Department of Veterans Affairs **VHA Notice 2020-02**
Veterans Health Administration
Washington, DC 20420 **January 17, 2020**

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, to be implemented within 120 days from the date of publication (by May 17, 2020).

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

2. BACKGROUND

a. Vaccines can lose their potency when exposed to excessive heat, cold, or light with subsequent exposures to improper conditions resulting in loss of potency. While exposure to any inappropriate conditions can affect potency of refrigerated vaccines, a single exposure to freezing temperatures (0 degrees Celsius or colder) will destroy some vaccines. Liquid vaccines that contain an adjuvant can permanently lose potency when exposed to freezing temperatures.

b. VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017, requires the Chief of Pharmacy Services to ensure monitoring of the temperatures for medication refrigerators and freezers to meet The Joint Commission and United States Pharmacopoeia (USP) standards.

c. Although The Joint Commission does not have an Environment of Care standard for specific design quality or other criteria for medication refrigerators and freezers, it recognizes that medication refrigerators likely require a significantly higher level of design quality than a food refrigerator to maintain acceptable temperature ranges and agrees with the U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC) recommendation not to store vaccines in dormitory-style (or bar-style), combined refrigerator or freezer units under any circumstances. ***NOTE:*** *For more information on proper vaccine storage and handling, please see the CDC Web site 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 measurement of the accuracy of a temperature monitoring device's reading against National Institute of Standards and Technology (NIST) standards.

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

d. **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. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage.

e. **Pharmaceutical Grade Purpose-built Refrigerator or Freezer.** A pharmaceutical grade purpose-built refrigerator or freezer is designed specifically for storage of 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.

f. **Temperature Excursion.** Temperature excursion is any temperature reading that is outside the recommended range for vaccine storage as defined by the vaccine manufacturer's package insert.

g. **Uncertainty.** Uncertainty is the quantification of the doubt about the measurement result.

4. RESPONSIBILITIES

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

(1) Ensuring all Department of Veterans Affairs (VA) medical facilities in their VISN implement this notice within 120 days from the day of publication (by May 17, 2020).

(2) Ensuring that all medication storage refrigerators and freezers are inspected to determine if they are of pharmaceutical grade, are continuously monitored with primary and secondary response plans and that refrigerators and freezers used to store vaccines and medications are included in routine inspections by VA medical facilities. It is especially important to determine suitability of storage prior to receipt of the influenza vaccine in September 2019. ***NOTE:*** *Any refrigerators and freezers that do not meet requirements must be replaced.*

(3) Certifying via Email to VHAPBMPharmacyOperations@va.gov that VA medical facility actions are completed no later than 120 days from the date this notice is

published (by May 17, 2020) and 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 the cost of lost medication or vaccines included.

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

(1) Implementing this VHA notice no later than 120 days after publication (by May 17, 2020).

(2) Ensuring a VA medical facility standard operating procedure (SOP) is in place to immediately detect temperature excursions, and to immediately take corrective action to prevent medication deterioration or damage. At a minimum, the SOP must:

(a) Require 24 hour-a-day, 7 day-per-week monitoring of temperature histories with a process to immediately identify temperature excursions and escalation of temperature excursion alerts to a secondary response group that will immediately move medications to suitable alternate storage location. ***NOTE:*** *In some VA medical facilities, centralized monitoring of medication refrigerators and freezers is performed by boiler plant operators or security and law enforcement staff.*

(b) Ensure that the buffered probe of the DDL is placed in the center of the unit with the vaccines and medications.

(c) Ensure that food and beverages are not stored with vaccines or medications.

(d) Define the frequency of cleaning the inside of the unit to discourage bacterial and fungal growth.

(e) Ensure that all units are plugged into a VA medical facility emergency outlet.

(f) Ensure that vaccines and medications exposed to temperature excursions are not used for patient care and are returned to Pharmacy Services for appropriate disposal if necessary, and that an Issue Brief is prepared and sent to PBM and Biomedical Engineering in VA Central Office for information or action.

(3) Ensuring a process is in place to perform and document the maintenance of the pharmaceutical grade purpose-built refrigerators or freezers as recommended by the manufacturer. The following routine maintenance tasks are required for all units:

(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. 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.

(4) Ensuring an Issue Brief is submitted through the VISN for any pharmaceutical refrigerator or freezers failures with loss of medications or vaccines itemized with cost.

c. **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 Biomedical Engineering or designee to ensure Pharmacy Services and other VA medical facility locations (e.g., Nursing Units, Research Centers) that store medications which must be refrigerated or frozen, use pharmaceutical grade purpose-built refrigerators or freezers exclusively, that these units are monitored by DDL, and that they are connected to emergency power sources.

(2) Ensuring newly installed or repaired pharmaceutical grade purpose-built 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.

d. **VA Medical Facility Chief of Biomedical Engineering.** The VA medical facility Chief of Biomedical Engineering 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 DDL with 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 uncertainty of +/-0.5 degrees Celsius.

(f) Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures no less frequently than every 30 minutes.

(g) Ability to trigger electronic alerts for temperature excursions.

(h) A current and valid Certificate of Calibration Testing.

(3) Conducting Certificate of Calibration testing every 1 to 2 years, or more frequently if recommended by the manufacturer.

(4) Evaluating the placement of the pharmaceutical grade purpose-built refrigerators or freezers to ensure the room is well ventilated, with space between the unit, ceiling, walls, the cover of the motor compartment is not blocked, and that they are connected to an emergency power source.

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

5. RESPONSIBLE OFFICE: The VHA Office of Pharmacy Benefits Management Services (10P4P) is responsible for the content of this VHA notice. Questions may be addressed to: VHAPBMPharmacyOperations@va.gov.

6. REFERENCES

a. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Vaccine Storage & Handling Toolkit. January 2018. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

b. The Joint Commission. Standards FAQ Details. Refrigerator-Design Quality. https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=959&StandardsFAQChapterId=64&ProgramId=0&ChapterId=0&IsFeatured=False&IsNew=False&Keyword.

7. RESCISSION: This VHA notice will expire and be archived as of January 31, 2021.

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

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for Health
for Policy and Planning

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