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California Department of Public Health



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TO: All Facilities

SUBJECT: Medication Safety: Storage of Medications Requiring Refrigeration

BACKGROUND: The Department of Public Health's Center for Health Care Quality Licensing and Certification Program is issuing this letter to address concerns pertaining to the safe use of medications that require refrigeration. The concerns identified have been noted throughout the state and have resulted in both licensing and federal noncompliance determinations, including Immediate Jeopardy declarations.

Failure to store medications at the appropriate temperature, as specified by the manufacturer, can have significant impact on patient care. Numerous medications have minimal tolerances for temperatures outside a relatively narrow range and once the manufacturer's established limits are breached, the product may be rendered less than optimally effective or ineffective. This is particularly true for the majority of vaccines.

In 2006, the World Health Organization published a document entitled, "Temperature Sensitivities of Vaccines." This document indicates that "More than two million deaths were averted by immunization, as well as an additional 600,000 hepatitis-B-related deaths that would otherwise have occurred in adulthood.... However, despite this, more deaths could be prevented and illnesses avoided, if vaccines which are sensitive both to excessive heat and excessive cold, were transported and stored correctly."

To ensure optimal efficacy of vaccines, it is important that careful attention be directed to the handling and storage of these products. The Department has identified a number of facilities that have stored vaccines at excessive temperatures, both heat and cold, outside manufacturers' recommended ranges. In several instances, cold sensitive vaccines were subjected to freezing temperatures for months to years prior to identification by Licensing and Certification personnel. These failures necessitated patient notification and, in some cases, revaccination of thousands of patients.

REFRIGERATION TEMPERATURE REQUIREMENTS:

The expected storage temperature range for medications requiring refrigeration is 36 to 46 degrees Fahrenheit.

This requirement is codified in California Code of Regulations (CCR) Title 22 for:

- General Acute Care Hospitals – Section 70263(q)(6)
- Acute Psychiatric Hospitals – Section 71233(q)(6)
- Skilled Nursing Facilities – Section 72357(f)
- Intermediate Care Facilities (ICF) – Section 73365(f)
- ICF/Developmentally Disabled – Section 76403(f)
- ICF/Developmentally Disabled - Habilitative – Section 76901(f)
- Primary Care Clinics – Section 75037(d)
- Psychiatric Health Facilities – Section 77079.3(f)
- Adult Day Health Centers – Section 78317(g)(6)
- Chemical Dependency Recovery Hospital – Section 79215(j)
- Correctional Treatment Center – Section 79651 (f)

For health care facilities not specifically noted above, the Department recommends that all medications requiring refrigeration be stored at a temperature between 36 and 46 degrees Fahrenheit.

PRINCIPLES OF PROPER MEDICATION STORAGE INCLUDE:

- Development and implementation of policies and procedures to ensure safe storage of medications under proper conditions (e.g., temperature, humidity, protection from light and security).
- Development and implementation of policies and procedures to identify, remove, and properly dispose of outdated, contaminated, recalled, or otherwise unusable drug products throughout the health care organization. Additionally, development and implementation of policies and procedures to ensure that any patients who may have received a contaminated, recalled or otherwise unusable drug product are quickly identified notified and evaluated for potential untoward outcome.
- Storage equipment (e.g., refrigerators, thermometers, carts and cabinets.) is maintained in accordance with standards of practice and/or manufacturer recommendations to ensure proper functioning.

- Adherence to pharmaceutical manufacturer requirements for product storage.
- An alerting system to quickly identify situations where high and low refrigerator temperature limits are exceeded. (This would also be applicable to medical devices used for warming intravenous and irrigating solutions.)
- All medication storage areas must be periodically inspected by qualified staff in accordance with facility policy, standards of practice and/or regulatory requirements to ensure that medications are safely and properly stored.
- For refrigerators used to store vaccines, the temperature should be monitored and recorded twice a day.

If you have questions, please contact Loriann De Martini, Pharm.D. Chief Pharmaceutical Consultant at 916.552.8645 or Loriann.demartini@cdph.ca.gov.

Sincerely,

Original Signed by Kathleen Billingsley, R.N.

Kathleen Billingsley, R.N.
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