
MM.9 The hospital has a system for procurement of medications that are not on the hospital's formulary (non-formulary medications).

- MM.9.1 There is a policy and procedure for selection, approval, and procurement of non-formulary medications within an acceptable time frame.
 - MM.9.2 A patient-specific non-formulary drug request form is readily available.
 - MM.9.3 There is proper handling of non-formulary drug requisition within an acceptable time frame.
 - MM.9.4 There is a regular review of non-formulary drug requests by the pharmacy and therapeutics committee or an equivalent multidisciplinary body.
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Standard Intent:

Occasionally, hospitals may encounter some clinical conditions where formulary medication(s) are ineffective or may be contraindicated. Treating physician may also believe it is appropriate to continue therapy for a patient who had been stabilized on a non-formulary medication before admission to hospital and where changing to another medication is considered detrimental. Hospitals should establish a process for procurement of patient specific non-formulary medications within an acceptable time frame. A register of all non-formulary medication requests should be kept by the pharmacy and periodically reviewed by the pharmacy and therapeutics committee to evaluate prescribers' adherence to the formulary list and to help in deciding whether or not to add drugs onto the formulary.

MM.10 The hospital has a system for handling out of stock, shortage and disaster needs of medications.

- MM.10.1 The hospital implements a policy and procedure on proper communication of medication shortage and outage to prescribers and other healthcare professionals involved in medication management and obtaining medications in the event of a disaster.
 - MM.10.2 The pharmacy and therapeutics committee develops and approves medication substitution protocols in the event of medication shortage or outage.
 - MM.10.3 There is implementation of the hospital approved medication substitution protocols and staff awareness.
 - MM.10.4 There is a plan for emergency preparedness to respond to the special and large demand of medications during internal and external disasters. The plan is tested for effectiveness and integrated with the general hospital plan.
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Standard Intent:

Hospitals are experiencing a rapidly increasing frequency of drug shortages, which have caused numerous difficulties for clinicians and patients. Drug shortages are caused by many factors and adversely affect patient care. Management strategies need to be developed for handling out-of-stock medications to ensure continuity of patient care. This includes timely communication with clinicians, development and approval of

medication substitution protocols by the pharmacy and therapeutics committee. Any hospital emergency preparedness plan should take in consideration the special and large demand of medications during internal and external disasters.

MM.11 The hospital has a safe and secure system for the storage of regular medications and nutrition products in stores, pharmacies, and patient care areas.

- MM.11.1 There is a policy and procedure on proper storage and control of medications, nutrition products, and free medical samples (from the point of receipt until the point of administration).
- MM.11.2 There is a policy and procedure to control the access of pharmaceutical care and non-pharmaceutical care staff to stores, pharmacies, and patient care areas including after hours and in case of emergency (e.g., fire, flood).
- MM.11.3 There are measures in place to secure medications storage areas including limited access, proper locking procedures, and door keys handling.
- MM.11.4 Only authorized individuals have access to stored medications.
- MM.11.5 Medications are stored in a way to avoid mixing with labels showing the drug name and expiry date.
- MM.11.6 No medications are stored directly on floor (a minimum of ten centimeters is left to manage spills). Medications are not stacked so high to block sprinklers or come in contact with overhead lights or pipes.
- MM.11.7 Medications are stored according to manufacturer's recommendations (temperature, light, humidity, sanitation).
- MM.11.8 There is an appropriate storage area for regular medications with controlled temperature (between 18 and 25 degrees centigrade), twenty-four hours a day, seven days a week.
- MM.11.9 The room air temperature is checked and documented at least once daily on the temperature log sheet.
- MM.11.10 Temperature records are kept for at least three years.
- MM.11.11 All antiseptics, disinfectants, and medications for external use are stored separately from enteral and injectable medications.
- MM.11.12 The "first expiry/ first out" (FEFO) principle is followed.
- MM.11.13 All medication storage areas are inspected at least monthly by the pharmaceutical care according to the hospital policy to ensure proper storage of medications. Inspection includes, but is not limited to: availability, stock level, expiry date, and storage conditions.
- MM.11.14 Expired and damaged medications are clearly labeled and separated from other drugs until its removal and proper destruction.
- MM.11.15 Medication quality issues are reported to the Saudi FDA, as required.