



SE11

MEDICATION MANAGEMENT

The healthcare facility optimizes medication management by adhering to strict protocols throughout the healthcare facility. E.g. the healthcare facility procures medication through approved suppliers only and keeps stock in a temperature controlled room to ensure correct storage conditions. Access to medication throughout the healthcare facility is controlled, and stock levels for essential drugs are in line with utilization rates. Medication is prescribed by authorized staff only, in accordance with clinical guidelines and prior to administering or dispensing medication, the identity of patients is verified, and prescriptions are crosschecked for contraindications. All dispensed medication is adequately labelled, patients receive clear instructions for use, and are educated on recognizing side effects. Patients and medical staff monitor the response to treatment and when applicable, the dosage or type of medication is adjusted.

The SafeCare standards cover the full range of clinical services and management functions for healthcare facilities in 13 Service Elements. These Service Elements contain a number of standards that relate to specific services or functions. The rationale of each standard is explained by the standard intent and gives you an idea what the standard really entails.

Each standard contains measurable elements, also called criteria. Measurable elements are related to specific processes, assets or documents (e.g. process for triage, resuscitation equipment or a job description for the lab manager). Compliance to each measurable element is assessed, and scores awarded are either Fully Compliant (FC), Partially Compliant (PC), Non-Compliant (NC) or Not Applicable (NA). The combined scores of the underlying measurable elements reflect the level of compliance to the whole standard.

11.1 MANAGEMENT AND STAFFING

11.1.1 Medication use is managed and organized to enable safe service delivery to meet the patient needs, complies with applicable laws and regulations and is under the direction of a qualified individual.

STANDARD INTENT:

Medications, as an important resource in patient care, must be organized effectively and efficiently. Medication management is not only the responsibility of the pharmaceutical service but also of managers and healthcare practitioners. How this responsibility is shared depends on the healthcare facility's structure and staffing. In those cases in which a pharmacy is not present, medications may be managed on each clinical unit according to healthcare facility policy. In other cases, where there is



a central pharmacy, the pharmacy may organize and control medications throughout the healthcare facility.

Effective medication management includes all parts of the healthcare facility, inpatient, outpatient, and specialized units if applicable. In all cases, a qualified individual directly supervises the activities of the pharmacy or medication service. The individual is trained and, if required, appropriately licensed and/or certified. Applicable laws and regulations are incorporated into the organizational structure and the operations of the medication management system used in the healthcare facility.

A healthcare facility should develop policies and procedures to guide processes regarding medication management:

- safe prescribing, ordering and administering medications in the healthcare facility;*
- scope and limitations to the responsibilities and activities of the staff who handle medication documentation requirements;*
- the use of non-written medication orders;*
- the availability and use of medication samples;*
- documentation and management of any medications, brought into the healthcare facility for or by the patient;*
- self-administration of medication by the patient;*
- dispensing of medications at the time of the patient's discharge;*
- preparing, handling, storing and distributing parenteral and enteral nutrition products;*
- storing, handling, distributing and dispensing hazardous medications; and*
- the security of staff, equipment and stock.*

Meetings about medication management should be kept regularly but are dependent on the size of the healthcare facility and the number of staff and activities. Weekly meetings are preferred and records should be kept of the meetings held.

MEASURABLE ELEMENTS:

11.1.1.1 A designated, licensed individual directly supervises the activities of the pharmacy or pharmaceutical service.

11.1.1.2 Job descriptions clearly define scope and limitations to the responsibilities and activities of the staff who manage medications.



- 11.1.1.3 A written document identifies how medication use is organized and managed throughout the healthcare facility in keeping with applicable laws, regulations and professional practices.
- 11.1.1.4 Key members of staff regularly meet to discuss medication management.

11.2
STOCK SELECTION
AND PROCUREMENT

11.2.1 An appropriate selection of medications are in continuous supply or readily accessible at all times.

STANDARD INTENT:

Each healthcare facility must decide which medications to make available for prescribing and ordering by the healthcare practitioners. This decision is based on the healthcare facility's mission, patient needs, and types of services provided. The healthcare facility develops a list (often referred to as a formulary) of all the medications it stocks or that are readily available from outside sources. In some cases, laws and regulations may determine the medications on the list or the source of those medications. Medication selection is a collaborative process that includes practitioner needs, patient needs, safe medication practices as well as economic parameters. Medications are occasionally out of stock due to delayed delivery, national shortages, or other reasons not anticipated through normal inventory control. When medications are out of stock the practitioners are notified and alternatives recommended.

On occasion, medications are needed which are not stocked or readily available to the healthcare facility. The healthcare facility must have a process to approve and procure such medications. Also, there are occasions when medications are needed during the night or when the pharmacy is closed. Each healthcare facility needs to plan for these occurrences and educate staff on procedures to follow in the event they occur.

MEASURABLE ELEMENTS:

- 11.2.1.1 Medications are available to meet patient needs and alternatives when medications are out of stock.
- 11.2.1.2 There is an up to date list of medications that are kept in stock.
- 11.2.1.3 There is a (manual or automated) stock management system to ensure that minimum and maximum stock levels are maintained.
- 11.2.1.4 There is a process for healthcare workers to obtain medicines within the healthcare facility during the night or when the pharmacy is closed.



11.2.2 Medications are procured according to guidelines that ensure safety and effectiveness.

STANDARD INTENT:

The medication procurement process must be carefully followed to ensure that medicines remain in good condition so that they will be most effective. In order to ensure that medications are not substituted with counterfeit products, damaged or tampered with during procurement and transportation, the healthcare facility should work with a set of approved suppliers that understand the importance of maintaining the security of medicines at the appropriate temperature. When medications or medical devices are recalled by the manufacturer (supplier), it is important to remove these materials from circulation as soon as possible.

MEASURABLE ELEMENTS:

- 11.2.2.1** A procurement guideline is available and conforms to country-specific requirements regarding a secure supply chain, and regarding specific agents and preferred/approved suppliers.
- 11.2.2.2** Where healthcare facility staff transports procured medications themselves, they are guided to ensure this is done according to manufacturers' instructions.
- 11.2.2.3** There is a system which allows for effective recalling of drugs and medical devices (e.g. laboratory kits) distributed in the healthcare facility when required.
- 11.2.2.4** The medication supply chain is monitored and there is evidence that the medication is procured at preferred, low risk, suppliers.

**11.3
CONTROL
AND STORAGE
OF MEDICATION**

11.3.1 Adequate storage area(s) and equipment are available for the safe and effective storage of medications (including medical consumables).

STANDARD INTENT:

Medications may be stored within a storage area, in a pharmacy or pharmaceutical service, or on the patient care units in unit pharmacies or the nursing station in the clinical unit. In all locations where medications are stored, the healthcare facilities must ensure that stored medications everywhere:



- *Can be accessed efficiently;*
- *Are protected from loss, misuse or theft;*
- *Are stored under conditions suitable for product stability.*

MEASURABLE ELEMENTS:

- 11.3.1.1** The main storage area is protected from heat and light and the temperature is monitored and effectively regulated.
- 11.3.1.2** Medications are stored in a lockable storage area or cabinet, which is accessible only to authorized staff.
- 11.3.1.3** The size and layout of the storage area(s) is appropriate for the services provided and is well ventilated.
- 11.3.1.4** Where necessary, a dedicated refrigerator for medication is available and the temperature is monitored.

11.3.2 Hazardous and controlled medications are properly stored and are properly labelled.

STANDARD INTENT:

The healthcare facility needs to ensure that:

- *controlled substances are accurately accounted for according to applicable laws and regulations;*
- *medications and chemicals used to prepare medications are accurately labelled with contents, expirations dates, and warnings;*
- *expirations dates are regularly checked;*
- *hazardous and flammable materials are stored in dedicated and clearly labelled storage areas according to specifications.*

Expiry dates need to be checked. When there is a digital system in place these checks can be performed by the IT system because all the dates of expiry are entered in the system. When there is a manual bin card system this should preferably be performed daily or weekly. Administration records of this process should be kept accordingly.

MEASURABLE ELEMENTS:

- 11.3.2.1** Medications are labelled with essential information according to national regulations.



- 11.3.2.2 Where DDA (dangerous drug act) medication is available these are clearly labelled and controlled.
- 11.3.2.3 Hazardous and flammable materials are clearly labelled and stored appropriately.
- 11.3.2.4 All pharmaceuticals, vaccines or medical consumables are regularly checked for expiry dates and checks are recorded.

**11.4
PRESCRIBING
AND DISPENSING
OF MEDICATION**

11.4.1 Medications are prescribed in a safe and controlled manner.

STANDARD INTENT:

Selecting a medication to treat a patient requires specific knowledge and experience. The healthcare facility identifies those individuals with the appropriate knowledge and experience and who are also permitted by licensure, certification, laws or regulations to prescribe or order medications.

Safe prescribing and ordering of medication is guided by healthcare facility policies and procedures. To improve patient safety, the healthcare facility defines the required elements of a complete order or prescription (both written and verbal). Verbal orders are written down and verified with the prescriber.

MEASURABLE ELEMENTS:

- 11.4.1.1 Prescriptions contain all relevant information according to the national guidelines.
 - 11.4.1.2 The healthcare facility has identified those staff members that are authorized to prescribe medication.
 - 11.4.1.3 Prescription pads and order books are accessible to authorized persons only.
 - 11.4.1.4 When verbal/telephonic medication orders are used, they are written down and verified according to legislation and/or healthcare facility policy.
- 11.4.2 The healthcare facility dispenses medications in a safe and controlled environment and according to patient needs.**



STANDARD INTENT:

The organization dispenses medications in a clean and safe environment and in a way that complies with laws, regulations and professional practice standards. The healthcare facility takes patient confidentiality and needs into account during the dispensing process. This includes adequate privacy in the dispensing area and secure storage of prescriptions. In the dispensing process staff informs the patient of available generic equivalents, if available.

MEASURABLE ELEMENTS:

- 11.4.2.1** There is a clean, well ventilated, designated area with good lighting for preparing and dispensing medication.
- 11.4.2.2** The dispensing area is adequately furnished and allows for privacy for patients.
- 11.4.2.3** Prescriptions are securely stored to protect patient confidentiality and avoid abuse.
- 11.4.2.4** Dispensing staff informs the patient of available generic equivalents.

- 11.4.3** **A system is used to dispense the correct medication in the right dose to the right patient.**

STANDARD INTENT:

All medication distribution points throughout the healthcare facility (inpatient and outpatient) use the same system for preparing and dispensing medications. The healthcare facility dispenses medications in the most ready to administer form possible to minimize opportunities for error during dispensing, distribution and administration. When a medication is removed from its original packaging and not immediately administered, the medication must be labelled with name, dosage, date of preparation and expiration. Instruction for use is provided. The system supports accurate dispensing of medications in a timely manner.

MEASURABLE ELEMENTS:

- 11.4.3.1** Medications dispensed are clearly labelled with the name of the medication, dose, name of the patient, date and instruction for use.
- 11.4.3.2** There is a uniform medication dispensing and distribution system in the healthcare facility that supports accurate and timely dispensing.



11.4.3.3 A standard operating procedure (SOP) guides dispensing staff to check and review written instructions of a designated healthcare worker for drug dispensing.

11.4.3.4 Dispensing staff has quick access to patient information to check for allergies or contra-indications for particular medications.

**11.5
ADMINISTRATION
OF MEDICATION**

11.5.1 There is a mechanism for facilitating communication between the doctor and pharmacy regarding drug reactions.

STANDARD INTENT:

When medicines are administered within a healthcare facility, it is important that the staff monitors this process closely in order to ensure that the medicine is having a positive effect and not causing any allergic or adverse drug reactions. If the medication dosage needs adjustment, or if multiple medications are causing a drug-interaction, these must be documented in a timely manner. Documentation of adverse drug reactions and medication errors protects patients and also identify opportunities to make medication management safer for all patients in the healthcare facility.

MEASURABLE ELEMENTS:

11.5.1.1 Staff is guided in recording and reporting of medication errors or adverse drug reactions.

11.5.1.2 Adverse drug reactions are recorded and reported in accordance to healthcare facility policy.

11.5.1.3 Adverse drug reactions and medication errors are discussed in medical meetings.

11.5.1.4 There is evidence that active follow up is performed in relation to adverse drug reactions and medication errors.