



BOTSWANA NATIONAL HEALTH QUALITY STANDARDS FOR CLINICS

11. Medication Management

These forms are designed to be used by both hospital personnel and external surveyors. The following information must be provided after each survey, before submitting the completed survey forms.

1. NAME OF HOSPITAL/CLINIC/FACILITY: _____

2. BASELINE/INTERNAL SURVEY INFORMATION:

Title and name of person who completed this document: _____

Post and position held: _____

Date of survey: _____

3. EXTERNAL SURVEY INFORMATION:

Name of external surveyor: _____

Date of external survey: _____

GUIDE TO COMPLETION OF FORM

N.B. Hospital staff are please to use BLACK ink at all times. The external surveyors are requested to use RED ink at all times.

Please circle the rated compliance with the criterion, e.g. NA (Not applicable), NC (Non-compliant), PC (Partially compliant), C (Compliant).

The default category affected is designated on the form for each criterion as follows:

1. patient and staff safety
2. legality
3. patient care
4. efficiency
5. structure
6. basic management
7. basic process
8. evaluation

The seriousness of the default is designated on the form for each criterion as follows:

1. mild
2. moderate
3. serious
4. very serious

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| <p><u>Documents Checked</u></p> <p>Surveyor:</p> <p>Surveyor:</p> |
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11.1 Management of the Service

11.1.1 Standard

Medication use is organised throughout the facility to meet the needs of patients.

Standard Intent: As an important resource in patient care, the use of medication is managed effectively and efficiently throughout the organisation.

Applicable laws and regulations are incorporated into the organisational structure and the operations of the medication management system used in the organisation.

Where the organisation dispenses medication it must be an approved licensed site with the relevant personnel having approved licences issued for that site in accordance with national legislation.

A registered pharmacist directly supervises the activities of the pharmacy or pharmaceutical service.

| | Criterion | Comments |
|--|---|-----------------|
| | | Recommendations |
| Criterion 11.1.1.1 Critical: .. Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | A designated individual, who is suitably qualified, has clearly defined responsibilities and accountability for all aspects of the pharmaceutical service. | |
| Criterion 11.1.1.2 Critical: .. Catg: Basic Process + Legality Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Individuals who dispense medications act in accordance with legislation affecting pharmacy practice and current pharmaceutical, medical and nursing guidelines. | |
| Criterion 11.1.1.3 Critical: .. Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | The scope of and limitations to the responsibilities and activities of the personnel who manage medications are clearly defined. | |



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| Criterion 11.1.1.4 | The pharmaceutical service is coordinated with other related services within the health facility. | |
| Critical: .. | | |
| Catg: Basic Process + Efficiency | | |
| Compliance | | |
| NA NC PC C | | |
| Default Severity for NC or PC = 4 Very Serious | | |

11.2 Facilities and Equipment

11.2.1 Standard

Adequate facilities are available for the safe storage and dispensing of medications.

Standard Intent: Secure storage systems ensure that pharmaceuticals and related substances are held under conditions that conform to statutory requirements and the manufacturer's requirements.

There are arrangements for ensuring the security of medicines, including alarm systems, door access controls, and safes/vaults for storing controlled medicines.

Medications stored and dispensed from areas outside the pharmacy, for example patient care units, comply with the same safety measures.

There is a register, log or other mechanism to monitor and account for controlled substances.

Deep freeze, refrigeration, cold room and cool area facilities are provided for safe storage of certain medications. There is a mechanism for ensuring that the correct temperature is maintained throughout the life of the medications. Deep freezers and refrigerators are defrosted when necessary. Doors, hinges and seals are all functional.

| | Criterion | Comments |
|--|---|-----------------|
| | | Recommendations |
| Criterion 11.2.1.1 | The design and layout of the pharmacy must permit a logical, safe flow of work, adequate storage space, effective communication and supervision and must ensure effective cleaning and maintenance. | |
| Critical: .. | | |
| Catg: Basic Management + Physical Struct | | |
| Compliance | | |
| NA NC PC C | | |
| Default Severity for NC or PC = 3 Serious | | |
| Criterion 11.2.1.2 | Secure facilities for the storage of medications include, but are not limited to, lockable storage facilities, ceiling cages, burglar guards and alarm systems with keypads. | |
| Critical: .. | | |
| Catg: Basic Management + Physical Struct | | |
| Compliance | | |
| NA NC PC C | | |
| Default Severity for NC or PC = 3 Serious | | |



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| Criterion 11.2.1.3 Critical: '' Catg: Basic Management + Physical Struct Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | The storage area is easily accessible from the dispensing room. | |
| Criterion 11.2.1.4 Critical: '' Catg: Basic Management + Physical Struct Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | Medication storage areas are protected from heat and light and are effectively ventilated. | |
| Criterion 11.2.1.5 Critical: '' Catg: Basic Management + Physical Struct Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | A dedicated refrigerator is available for those medications requiring storage at low temperatures. | |
| Criterion 11.2.1.6 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | A monitoring log is kept of the refrigerator temperature. | |
| Criterion 11.2.1.7 Critical: '' Catg: Basic Management + Physical Struct Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | The work bench for preparing medicines for dispensing should be clean, tidy and well organised. | |



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| Criterion 11.2.1.8 | The area where medicines are dispensed to the patients is easily accessible, adequately furnished and allows for reasonable privacy when advice is given. | |
| Critical: .. | | |
| Catg: Basic Management + Physical Struct | | |
| Compliance | | |
| NA NC PC C | | |
| Default Severity for NC or PC = 3 Serious | | |



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11.3 Policies and Procedures

11.3.1 Standard

There is a collaborative effort to develop and monitor policies and procedures for the pharmaceutical service.

Standard Intent: Safe pharmaceutical practices are guided by organisational policies and procedures. Medical, nursing, pharmacy and administrative personnel participate in a collaborative process to develop and monitor the policies and procedures.

The clinical and managerial leaders use a collaborative process to develop policies and procedures and train the personnel to implement them correctly.

It is particularly important that the policies or procedures indicate:

- how planning will occur
- the documentation required for the care team to work effectively
- special consent considerations
- monitoring requirements
- special qualifications or skills of personnel involved in the care process, and
- the availability and use of resuscitation equipment, e.g. the relevant medication.

Clinical guidelines are frequently helpful and may be incorporated in the process. Monitoring provides the information required to ensure that the policies and procedures are adequately implemented and followed for all relevant patients and services.

Policies and procedures should focus on high risk procedures, for example:

- a) safe prescribing, ordering, transcribing and administering medications in the organisation
- b) documentation requirements
- c) the use of verbal medication orders
- d) the availability and use of medication samples
- e) documentation and management of any medications brought into the organisation for or by the patient
- f) self-administration of medication by the patient
- g) dispensing of medications at the time of the patient's discharge, and
- h) the security of staff, equipment and stock.

| | Criterion | Comments |
|---|--|-----------------|
| | | Recommendations |
| Criterion 11.3.1.1 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | Policies and procedures are developed and implemented for identified processes, which include at least those from a) to h) in the intent above. | |
| Criterion 11.3.1.2 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | Policies and procedures are implemented to ensure that medications are procured according to national guidelines regarding specific agents and approved suppliers. | |



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| Criterion 11.3.1.3 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | Policies and procedures are implemented to ensure that medications are transported to the facility in accordance with manufacturers' guidelines, with specific emphasis on maintaining cold chain requirements. | |
| Criterion 11.3.1.4 Critical: '' Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Policies and procedures are implemented to ensure that medications are dispensed on the written instructions/prescription of a designated healthcare worker who is qualified and/or experienced in their use. | |



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11.4 Access to Appropriate Medication

11.4.1 Standard

An appropriate selection of medications for prescribing or ordering is stocked or readily available.

Standard Intent: Every organisation must decide which medications to make available for prescribing and ordering by the care providers. This decision is based on the organisation's mission, patient needs and the types of services provided. The organisation develops a list of all the medications it stocks or that are readily available from outside sources. In some cases, laws or regulations may determine the medications on the list or the source of those medications. Medication selection is a collaborative process, which considers patient needs and safety as well as economics. The organisation has a method, such as a committee, for monitoring and maintaining this medication list and for monitoring the use of medication within the organisation.

Managing medication use in an organisation requires an understanding of the sources and uses of medications not prescribed or ordered within the organisation.

On occasion, medications not readily available to the organisation are needed. There are also occasions where medications are needed at times when pharmacies are closed. Each organisation needs to plan for these situations and to educate the personnel regarding the procedures to follow should they occur. When patient emergencies occur, quick access to appropriate emergency medications is critical. Each organisation plans the location of emergency medications and the medications to be supplied in these locations. To ensure access to emergency medications when needed, the organisation establishes a procedure or process to prevent theft or loss of the medications and to ensure that medications are replaced when used or when damaged or out of date. Each organisation also needs to determine its role in providing medications to patients at discharge. Those who prescribe or order medication know what medications, if any, are available and how to obtain them.

| | Criterion | Comments |
|---|---|-----------------|
| | | Recommendations |
| Criterion 11.4.1.1 Critical: '' Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | There is a list of the medications stocked in the organisation or readily available from outside sources. | |
| Criterion 11.4.1.2 Critical: '' Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Priority essential drugs are in stock. | |



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| Criterion 11.4.1.3 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | There is a process for obtaining required medications that are not stocked or normally available to the organisation. | |
| Criterion 11.4.1.4 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | There is a process for healthcare workers to obtain medicines within the facility when the pharmacy is closed. | |
| Criterion 11.4.1.5 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | There is a list of medications available in the emergency cupboard, where relevant. | |
| Criterion 11.4.1.6 Critical: '' Catg: Basic Process + Pat & Staff Safety Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | There is a system for recalling drugs, when required. | |



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11.5 Control and Storage of Medication

11.5.1 Standard

Medications are stored in a secure and clean environment.

Standard Intent: The pharmacy or pharmaceutical service stores and dispenses medications in a clean and secure environment, which complies with laws, regulations and professional practice standards. In particular, medications are clearly labelled, which includes the following:

- generic name and strength of medicine
- dose, frequency and duration of course
- date of dispensing and expiry date
- name of patient
- name/address of supplier
- child safety warning
- batch number.

Medications stored and dispensed from areas outside the pharmacy, for example patient care units, comply with the same safety measures.

There is a registry, log or other mechanism for monitoring and accounting for controlled substances.

| | Criterion | Comments |
|--|---|-----------------|
| Criterion 11.5.1.1 Critical: '' Catg: Basic Process + Physical Struct Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Medications are stored in a locked storage device or cabinet, which is accessible only to authorised personnel. | Recommendations |
| Criterion 11.5.1.2 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | There is a system for ensuring that maximum and minimum stock levels are maintained. | |
| Criterion 11.5.1.3 Critical: '' Catg: Basic Process + Pat & Staff Safety Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Medications are legibly marked and securely labelled. | |



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| Criterion 11.5.1.4 Critical: .. Catg: Basic Process + Physical Struct Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Medications controlled by law or organisational policy are stored in a cabinet of substantial construction, for which only authorised personnel have the keys. | |
| Criterion 11.5.1.5 Critical: 0 Catg: Basic Process + Legality Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Medications controlled by law or organisational policy are accurately accounted for in a specific register. | |
| Criterion 11.5.1.6 Critical: .. Catg: Basic Process + Pat & Staff Safety Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Hazardous and flammable materials are stored in accordance with relevant regulations. | |
| Criterion 11.5.1.7 Critical: .. Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | All pharmaceuticals, vaccines or medical consumables are regularly checked for expiry dates and checks are recorded. | |
| Criterion 11.5.1.8 Critical: .. Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | An inventory management system, manual (stock cards) or automated, is in place and functioning appropriately, e.g. to monitor and control stock losses. under quarantine, e.g. expired stock, compounded products. | |



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| Criterion 11.5.1.9 | Separate designated storage areas are provided for materials | |
| Critical: '' | | |
| Catg: Basic Management + Physical Struct | | |
| Compliance | | |
| NA NC PC C | | |
| Default Severity for NC or PC = 3 Serious | | |

11.6 Prescribing of Medication

11.6.1 Standard

There is a process to ensure the safe and legal prescribing of medication.

| | Criterion | Comments |
|---|--|-----------------|
| | | Recommendations |
| Criterion 11.6.1.1 | Only those permitted by national laws and regulations prescribe medication. | |
| Critical: '' | | |
| Catg: Basic Process + Legality | | |
| Compliance | | |
| NA NC PC C | | |
| Default Severity for NC or PC = 4 Very Serious | | |
| Criterion 11.6.1.2 | Prescriptions conform to legal requirements. | |
| Critical: '' | | |
| Catg: Basic Process + Legality | | |
| Compliance | | |
| NA NC PC C | | |
| Default Severity for NC or PC = 4 Very Serious | | |
| Criterion 11.6.1.3 | Prescription pads and order books are accessible to authorised persons only. | |
| Critical: '' | | |
| Catg: Basic Process + Efficiency | | |
| Compliance | | |
| NA NC PC C | | |
| Default Severity for NC or PC = 3 Serious | | |



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| Criterion 11.6.1.4 Critical: .. Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | There is a process for placing limits, when appropriate, on the prescribing or ordering practices of individuals. | |
| Criterion 11.6.1.5 Critical: .. Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | The use of verbal/telephonic medication orders is documented. | |

11.7 Dispensing Medication

11.7.1 Standard

The organisation adheres to laws, regulations and professional standards of practice when dispensing medications.

Standard Intent: A registered pharmacist reviews each prescription or order for medication. When questions arise, the individual who prescribed or ordered the medication is contacted.

The dispenser signs the prescription. When a pharmacy technician or interns dispense, they are supervised and their signatures, as dispensers, are countersigned by a registered pharmacist.

The organisation dispenses medications in the most ready-to-administer form possible, to minimise opportunities for error during distribution and administration. The central pharmacy and other medication distribution points throughout the organisation use the same system. The system supports accurate dispensing of medications in a timely manner.

| | Criterion | Comments |
|--|---|-----------------|
| | | Recommendations |
| Criterion 11.7.1.1 Critical: .. Catg: Basic Process + Legality Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Pharmacy personnel act in accordance with legislation and current pharmaceutical, medical and nursing guidelines. | |



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|---|---|--|
| Criterion 11.7.1.2 Critical: '' Catg: Basic Process + Pat & Staff Safety Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | Medications are prepared and dispensed in a safe and clean environment. | |
| Criterion 11.7.1.3 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | There is a uniform medication dispensing and distribution system in the organisation. | |
| Criterion 11.7.1.4 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | The system supports accurate and timely dispensing. | |
| Criterion 11.7.1.5 Critical: '' Catg: Basic Process + Pat & Staff Safety Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Medications are securely and legibly labelled with relevant information as required by organisational policy. | |
| Criterion 11.7.1.6 Critical: '' Catg: Basic Process + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | A register is maintained of all medicines dispensed. | |



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| Criterion 11.7.1.7 Critical: '' Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | The person prescribing and dispensing the medicine has access to patient information that would contra-indicate particular medicines. | |
| Criterion 11.7.1.8 Critical: '' Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | The person dispensing the medicine informs the patient of available generic equivalents. | |
| Criterion 11.7.1.9 Critical: '' Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | There is a mechanism for facilitating communication between the prescriber and the pharmacy regarding drug reactions. | |
| Criterion 11.7.1.10 Critical: '' Catg: Basic Process + Legality Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Prescriptions are securely stored in accordance with legislation or organisational policy. | |



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11.8 Administration of Medication

11.8.1 Standard

Medications are administered in a manner that ensures safety and effectiveness.

| | Criterion | Comments |
|--|---|-----------------|
| | | Recommendations |
| Criterion 11.8.1.1 Critical: '' Catg: Basic Process + Legality Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Only those permitted by national laws and regulations administer medications. | |
| Criterion 11.8.1.2 Critical: <input type="checkbox"/> Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Medications are verified against the prescription or order, including the dosage and route of administration. | |
| Criterion 11.8.1.3 Critical: '' Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Patients are identified before medications are administered. | |
| Criterion 11.8.1.4 Critical: '' Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | Medications are administered as prescribed. | |
| Criterion 11.8.1.5 Critical: '' Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 3 Serious | The therapeutic results of medication are monitored. | |



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| Criterion 11.8.1.6 Critical: '' Catg: Basic Process + Patient Care Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Adverse drug reactions are observed, monitored and reported. | |
| Criterion 11.8.1.7 Critical: '' Catg: Basic Process + Pat & Staff Safety Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious | Medication errors are reported in accordance with policy. | |