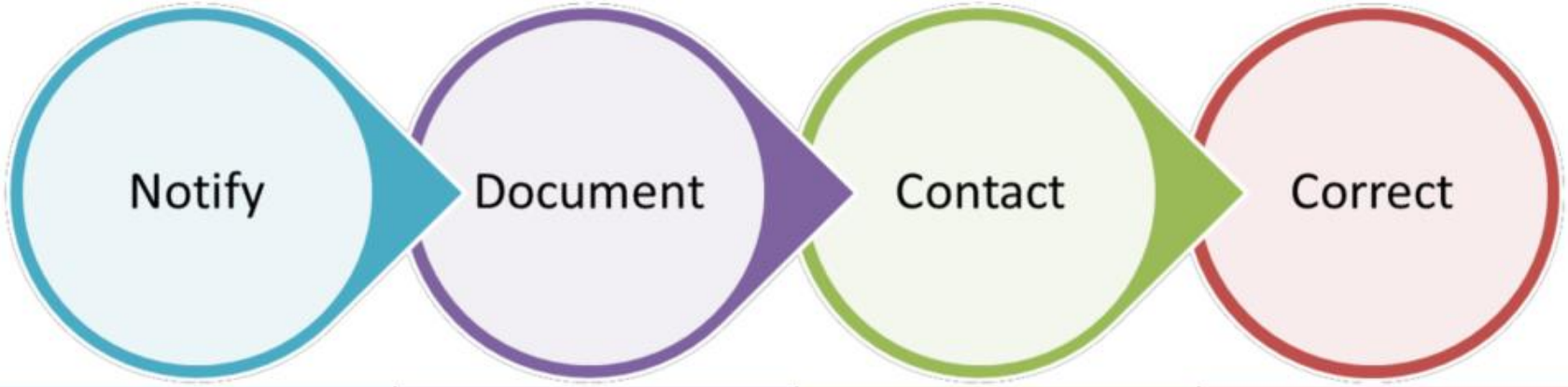
ATTACHMENT A
Vaccine Inventory Guide

Vaccine	Storage temperature	Preparation and administration	Manufacturer contact information
COVID19 (Moderna)	-25°C and -15°C (-13°F and 5°F) 2°C and 8°C (36°F and 46°F) for 30 days	After reconstitution with sterile normal saline, give within 6 hours 0.3ml intramuscularly	1-866-MODERNA (1-866-663-3762)
COVID19 (Pfizer)	-80°C to -°60C (-112°F to -76°F) -25°C to -15°C (-13°F to 5°F) for up to 2 weeks 2°C and 8°C (36°F and 46°F) for 5 days	0.5ml intramuscularly	Pfizer COVID line 1-800-438-1985
COVID19 (Janssen) AKA Johnson & Johnson	2°C to 8°C (36°F to 46°F) 9°C to 25°C (47°F to 77°F) for up to 12 hours	0.5ml intramuscularly	Janssen 1-800-565-4008
Hepatitis A (VAQTA)	2°C and 8°C (36°F and 46°F)	1 ml intramuscularly	Merck 800-444-2080
Hepatitis B (Engerix-B)	2°C and 8°C (36°F and 46°F)	1 ml intramuscularly	GSK 866-475-8222
Human Papillomavirus (Gardisil-9)	2°C and 8°C (36°F and 46°F)	0.5ml intramuscularly	Merck 800-444-2080
Measles, Mumps, Rubella (M-M-R II)	-50°C and +8°C (-58°F and 46°F) Do not freeze diluent	After reconstitution with manufacturer diluent, give immediately or return to refrigerator for up to 8 hours. 0.5ml subcutaneously	Merck 800-444-2080
PCV13 (Prevnar-13)	2°C and 8°C (36°F and 46°F)	0.5ml intramuscularly	Pfizer 800-505-4426
PPSV (Pneumovax-23)	2°C and 8°C (36°F and 46°F)	0.5ml intramuscularly or subcutaneously	Merck 800-444-2080
Tetanus-diphtheria (Tenivac)	2°C and 8°C (36°F and 46°F)	0.5ml intramuscularly	Sanofi Pasteur 800-822-2463
Tetanus-diphtheria-pertussis (Adacel)	2°C and 8°C (36°F and 46°F)	0.5ml intramuscularly	Sanofi Pasteur 800-822-2463
Varicella zoster (Shingrix)	Store both adjuvant and lyophilized vaccine 2°C and 8°C (36°F and 46°F)	After reconstitution with manufacturer diluent, give immediately or return to refrigerator for up to 6 hours. 0.5ml intramuscularly	GSK 866-475-8222
Influenza quadrivalent vaccine	2°C and 8°C (36°F and 46°F)	0.5ml intramuscularly	GSK (fluarix) 866-475-8222 Sanofi Pasteur (Flublok) 800-822-2463
Influenza vaccine, adjuvanted (Fluad)	2°C and 8°C (36°F and 46°F)	0.5ml intramuscularly	Seqirus 855-358-8966
Influenza vaccine, high dose (Fluzone)	2°C and 8°C (36°F and 46°F)	0.7ml intramuscularly	Sanofi Pasteur 800-822-2463

**Document information for any vaccines used at RHC not included in this attachment

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside recommended ranges is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



Notify	Document	Contact	Correct
➢ Notify the primary/back-up vaccine coordinator immediately or report the problem to a supervisor. ➢ Notify staff by labeling exposed vaccines, **'DO NOT USE'**, and quarantine them. Do not discard these vaccines and move them into a unit that is operating within the recommended temperature range.	➢ Document details of the temperature excursions. Include: • Date and time • Description of the event • Length of time vaccine may have been affected • Vaccines affected	➢ Call the Vaccine Manufacturer to discuss the temperature excursion. ➢ Be prepared to answer questions about what caused the incident and review the temperature log.	➢ If the data logger alarms repeatedly, do not dismiss the alarm until you have determined and addressed the cause. ➢ Check the basics, including: • Power supply • Unit door(s) • Thermostat setting • Ice build-up in freezers ➢ If you believe the storage unit has failed, implement emergency vaccine SOP. ➢ **Never allow vaccines to remain in a nonfunctioning unit that is out of temperature range.**

ATTACHMENT C
Staff Signature Page

By signing below, I attest that I have read, understood, and will follow this RHC SOP 105.5.

_____
Staff Signature

_____
Staff Printed Name

_____
Date