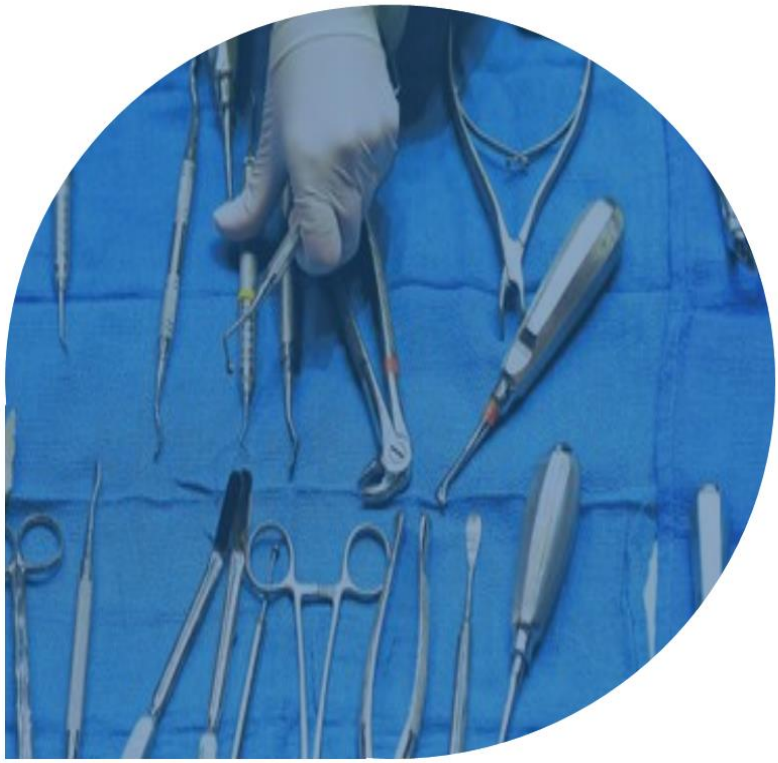
OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care



Pharmacy

v1.2

# Regulatory Private Acute Hospital Inspection tool

# Official Sign-Off

The National Health Act, 2003 (Act No. 61 of 2003) provides for quality requirements and standards in respect of health services provided by health establishments to the public. The main objective is to promote and protect the health and safety of the users of health services and contribute to improved outcomes and improved population health.

To achieve this mandate, standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Private Acute Hospitals.

**Acknowledgements**

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- The WHO technical team for providing guidance on the very first draft inspection tools database
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- Former Health Standards Development and Training unit Director Dr Grace Labadarios
- Systems, Data Analysis and Research unit Director Dr Thabiso Makola who is also the Acting Director for Health Standards Development and Training unit
- The Health Standards Development and Training unit (Mr Jabu Nkambule who led the team and worked tirelessly with the leadership of Hospital Association of South Africa (HASA) during various development stages of the tool, Ms Florina Mokoena, Ms Mosehle Matlala, Ms Busisiwe Mashinini) and contract workers Ms Thresia Pather and Ms Busi Ngubane for the development of the Private Acute Hospital Inspection tools.
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- Provincial Department of Health private hospital licensing units' personnel (Ms Pinki Belot - Free State Province, Ms Dimakatso Moeketsi and Ms Zandile Nzuza - Kwa-Zulu Natal -Province, Ms Kim Jacobs - Western Cape Province, Ms Bulelwa Peter - Eastern Cape Province, Ms Pakama Nqadala
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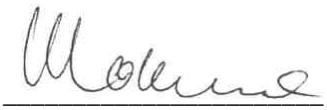
- The Certification and Enforcement Committee of the OHSC Board for reviewing the tools and for recommending to the Board for approval.
- The Hospital Association of South Africa (HASA) for their commitment and constructive engagements during the consultative process and for affording the OHSC an opportunity to conduct scoping visits in the private hospital health establishments.

It is hereby certified that these Regulatory Private Acute Hospital Inspection tools version 1.2 was developed by the Office of Health Standards Compliance.



Ms. W Moleko
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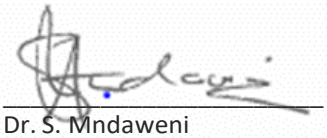

Dr. S. Mndaweni
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Date: 31/03/2022

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|---|
| Facility:<br><br>Date: |

- **Tool Name:** Regulatory Private Acute Hospital inspection tool
- v1.2- Final **HEs Type:** Hospitals
- **Sector:** Private

**Specialization:** Private Acute Hospital

**Created By: Health Standards Development and Training**

# 9 Pharmacy

**Domain 9.1 USER RIGHTS**

**Sub Domain 9.1.1 4** User information

**Standard 9.1.1.1 4(1)** The health establishment must ensure that users are provided with adequate information about the health care services available at the health establishment and information about accessing those services.

**Criterion 9.1.1.1.1 4(2)(a)(ii) The health establishment must provide users with information relating to service opening and closing times.**

**9.1.1.1.1.1** Legible signage at the entrance to the pharmacy indicates the days and times when services are offered.

**Assessment type:** Observation - **Risk rating:** Essential measure

The service opening and closing times (where applicable) must be displayed at the entrance of the pharmacy. The information must be legible.

Not applicable: Never

| Score | Comment |
|---|---|
| | |

**Criterion 9.1.1.1.2 4(2)(a)(iv) The health establishment must provide users with information relating to the complaints, compliments and suggestions management system.**

**9.1.1.1.2.1** A system to provide users with information on complaints management procedure is available.

**Assessment type:** Observation - **Risk rating:** Essential measure

There must be a system in place to inform users on the procedure for complaints in the unit. This can be a manual or electronic system Not applicable: Never

| Score | Comment |
|---|---|
| | |

**Domain 9.2 CLINICAL GOVERNANCE AND CLINICAL CARE**

**Sub Domain 9.2.1 7** Clinical management

**Standard 9.2.1.1 7(1)** The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

**Criterion 9.2.1.1.1 7 The health establishment implements process to ensure environmental cleanliness.**

**9.2.1.1.1.1** All cleaning work completed is verified by the cleaning supervisor or delegated person.

**Assessment type:** Document - **Risk rating:** Essential measure

Daily inspections will ensure the cleanliness of the pharmacy. The person responsible for overseeing the cleaning service must inspect the pharmacy daily to confirm that cleaning has been carried out according to the schedule and that all areas attended to have been effectively cleaned. Monitoring tools (including, but not limited to checklists/ tick sheets) listing all cleaning tasks must be completed for each room or area. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**9.2.1.1.1.2** The unit is observed to be clean.

**Assessment type:** Observation - **Risk rating:** Vital measure

Inspector to observe general cleanliness of the unit including but not limited to whether the unit is free of dirt, dust and stains. Not applicable:

Never

| Score | Comment |
|---|---|
| | |

**Criterion 9.2.1.1.2 7 Healthcare providers are informed on the health establishment and their specific responsibilities.**

**9.2.1.1.2.1** Health care personnel have been informed about the policy or standard operating procedure or procedure or guideline of the unit and health establishment.

**Assessment type:** Document - **Risk rating:** Essential measure

Documented evidence that personnel have been informed about the policy or standard operating procedure or procedure or guideline must be available. This could include but is not limited to distribution lists which include personnel signatures to indicate they have read and understood the document (which must be dated and signed), proof of attendance at meetings where policies, guidelines and standard operating procedures are discussed, or similar evidence for electronic distribution which could include but not limited to email distribution or documents deposited in intranet or other electronic platforms. Score 1 if such evidence is available and score 0 if it is not available.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. Management of adverse events | | |
| 2. Accessing medicines after hours | | |
| 3. Reporting of adverse drug reactions | | |
| 4. Storage of schedule 6 medicines | | |
| 5. Cold chain management | | |
| 6. Stock taking (counting) procedures | | |
| 7. Calculation and use of minimum, maximum and reorder/preferred stock levels. | | |
| 8. Managing recall of medicines | | |
| 9. Separation and disposal of expired, obsolete and unusable medicines | | |

**Standard 9.2.1.2 7(2)** (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

**Criterion 9.2.1.2.1 7 The pharmacy must be licensed by the Director-General of the National Department of Health.**

**9.2.1.2.1.1** The licence for the pharmacy issued by the Director-General of the National Department of Health is available.

**Assessment type:** Document - **Risk rating:** Vital measure

This will promote user safety by ensuring that the pharmacy meets all legal requirements. The licence issued by the Director-General of the National Department of Health must be available (displayed or filed). Please note: In terms of section 22(9) of the Pharmacy Act, 53 of 1974, under the section title “Licensing of pharmacies”, a “person registered to carry on the business of a pharmacy at the commencement of this Act shall be deemed to be licensed in terms of section 22(1) of the Act.” Given the amendment made to section 22 of the Act in 2003, pharmacies who were registered only with the South African Pharmacy Council (SAPC) as per the old requirements, are deemed to be registered but are required to submit an application for a pharmacy licence to the Director-General of the national Department of Health

(NDoH) in the event that the pharmacy changes ownership or relocates to new premises. Not applicable: Never

| Score | Comment |
|---|---|

| | |
|---|---|
| | |

**Criterion 9.2.1.2.2 7 The pharmacy must be registered with the South African Pharmacy Council.**

**9.2.1.2.2.1** The current certificate of recording of a pharmacy with the South African Pharmacy Council or proof of the annual fee payment is available.

**Assessment type:** Document - **Risk rating:** Vital measure

The current certificate of registration of the health establishment's pharmacy with the South African Pharmacy Council or proof that the annual fee payment is up to date must be visibly displayed in the pharmacy. Not applicable: To pre-May 2003 pharmacies. *Pre-May 2003 Pharmacies refers to all Pharmacies that were registered with SAPC on or before this date and they are deemed to be licensed* Reference: South African Pharmacy Council: Pharmacy Inspections and Guide to Compliance.

| Score | Comment |
|---|---|
| | |

**Criterion 9.2.1.2.3 7 The designated pharmacist must be registered with the South African Pharmacy Council.**

**9.2.1.2.3.1** The current certificate of registration with the South African Pharmacy Council must be available for the responsible pharmacist.

**Assessment type:** Document - **Risk rating:** Vital measure

A pharmacy managed by a qualified and registered person will promote the safety of users and health care personnel, as the pharmacy will be supervised by a skilled and knowledgeable person. The current certificate of registration with the South African Pharmacy Council of the responsible pharmacist must be available, or proof that payment of the annual fee is up to date must be visibly displayed in the pharmacy or available in a file. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**9.2.1.2.3.2** Proof of registration with the South African Pharmacy Council of all pharmacists(s)and pharmacist assistant(s) is available.

**Assessment type:** Document - **Risk rating:** Vital measure

Definition according to the Pharmacy Act: Pharmacist's assistant means a natural person registered in one of the following categories:(a) pharmacist's assistant (learner basic);(b) pharmacist's assistant (basic);(c) pharmacist's assistant (learner post-basic);(d) pharmacist's assistant (post -basic);(e) pharmacy technician (learner) (f) pharmacy technician (student);(f) pharmacy technician (trainee);(q) pharmacy technician; or(h) pharmacy student; which constitute the various categories of pharmacy support personnel registered as such in terms of the Act' The current certificate of registration with the South African Pharmacy Council of all pharmacist(s), pharmacist assistant(s) must be visibly displayed in the pharmacy or available in a file. Electronic evidence will be accepted. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**Criterion 9.2.1.2.4 7 Practices for dispensing medicines must comply with the Pharmacy Act 53 of 1974, the Medicines and Related Substances Act 101 of 1965 and relevant regulations.**

**9.2.1.2.4.1** Medicines dispensed for users are labelled in accordance with applicable legislation.

**Assessment type:** Observation - **Risk rating:** Vital measure

Request permission from three users to assess the medicine that has been dispensed to them on the day of the inspection. Verify whether the medicine dispensed complies with the requirements below. Score 1 if the aspect is compliant and 0 if not compliant.

| Score | Comment |
|---|---|

| | |
|---|---|
| | |

Unit 1 User 1

| Aspects | Score | Comment |
|---|---|---|
| 1. Labels of dispensed medicines are clear and legible | | |
| 2. Label affixed to medicine does not obstruct or cover the expiry date | | |
| | | |
| 3. Label affixed to medicine includes user's name | | |
| 4. Label affixed to medicine includes the name of the medicine | | |
| 5. Label affixed to medicine includes dosage and directions for use | | |
| 6. Label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed | | |
| 7. Label affixed to medicine includes date of dispensing | | |
| 8. Reference number or prescription number (where applicable) | | |
| 9. Cautionary or advisory labels and instructions (where appropriate) | | |

Unit 2 User 2

| Aspects | Score | Comment |
|---|---|---|
| 1. Labels of dispensed medicines are clear and legible | | |
| 2. Label affixed to medicine does not obstruct or cover the expiry date | | |
| 3. Label affixed to medicine includes user's name | | |
| 4. Label affixed to medicine includes the name of the medicine | | |
| 5. Label affixed to medicine includes dosage and directions for use | | |
| 6. Label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed | | |
| 7. Label affixed to medicine includes date of dispensing | | |
| 8. Reference number or prescription number (where applicable) | | |
| 9. Cautionary or advisory labels and instructions (where appropriate) | | |

Unit 3 User 3

| Aspects | Score | Comment |
|---|---|---|
| 1. Labels of dispensed medicines are clear and legible | | |
| 2. Label affixed to medicine does not obstruct or cover the expiry date | | |
| 3. Label affixed to medicine includes user's name | | |

| | | |
|---|---|---|
| 4. Label affixed to medicine includes the name of the medicine | | |
| 5. Label affixed to medicine includes dosage and directions for use | | |
| 6. Label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed | | |
| 7. Label affixed to medicine includes date of dispensing | | |
| 8. Reference number or prescription number (where applicable) | | |
| 9. Cautionary or advisory labels and instructions (where appropriate) | | |

**Criterion 9.2.1.2.5 7 Users must obtain their medicines from the pharmacy on the day of their visit.**

**9.2.1.2.5.1** Scripts in the pharmacy are correlated with the medicines dispensed to confirm that medicines were received as prescribed.

**Assessment type:** Patient record audit - **Risk rating:** Vital measure

Select user scripts in the pharmacy and ask the pharmacist to show what medicines were dispensed against this script. Select scripts from different units which Includes but not limited to Emergency unit, Medical ward, Paediatric ward. If all medicines as prescribed were dispensed, score 1. If the user has not received all the medicines as prescribed, score 0.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. Prescription 1 | | |
| 2. Prescription 2 | | |
| | | |
| 3. Prescription 3 | | |
| 4. Prescription 4 | | |
| 5. Prescription 5 | | |

**Criterion 9.2.1.2.6 7 Medicines must be stored and managed in compliance with the Pharmacy Act 53 of 1974, the Medicines and Related Substances Act 101 of 1965 and the relevant rules and regulations.**

**9.2.1.2.6.1** The pharmacy has functional room thermometer(s).

**Assessment type:** Observation - **Risk rating:** Vital measure

Functional room thermometer(s) must be available. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**9.2.1.2.6.2** The temperature of the pharmacy is maintained within the safety range.

**Assessment type:** Document - **Risk rating:** Vital measure

Use the checklist below to verify whether the temperature in the pharmacy is maintained between 15 and 25 degrees Celsius. Score 1 if the aspect is compliant and 0 if not compliant.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. The temperature of the pharmacy is recorded daily. Explanatory note: Request temperature monitoring sheets from the previous three months. This serves to assess whether the health establishment consistently monitors the room temperature. | | |
| 2. The temperature of the pharmacy is maintained between 15 and 25 degrees Celsius<br>References:<br>https://www.who.int/medicines/areas/quality_safety/quality_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf? ua=1 https://path.azureedge.net/media/documents/TS_opt_crt_storage_rpt.pdf. | | |

**9.2.1.2.6.3** Procedures to maintain the cold chain for vaccines and thermolabile medicines are implemented.

**Assessment type:** Observation - **Risk rating:** Vital measure

Use the checklist below to verify whether the cold chain for vaccines and thermolabile medicines is maintained. Score 1 if compliant with the aspect below and 0 if not compliant.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. Pharmacy has a vaccine or medicine refrigerator with a thermometer. Explanatory note: The vaccine or medicine refrigerator may be located in any space in the pharmacy. A domestic refrigerator will be scored non-compliant. | | |
| 2. Temperature of refrigerator is recorded twice daily, seven hours apart (check three months' records) | | |
| 3. Temperature of refrigerator is maintained between 2 and 8 degrees Celsius (check three months' records) | | |
| 4. The pharmacy has a cooler box for transporting or temporary storage of thermolabile medicines including vaccines. | | |
| 5. There is a functional thermometer in the cooler box | | |

**9.2.1.2.6.4** The policy or standard operating procedure or procedure or guideline for the management of medicines is available.

**Assessment type:** Document - **Risk rating:** Vital measure

Verify whether the aspects listed below are included and explained in the document for the management of medicines. The information can be detailed in a single document or several separate documents. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and explained and 0 if not included or not explained.

| Score | Comment |
|---|---|
| | |
| | |

| Aspects | Score | Comment |
|---|---|---|

| | | |
|---|---|---|
| 1. Storage and organisation of pharmacy | | |
| 2. Security and control of access to pharmacy | | |
| 3. Cold chain management | | |
| 4. Emergency medicine cupboard or trolley management | | |
| 5. Calculation and use of minimum, maximum and reorder/preferred stock levels | | |
| 6. Completion and management of stock (bin) cards and/or electronic stock monitoring system | | |
| 7. Stocktaking or counting procedure | | |
| 8. Procurement or ordering of medicines | | |
| 9. Ordering and delivery schedule for stock | | |
| 10. Receipt of medicines into the pharmacy | | |
| 11. Managing return of stock to the supplier | | |
| 12. Issuing of medicines to units | | |
| 13. Medicine availability monitoring procedure/guide | | |
| 14. Disposal of expired, obsolete, unusable and user-returned medicines | | |
| 15. Managing recall of medicines | | |
| 16. Storage and control of schedule 6 medicines | | |

**Criterion 9.2.1.2.7 7 A system to manage adverse drug reactions must be implemented.**

**9.2.1.2.7.1** A policy or standard operating procedure or procedure or guideline for the reporting of adverse drug reactions is available.

**Assessment type:** Document - **Risk rating:** Essential measure

Verify whether the information to be reported in the document includes the aspects listed below. The document must as minimum comply with the following requirements: Title of the document, Name of the health establishment or hospital group, signed and dated by the accounting officer or delegated person, signed and dated by the compiler or chairperson of committee that developed the document (optional), date of implementation, documents must be reviewed at a minimum every 5 years, summary of changes made to each version of the document (optional).NB: Document could be from the corporate head office (signed by the CEO or delegated person), electronic date and signature is acceptable. The document must meet these requirements to be considered for review. Score 1 if the aspect is included and 0 if not included.

| **Score** | **Comment** |
|---|---|
| | |

| **Aspects** | **Score** | **Comment** |
|---|---|---|
| 1. Name of health establishment reporting adverse drug reaction | | |
| 2. User's details, including name, registration number, age and gender | | |
| 3. Details about drug suspected to have caused the reaction | | |
| 4. Details of all other medicines the user was taking at the time of the reaction | | |

| | | |
|---|---|---|
| 5. Date and time of reaction | | |
| 6. Description of reaction | | |
| 7. Interventions made in response to reaction | | |
| 8. User outcome | | |
| 9. Laboratory results, if available | | |
| 10. Details of any other medical conditions of the user | | |
| | | |
| 11. Name and qualification of person reporting adverse drug reaction<br>Reference:<br>https://www.sahpra.org.za/wpcontent/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf | | |

**9.2.1.2.7.2** An adverse drug reaction reporting register is available in the unit.

**Assessment type:** Document - **Risk rating:** Vital measure

The manual or electronic register must include the following: name of affected person, date of incident, time of incident, nature of incident. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**9.2.1.2.7.3** Adverse drug reactions are reported to South African Health Products Regulatory Authority (SAHPRA).

**Assessment type:** Document - **Risk rating:** Vital measure

Adverse drug reactions must be reported using the correct procedure. Request records from the previous six months, and evidence of reporting (may be manual or electronic). Not applicable: Where no adverse drug reactions were reported. Reference: https://www.sahpra.org.za/healthproducts-vigilance/ https://medsafety.sahpra.org.za/

| Score | Comment |
|---|---|
| | |

**Criterion 9.2.1.2.8 7 An updated computerised or manual (stock cards) inventory management system for medical supplies must be in place.**

**9.2.1.2.8.1** There are systems in place to ensure optimum availability of medicines.

**Assessment type:** Observation - **Risk rating:** Vital measure

A system to monitor and ensure availability of medicines must be available. The system can be manual or electronic. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**Sub Domain 9.2.2 8** Infection prevention and control programmes

**Standard 9.2.2.1 8(1)** The health establishment must maintain an environment, which minimises the risk of disease outbreaks, the transmission of infection to users, health care personnel and visitors.

**Criterion 9.2.2.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.**

**9.2.2.1.1.1** Hand washing facilities are available.

**Assessment type:** Observation - **Risk rating:** Vital measure

Inspect the hand washing facilities for the items listed below. Score 1 if the item is available and 0 if not available.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. Hand washing basin. Explanatory note: The basin must not be blocked, broken, have deep cracks causing leaking of water, or have hairline cracks. | | |
| 2. Poster on correct hand washing technique | | |
| 3. Poster on the correct use of alcohol-based hand rub. Explanatory note: Posters must be placed at strategic places and above alcohol dispensers in the health establishment as stipulated in page 33 of Practical Manual for Implementation of IPC Strategic framework March 2020. | | |
| 4. Taps | | |
| 5. Running water | | |
| 6. Plain liquid soap or Chlorhexidine based soap | | |
| 7. Wall mounted soap dispenser | | |
| 8. Paper towels | | |
| 9. Paper towel dispenser | | |
| 10. Bin | | |
| | | |
| 11. Alcohol based hand rub. | | |

**Criterion 9.2.2.1.2 8(2)(d) The health establishment must ensure that health care personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations.**

**9.2.2.1.2.1** Personal protective equipment is available and worn.

**Assessment type:** Observation - **Risk rating:** Vital measure

Verify whether the protective clothing and equipment listed below is available and worn. Score 1 if the item is available and worn and score 0 if not available or not worn. Score NA where, at the time of the inspection, pharmacy personnel are not in a situation requiring them to wear protective clothing. NB: Pharmacies that prepare compounded treatments or medication will require personal protective equipment. Where the pharmacy does not perform procedures that require the personal protective equipment, score Not applicable.

| Score | Comment |
|---|---|
| | |

Unit 1 Pharmacy health care provider 1: Available

| Aspects | Score | Comment |
|---|---|---|
| 1. Gloves non-sterile | | |
| 2. Disposable gowns or aprons | | |
| 3. Face masks | | |
| 4. Protective eyewear (goggles) | | |
| 5. Sterile gloves (when performing sterile procedures e.g., when preparing chemotherapy medication) | | |

Unit 2 Pharmacy health care provider 1: Worn

| Aspects | Score | Comment |
|---|---|---|
| 1. Gloves non-sterile | | |
| 2. Disposable gowns or aprons | | |
| 3. Face masks | | |
| 4. Protective eyewear (goggles) | | |
| 5. Sterile gloves (when performing sterile procedures e.g., when preparing chemotherapy medication) | | |

Unit 3 Pharmacy health care provider 2: Available

| Aspects | Score | Comment |
|---|---|---|
| 1. Gloves non-sterile | | |
| 2. Disposable gowns or aprons | | |
| 3. Face masks | | |
| 4. Protective eyewear (goggles) | | |
| 5. Sterile gloves (when performing sterile procedures e.g., when preparing chemotherapy medication) | | |

Unit 4 Pharmacy health care provider 2: Worn

| Aspects | Score | Comment |
|---|---|---|
| 1. Gloves non-sterile | | |
| 2. Disposable gowns or aprons | | |
| 3. Face masks | | |
| 4. Protective eyewear (goggles) | | |
| 5. Sterile gloves (when performing sterile procedures e.g., when preparing chemotherapy medication) | | |

**Sub Domain 9.2.3 9** Waste management

**Standard 9.2.3.1 9(1)** The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

**Criterion 9.2.3.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.**

**9.2.3.1.1.1** The pharmacy has appropriate containers for disposal of all types of waste.

**Assessment type:** Observation - **Risk rating:** Vital measure

Verify whether the waste containers listed below are available. Health care risk waste containers must have the appropriate international hazard symbol and be marked as prescribed in SANS 10248-1: Management of Health Care Waste, Part 1: Management of healthcare risk waste from a health facility. Where a particular type of waste is not generated in the pharmacy, score NA.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|

| | | |
|---|---|---|
| 1. Chemical waste, including pharmaceutical, cytotoxic or genotoxic (dark green) | | |
| 2. General waste (black, beige, white or transparent packaging can be used) | | |

**Criterion 9.2.3.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.**

**9.2.3.1.2.1** There is a temporary healthcare risk waste storage area.

**Assessment type:** Observation - **Risk rating:** Essential measure

In all areas where waste is held for collection and removal to the central storage area, a designated area for temporary storage of waste must be available. Some health establishments will have a purpose-built temporary waste storage area, others will utilise a specific area within the available space for healthcare risk waste such as pharmaceutical waste, where compounding is done in the pharmacy. Score 1 if the aspect is compliant and 0 if not compliant, or where there is no designated area. Score NA for any aspects not found in the temporary waste storage area.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. Space available to store waste containers | | |
| 2. Area is well ventilated | | |
| 3. Area is well lit | | |
| 4. Area has impervious floor surfaces (waterproof or resistant, not cracked) | | |

**9.2.3.1.2.2** Expired or obsolete medicine is discarded according to prescribed procedures.

**Assessment type:** Observation - **Risk rating:** Vital measure

Verify whether the health establishment complies with the procedure for discarding expired or obsolete medicine. Score 1 if the aspect is compliant and 0 if not compliant.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. Expired or obsolete medicine is placed in a dark green container marked with the words “Pharmaceutical waste” | | |
| 2. The required documentation is stored with the container or available on request. Explanatory note: This includes, but is not limited to, name of health establishment, date, expired or obsolete medicine, strength, dosage form, quantity, expiry date for expired items and signature of responsible person. | | |

**Domain 9.3 CLINICAL SUPPORT SERVICES**

**Sub Domain 9.3.1 10** Medicines and medical supplies

**Standard 9.3.1.1 10(1)** The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

**Criterion 9.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.**

**9.3.1.1.1.1** The stock control system shows minimum and maximum levels and/or reorder/preferred levels for medicine.

**Assessment type:** Observation - **Risk rating:** Essential measure

Each item held as stock must have documented minimum, maximum and/or reorder/preferred levels. These levels must be recorded on bin cards or equivalent. The system may be manual or electronic. Not applicable: Never

| Score | Comment |
|---|---|

| | |
|---|---|
| | |

**9.3.1.1.1.2** Stock levels of medicine on the shelves corresponds with recorded stock levels in the stock control system.

**Assessment type:** Observation - **Risk rating:** Essential measure

Select five items held as stock and verify the number of items available against the balance indicated on the bin cards or equivalent. The system may be manual or electronic. Score 1 if stock corresponds and 0 if it does not correspond.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. Item 1 | | |
| 2. Item 2 | | |
| 3. Item 3 | | |
| 4. Item 4 | | |
| 5. Item 5 | | |

**9.3.1.1.1.3** A stocktake of medicine was done in the past 12 months.

**Assessment type:** Document - **Risk rating:** Vital measure

Documented evidence of a formal stock take will be required, i.e. a report indicating that stock take has been completed in the previous 12 months. Report should include but not limited to expired medicine (if any) and its monetary value. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**9.3.1.1.1.4** The entries in the schedule 6 drug register are complete and correct.

**Assessment type:** Document - **Risk rating:** Vital measure

All columns in the registers must be completed comprehensively. Any omitted information noted during the review of the register will receive a non-compliant score. The inspector must confirm that all sections of the register have been completed correctly. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**9.3.1.1.1.5** The schedule 6 medicines held in the pharmacy correspond with the quantities documented in the drug register.

**Assessment type:** Document - **Risk rating:** Vital measure

Select three medicines from the schedule 6 medicine cupboard and verify whether the quantity available corresponds with the balance recorded in the register. Score 0 if the medicines do not correlate or if any of the columns have not been completed.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. Medicine 1 | | |

| | | |
|---|---|---|
| 2. Medicine 2 | | |
| 3. Medicine 3 | | |

**Criterion 9.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.**

**9.3.1.1.2.1** Medicines are available in the pharmacy and/or medicine storage room as per formulary or list

**Assessment type:** Observation - **Risk rating:** Vital measure

The pharmacy is expected to have a list (this can be manual or electronic) of medicines according to the services rendered. Request the formulary or list of medicines and randomly sample 25 items from different groups of medicine e.g. Antimicrobials, Analgesics, Gastrointestinal, Immunosuppressants, Central Nervous system, Medicine for Non communicable diseases (NCD). Check whether the selected items are available and not expired. Score 0 if the selected items are not available or expired or if there is no formulary or list of medicines available.

Not applicable: Never

| Score | Comment |
|---|---|
| | |

**9.3.1.1.2.2** Medicines in the pharmacy are stored and managed in accordance with Good Pharmacy Practice.

**Assessment type:** Observation - **Risk rating:** Vital measure

Inspect the aspects listed below in the cupboards or medicine shelves where medicines are kept. Score 1 if the aspect is compliant and 0 if not compliant.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. The cupboards or medicine shelves have sufficient space for the orderly arrangement of medicines | | |
| 2. The cupboards or medicine shelves are clean (no debris, no dust, no visible dirt in cupboard or shelves, nothing in the cupboards or shelves that is not directly related to the storage, dispensing or administration of medicine, nothing in the cupboards or shelves that represents an infection control risk, e.g. food) | | |
| 3. Medicines are stored according to a classification system | | |
| 4. There is no evidence of pests in the cupboards or medicine shelves | | |
| 5. Access control measures are in place to ensure that only authorised persons have access to the medicine | | |
| 6. A system is in place to ensure issuing or administration of medicine according to the 'first expired, first out' (FEFO) principle | | |
| 7. A system is in place to check expiry dates of medicines | | |

**9.3.1.1.2.3** There are no expired medicine(s) on the shelves.

**Assessment type:** Observation - **Risk rating:** Vital measure

Examine the expiry dates of five medicines on the pharmacy's shelves. Score 0 if any expired medicines are found on the shelves.

Not applicable: Never

| Score | Comment |
|---|---|

| | |
|---|---|
| | |

**9.3.1.1.2.4** The name and contact details of the pharmacist on duty for the provision of services after hours are available.

**Assessment type:** Observation - **Risk rating:** Essential measure

A document must be displayed listing the name and contact details of the pharmacist on duty after hours. The document must be signed and dated by the responsible pharmacist. Not applicable: If this is not part of the health establishment's operations or processes

| Score | Comment |
|---|---|
| | |

**9.3.1.1.2.5** A locked emergency cupboard for the supply of medicine after hours is available.

**Assessment type:** Observation - **Risk rating:** Vital measure

The emergency cupboard must be located in an area that can be accessed after hours and it must be kept locked. Access should be restricted to designated employees only. Not applicable: Where the emergency medicine cupboard is not kept in the unit or where the health establishment does not have an emergency cupboard as part of their system.

| Score | Comment |
|---|---|
| | |

**9.3.1.1.2.6** A stock management system is in place for medicines in the emergency cupboard.

**Assessment type:** Document - **Risk rating:** Essential measure

The stock in the emergency cupboard must be managed in the same way as stock in the wards or in the pharmacy. Minimum, maximum and reorder levels must be determined for all medicines held in the emergency cupboard and bin cards or equivalent must be completed. Not applicable: Where health establishment does not have an emergency cupboard as part of their system.

| Score | Comment |
|---|---|
| | |

**9.3.1.1.2.7** Medicines issued from the emergency cupboard are documented.

**Assessment type:** Document - **Risk rating:** Essential measure

All medicines dispensed from the emergency cupboard must be documented, including the date of issue, the health care provider issuing the medicine and the user to whom the medicine is issued. This information must be kept in the emergency cupboard. Not applicable: Where the health establishment does not have an emergency cupboard as part of their system.

| Score | Comment |
|---|---|
| | |

**Domain 9.4 GOVERNANCE AND HUMAN RESOURCES**

**Sub Domain 9.4.1 20** Occupational health and safety

**Standard 9.4.1.1 20(1)** The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.

**Criterion 9.4.1.1.1 20(2)(b) Awareness of safety and security issues must be promoted**

**9.4.1.1.1.1** The emergency evacuation plan is prominently displayed.

**Assessment type:** Observation - **Risk rating:** Essential measure
The evacuation plan must include amongst others: route/directions to be followed during evacuation, emergency exits and assembly point(s).
This must be displayed. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**9.4.1.1.1.2** The healthcare personnel are familiar with the emergency evacuation procedure.

**Assessment type:** Staff interview - **Risk rating:** Essential measure
Interview three health care personnel to establish whether they are able to explain the evacuation procedure as illustrated in the evacuation plan. Score 1 if they explain the procedure as illustrated in the evacuation plan and 0 if not. Where no evacuation plan is available, this measure must be scored 0.

| Score | Comment |
|---|---|
| | |

| Aspects | Score | Comment |
|---|---|---|
| 1. Healthcare personnel 1 | | |
| 2. Healthcare personnel 2 | | |
| 3. Healthcare personnel 3 | | |

**Domain 9.5 FACILITIES AND INFRASTRUCTURE**
**Sub Domain 9.5.1 14** Management of buildings and grounds
**Standard 9.5.1.1 14(1)** The health establishment and their grounds must meet the requirements of the building regulations.

**Criterion 9.5.1.1.1 14(2)(b) The health establishment must as appropriate for the type of buildings and grounds of the establishment have a maintenance plan for buildings and the grounds.**

**9.5.1.1.1.1** No obvious safety hazards are observed during the visit.

**Assessment type:** Observation - **Risk rating:** Vital measure
Inspect the surroundings for maintenance-related safety hazards in the unit, including but not limited to loose electrical wiring, collapsing ceiling or roof, collapsing doors. or any other type of safety hazards that represent a risk to the health and safety of personnel, users and visitors. Not applicable: Never

| Score | Comment |
|---|---|
| | |

**Criterion 9.5.1.1.2 14(2)(d) The health establishment must as appropriate for the type of buildings and grounds of the establishment have ventilation systems that maintain the inflow of fresh air, temperature, humidity and purity of the air within specified limits set for different service areas such as theatres, kitchen and isolation units.**

**9.5.1.1.2.1** The pharmacy has a functional air conditioner(s).

**Assessment type:** Observation - **Risk rating:** Vital measure
Verify whether the air conditioner(s) switches on and off and provides cold/cool air to the room in accordance with the temperature setting. Not applicable: Never

| Score | Comment |
|---|---|
| | |

| | |
|---|---|
| | |

**9.5.1.1.2.2** The unit has natural ventilation or functional mechanical ventilation.

**Assessment type:** Observation - **Risk rating:** Essential measure

The national building regulations stipulate that satisfactory ventilation is only provided by forcing outdoor air into a space mechanically or passively through either ducting or apertures open to the outside such as windows or ventilation grilles. Verify that the pharmacy area has natural ventilation (windows and doors that can be opened or functional mechanical ventilation (i.e. a ducting system). Not applicable: Never

| Score | Comment |
|---|---|
| | |

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