

HEADS UP...

TOPIC: Medication storage according to manufacturers' recommendations

SETTING: Ambulatory Health Care (AHC) Program

Why is this important?

Findings related to medication storage (MM.03.01.01 EP2) continue to appear in the most frequently scored standards and EPs in the ambulatory health care setting. While the number of high-risk findings across accredited organizations is not large, the potential for harm associated with inappropriate medication storage can be high. Organizations are encouraged to review their processes for medication storage and ensure their practices and processes are in alignment with the manufacturers' recommendations.

Scope of the Problem:

Time period: **January 1, 2021 through July 31, 2021**

Number of full surveys performed: **417**

Number of surveys with moderate to high-risk findings for MM.03.01.01 EP 2: **35 (8%)**

Relevant standard/EP: MM.03.01.01 The organization safely stores medications. **EP 2** The organization stores medications according to the manufacturers' recommendations. Note: This element of performance is also applicable to sample medications.

Sample survey observations [from surveyor notes] and contributing factors

Sample observations:

- Saline, IV Fluids, IV contrast stored at temperature greater than manufacturer's recommendation.
- Succinylcholine stored at room temperature for 60 days when package insert says 14 days.
- Inspection of the medication refrigerators revealed that although temperatures were being monitored each day the facility was open, staff had not been assessing if temperatures had been maintained within the range recommended by the manufacturer (36-46 degrees F) during hours when the facility was closed, for example, holidays and weekends.
- Vaccines via the Children's Vaccination Program were observed stored in a dormitory-style refrigerator.
- Manufacturer recommendations for medication stored in the mobile van stated to store at room temperature. The van's thermostat reflected a room temperature of 86 degrees.
- Observed that dental anesthetic cartridges were not stored according to manufacturer's instructions for use, cartridges were exposed to light and not stored in the original container.

Potential contributing factors:

- Leadership failed to ensure appropriate staff had access to manufacturer's instructions for use.
- Unclear staff roles and responsibilities.
- Lack of temperature documentation (lack of tracking logs).
- Lack of staff education regarding the monitoring of the med fridge temperature and whether or not the range was within manufacturer guidelines.
- Leadership failed to ensure the proper data related to temperatures was being recorded.

How to identify potential problems in your organization

Review your policies and procedures

- Does the organization have a written medication management policy and procedure? Does it also refer to sample medications?
- Does the organization have clearly defined policies and procedures to ensure the safe storage, security and management of medications?
 - Does this policy and procedure include information regarding the proper storage of medication based on the manufacturers' recommendations?
- How does your organization ensure your contracted pharmacy services comply with your expectations regarding medication storage (i.e., monitoring compliance with manufacturer guidance for medication storage in the clinics)?

Interview staff (e.g., clinicians and support staff)

- Are staff aware of their responsibilities related to the storage of medication?
- Staff can describe proper and safe medication storage procedures (including labeling and following manufacturer's guidelines).
- Staff know the appropriate temperature ranges for medication refrigerators and what to do if temperature are noted to be out of range. Staff demonstrate procedure for appropriate documentation on monitoring logs.
- Is education/training regarding the safe storage of medications provided to staff?

Assess your environment

- How does your organization ensure that all medication is correctly stored (including sample medications)?
- How does the organization ensure that medications are stored per manufacturer's recommendations? Per organization's policies?
- Are the manufacturer's instructions readily available and accessible for medications?
- Do you have a safety culture that supports personnel reporting issues with medication management and storage?
- Where applicable, examine the pre-procedure, procedure, and post-procedure recovery areas (including medication and crash carts) to ensure proper labeling and storage of medication. Check treatment trays that contain medications as well.
- Review a sample of medication refrigerator logs for completeness. Are there instances where the temperature was out of range? Were appropriate follow-up actions taken?

Evaluate implementation

- Does the organization monitor and collect data on medication errors related to medication orders?
- Is there a clearly defined auditing system to monitor that medications are being stored properly and in alignment with manufacturer instructions?
 - How frequently are medications being audited? How are these audits documented?
 - Who is responsible for monitoring logs of medication checks?

What are some resources can assist me in mitigating risks in these areas?

- CDC. [Vaccine Storage and Handling Toolkit](#)
- The Joint Commission. [Medication Storage – Utilizing Literature to Extend Expiration Dating](#)
- [Institute for Safe Medication Practices \(ISMP\)](#)