Department of Veterans Affairs **VHA NOTICE 2021-16**
Veterans Health Administration
Washington, DC 20420 **August 9, 2021**

STORAGE OF VACCINES AND MEDICATIONS IN PHARMACEUTICAL GRADE PURPOSE-BUILT REFRIGERATORS AND FREEZERS AT VA MEDICAL FACILITIES

1. PURPOSE

a. The purpose of this Veterans Health Administration (VHA) notice is to standardize definitions, roles and responsibilities for the storage of vaccines and medications in pharmaceutical grade purpose-built refrigerators and freezers.

b. This VHA notice establishes interim policy, pending amendment of VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017.

c. This notice adds definitions for Cascade Alarm, Essential Electrical System and Temperature Monitoring System (see paragraph 3).

d. This notice rescinds the VHA Notice 2021-02, Storage of Vaccines and Medications in Pharmaceutical Grade Purpose-built Refrigerators and Freezers at VA Medical Facilities, dated January 20, 2021.

2. BACKGROUND

a. Vaccines and medications can lose their potency when exposed to excessive heat, cold or light. While exposure to any inappropriate conditions can affect potency of refrigerated vaccines, a single exposure to freezing temperatures (0 degrees Celsius or colder) may destroy some vaccines.

b. VHA Directive 1108.06 requires the Chief of Pharmacy Services to ensure monitoring of the temperatures for medication refrigerators and freezers to meet the U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC) recommendations. Medications and vaccines are not to be stored in dormitory-style, bar-style, combined refrigerator or freezer units under any circumstance. Pharmaceutical grade, purpose-built refrigerators provide consistent temperature control to avoid damaging fragile medications. ***NOTE:*** *For more information on proper vaccine storage and handling*, *please see the CDC website at: https://www.cdc.gov/vaccines/hcp/admin/storage/index.html.*

3. DEFINITIONS

a. **Buffered Temperature Probe.** A buffered temperature probe is 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 considered 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).

b. **Calibration.** Calibration is professional verification with written certification of the accuracy of a temperature monitoring device.

c. **Cascade Alarm (Escalation Process).** Cascade Alarm, or escalation process, is the process that occurs when a temperature excursion or power loss alert is received by the first response group (or individual), if no action is taken, a secondary response group will be contacted, if no action is taken, the cascade will continue until there is corrective action.

d. **Digital Data Logger.** Digital data logger (DDL) is an electronic device that records data digitally over time either with a built-in or external instrument or sensor and for the purposes of this Notice, will include details on how long a unit has been operating outside the recommended temperature range. The data must be maintained for three years.

e. **Dormitory-style or Bar-style Storage Unit.** A dormitory-style storage unit is a combination refrigerator or freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

f. **Essential Electrical System.** The Essential Electrical System (EES) as defined in National Fire Protection Association (NFPA) 99, Health Care Facilities Code is comprised of alternate sources of power and all connected distribution systems and ancillary equipment. The system is designed to ensure continuity of electrical power to designated areas and functions of a health care facility during disruption of normal power sources, and to minimize disruption within the internal wiring system.

g. **Pharmaceutical Grade Purpose-built Refrigerator or Freezer.** A pharmaceutical grade purpose-built refrigerator or freezer is designed specifically for storage of drugs and biologics. These often have microprocessor-based temperature control with a digital temperature sensor and fan-forced air circulation or multiple vents that promote uniform temperature. There are large or compact units available.

h. **Temperature Excursion.** Temperature excursion is any temperature reading that is outside the recommended temperature storage range for medications and vaccine storage as defined by the manufacturer.

i. **Temperature Monitoring System.** Temperature monitoring system is a system that provides continuous monitoring and alarm/alert notification of defined temperature excursions.

4. RESPONSIBILITIES

a. **Chief Consultant, Pharmacy Benefits Management.** The Chief Consultant, Pharmacy Benefits Management is responsible for issuing policy and guidance related to vaccine and medication storage in pharmaceutical grade refrigerators and freezers.

b. **Veterans Integrated Services Network Director**. The Veterans Integrated Services Network (VISN) Director is responsible for:

(1) Ensuring all VA medical facilities in their VISN comply with this notice.

(2) Ensuring that all medication storage refrigerators and freezers are all vaccine and medication storage refrigerators and freezers are managed through VA medical facility policy and standard operating procedures (SOPs).

(3) Ensuring all vaccine and medication storage refrigerators and freezers are pharmaceutical grade. ***NOTE:*** *Any refrigerators and freezers that are not pharmaceutical grade must be replaced prior to storage of medications and vaccines.*

(4) Ensuring all vaccine and medication storage refrigerators and freezers are equipped with a temperature monitoring system and that a cascade alarm process is implemented and tested.

(5) Ensuring refrigerators and freezers used to store vaccines and medications are included in each VA medical facility's routine maintenance and inspection program.

(6) Ensuring that any loss of medications or vaccines from refrigerator or freezers continue to be reported from the VA medical facility Director through the Issue Brief process with patient impact and the cost of lost medication or vaccines included.

c. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Implementing this VHA notice.

(2) Designating the oversight of the maintenance and the operation of medication refrigerators and freezers to the department that has the required competency and knowledge of the equipment.

(3) Ensuring a VA medical facility policy and SOP are in place to immediately detect temperature excursions, and take corrective action to prevent medication deterioration or damage. At a minimum, the VA medical facility policy and the SOP must:

(a) Require a temperature monitoring system that provides 24 hour-a-day, 7 day-per-week monitoring and logging of temperature data.

(b) Define the response procedure (including cascade alarm and response) that immediately reacts to temperature excursions and planned responses to ensure vaccines and medications are not adversely impacted. ***NOTE:*** *The alarm and response procedures must be tested upon installation, after any system changes or failures and at least semiannually thereafter.*

(c) Ensure that the temperature monitoring system is fully inspected, calibrated and tested upon installation, after any system change or failures, and at least semiannually thereafter.

(d) Ensure all medication refrigerators, freezers, and temperature monitoring systems are connected to emergency power automatically supplied by the VA medical facility's EES when such system is required at the VA medical facility in accordance with NFPA 70, Article 517 Part III and NFPA 99. If a VA medical facility is not required to have an EES, but has generator power, the generator must meet the requirements of NFPA 110 for installation, testing, and maintenance. If the VA medical facility does not have EES, emergency or generator power (such as a Community-Based Outpatient Clinic (CBOC)), then the following additional tasks must be included in the VA medical facility policy and SOP(s):

1. Provide power monitoring system to alert staff that the VA medical facility has experienced an electrical power loss.

2. Ensure a cascade alarm system is implemented and tested upon installation, after any system changes or failures and at least semiannually thereafter to respond to the loss of power alert in the same manner as response to a temperature monitoring system alarm. ***NOTE:*** *Staff responsible for securing medications must have access after standard business hours to the location.*

3. Test power and temperature monitoring systems quarterly and if there is a battery backup on the system, it must be tested at the same time.

4. Ensure the response process defines when staff are expected to arrive at the location when a power outage has occurred. The response must occur before the pharmaceutical grade refrigerator or freezer experiences a temperature excursion. This response process must be based on a documented risk analysis and it must be tested. ***NOTE:*** *The risk analysis must include the actual conditions the plan is anticipated to be activated under. Employees must not be exposed to hazardous conditions such as severe weather.*

5. Ensure staff can transport the refrigerated or frozen vaccines and medications to an alternative storage facility location that is compliant with this notice and VHA Directive 1108.07(1) Pharmacy General Requirements, dated March 10, 2017. The transport container must be equipped with temperature monitoring system.

(e) Ensure vaccines and medications exposed to temperature excursions are segregated from other medications and returned to Pharmacy Services for appropriate disposition.

(4) Ensuring a process is in place to perform and document the maintenance of the pharmaceutical grade purpose-built refrigerators or freezers as defined by and per the frequency recommended by the manufacturer. The following routine maintenance tasks are required for all units on a regular basis as determined by risk analysis:

(a) Check door seals to ensure they are not torn or brittle and there are no gaps between the seals and the body of the unit when the door is closed.

(b) Ensure door hinges are aligned so that the door opens and closes smoothly and fits squarely against the body of the unit.

(c) Clean unit coils and motor. ***NOTE:*** *Dust and dirt buildup can affect transfer of heat from the coils and prevent the unit from working efficiently*.

(d) Defrost manual-defrost freezers when the frost exceeds either 1 centimeter or the manufacturer's suggested limit.

(5) Ensuring an Issue Brief is submitted through the VISN for any pharmaceutical refrigerator or freezers failures with loss of medications or vaccines. Information should include an itemized list of lost medications and vaccines with cost, details regarding the excursion and action taken.

b. **VA Medical Facility Chief of Pharmacy.** The VA medical facility Chief of Pharmacy or designee is responsible for:

(1) Coordinating with the VA medical facility Chief of Facilities Management or designee to ensure Pharmacy Services and other VA medical facility locations (e.g., Nursing Units, Research Centers, CBOCs) that store medications which must be refrigerated or frozen, use pharmaceutical grade purpose-built refrigerators or freezers exclusively.

(2) Developing a location-specific retrieval plan that defines actions staff need to take with vaccines and medications when notified of a temperature or power excursion.

(3) Ensuring newly installed or repaired pharmaceutical grade refrigerators or freezers have at least 2 consecutive days of temperatures recorded within the recommended range before vaccines or medications are stored in the units.

(4) Ensuring the buffered probe of the DDL is placed in the center of the unit with the vaccines and medications, or as placed in the unit or recommended by the manufacturer.

(5) Ensuring food and beverages are not stored with vaccines or medications.

(6) Defining the frequency of cleaning the inside of the unit to discourage bacterial and fungal growth following manufacturer guidelines.

c. **VA Medical Facility Chief of Responsible Service.** ***NOTE:*** *In most VA medical facilities, refrigerators and freezers are managed by Facility Management.* The Responsible Service Chief or designee is responsible for:

(1) Ensuring the VA medical facility procures pharmaceutical grade purpose-built refrigerators or freezers of appropriate design and quality for vaccines and medications.

(2) Ensuring the VA medical facility procures and implements a temperature monitoring system with 24 hour-a-day, 7 day-per-week monitoring DDL capability and the following features:

(a) A detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®).

(b) Alarm for out-of-range temperatures.

(c) Low-battery indicator.

(d) Current, minimum, and maximum temperature display.

(e) Recommended accuracy of +/-0.5 degrees Celsius.

(f) Capable of sending a cascade alert if the monitoring system fails or goes off-line.

(g) Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures no less frequently than every 30 minutes and whenever there is an excursion.

(3) Ensuring a current and valid Certificate of Calibration is readily available for accreditation or regulatory reviews, and verifying the temperature monitoring system is continuously collecting and recording data.

(4) Evaluating that the placement of the pharmaceutical grade refrigerators or freezers are in well ventilated rooms with space between the unit, ceiling and walls. The unit must not be located next to sun-facing windows or with exposure to direct sunlight.

(5) Ensuring the pharmaceutical grade purpose-built refrigerators or freezers are placed on the VA medical facility equipment replacement plan prior to the unit's expected end of life cycle.

5. RESPONSIBLE OFFICE: The VHA Office of Pharmacy Benefits Management Services (12PBM) is responsible for the content of this VHA notice. Questions may be addressed to: VHAPBMPharmacyCompliance@va.gov.

6. REFERENCES

a. VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017.

b. VHA Directive 1108.07(1), Pharmacy General Requirements, dated March 10, 2017.

c. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Vaccine Storage & Handling Toolkit. March 2021. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

d. The Joint Commission. Standards FAQ Details. Refrigerator-Design Quality. https://www.jointcommission.org/standards/standard-faqs/laboratory/environment-of-care-ec/000001250/.

7. RESCISSION: This VHA notice will expire and be archived as of August 31, 2022.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Beth Taylor, DHA
Assistant Under Secretary for Health
for Patient Care Services

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