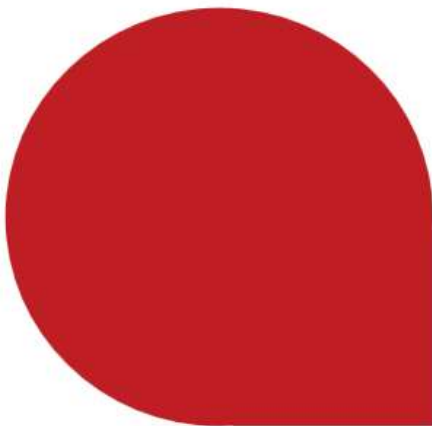




Office of Health Standards Compliance  
Ensuring quality and safety in health care



**v1.2.1**

**Pharmacy**

**Regulatory Private Acute  
Hospital Inspection tool**

Facility:
Date:

- **Tool Name:** Regulatory Private Acute Hospital Inspection Tool v1.2.1
- **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 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** Health care personnel must be informed about standard operating procedure and guidelines.

**9.2.1.1.1.1** 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. 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 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 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 for the responsible pharmacist with the South African Pharmacy Council is available.

**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 visibly displayed in the pharmacy.

Not applicable: Never

Score	Comment

**9.2.1.2.3.2** Proof of registration with the South African Pharmacy Council of all pharmacist(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.

**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 References: <a href="https://www.who.int/medicines/areas/quality_safety/quality_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf?ua=1">https://www.who.int/medicines/areas/quality_safety/quality_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf?ua=1</a> <a href="https://path.azureedge.net/media/documents/TS_opt_crt_storage_rpt.pdf">https://path.azureedge.net/media/documents/TS_opt_crt_storage_rpt.pdf</a> .		

**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

The aspects listed below are included and explained in the policy or standard operating procedure or procedure or guideline. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. 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 relevant authority responsible for approving the document, designation of the approver, date of implementation or approval, date of next review. Documents must be reviewed regularly up to the maximum of every 5 years. Document could be from the corporate head office. The document can be manual or electronic. The information may be detailed in a single document or in several documents.

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

The aspects listed below are included and explained in the policy or standard operating procedure or procedure or guideline. Score 1 if the aspect is included and explained, score 0 if it is not included or included but not explained. 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 relevant authority responsible for approving the document, designation of the approver, date of implementation or approval, date of next review. Documents must be reviewed regularly up to the maximum of every 5 years. Document could be from the corporate head office. The document can be manual or electronic. The information may be detailed in a single document or in several documents.

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		
Reference: <a href="https://www.sahpra.org.za/wpcontent/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf">https://www.sahpra.org.za/wpcontent/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf</a>		

**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 should not be blocked, broken, or have 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 worn.

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

Verify whether the protective clothing and equipment listed below is worn. Score 1 if the item is worn and score 0 if not worn. Score not applicable where, at the time of the inspection, pharmacy personnel are not in a situation requiring them to wear protective clothing. 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

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 2

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 not applicable.

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 not applicable 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 stock take of medicine was done in the past twelve 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 twelve 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

Request the medicine list or the formulary of the health establishments and randomly sample thirty items from various categories or groups of medicine. Check whether the sampled items are available and not expired. Score 1 if the sampled item is available 0 if the sampled item is not available or expired or if there is no formulary/ list of medicines available. Non-compliant sampled items to be recorded in the comment section. Should medicines be out of stock, substitutions will only be accepted if documented evidence of the recommended substitute from the pharmacist or responsible authority is available.

Score	Comment

Aspects	Score	Comment
1. Sampled medicine 1		
2. Sampled medicine 2		
3. Sampled medicine 3		
4. Sampled medicine 4		
5. Sampled medicine 5		
6. Sampled medicine 6		
7. Sampled medicine 7		
8. Sampled medicine 8		
9. Sampled medicine 9		
10. Sampled medicine 10		
11. Sampled medicine 11		
12. Sampled medicine 12		
13. Sampled medicine 13		
14. Sampled medicine 14		
15. Sampled medicine 15		
16. Sampled medicine 16		
17. Sampled medicine 17		
18. Sampled medicine 18		
19. Sampled medicine 19		
20. Sampled medicine 20		
21. Sampled medicine 21		
22. Sampled medicine 22		
23. Sampled medicine 23		
24. Sampled medicine 24		
25. Sampled medicine 25		
26. Sampled medicine 26		
27. Sampled medicine 27		
28. Sampled medicine 28		
29. Sampled medicine 29		
30. Sampled medicine 30		

**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. Access control measures are in place to ensure that only authorised persons have access to the medicine		
5. A system is in place to ensure issuing or administration of medicine according to the 'first expired, first out' (FEFO) principle		
6. 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 9.5 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)(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.

**9.5.1.1.1.1** 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

### 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.

#### Acknowledgments

Many people have contributed to the update of the Private Acute Hospital Inspection Tools version 1.2.1. The Office of Health Standards Compliance wishes to extend the most heartfelt acknowledgment and gratitude to the following:

- Health Standards Development and Training unit team (Ms. Izelle Loots, Mr. Jabu Nkambule, Ms. Busisiwe Mashinini, Ms. Derelene Hans, and Ms. Andiswa Mafilika) for the update of the Private Acute Hospital inspection tools.
- The internal OHSC teams (Compliance Inspectorate, for their contribution during the update of the Private Acute Hospital inspection tools).

**It is hereby certified that the Regulatory Private Acute Hospital Inspection tools version 1.2.1 was updated by the Office of Health Standards Compliance.**



SIGNATURE:

MS. WINNIE MOLEKO

EXECUTIVE MANAGER: HEALTH STANDARDS, DEVELOPMENT ANALYSIS AND SUPPORT

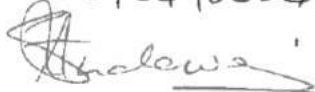
DATE: 1804/2024

SIGNATURE:

DR MATHABO MATHEBULA

CHIEF OPERATIONS OFFICER: OHSC

DATE: 23/04/2024



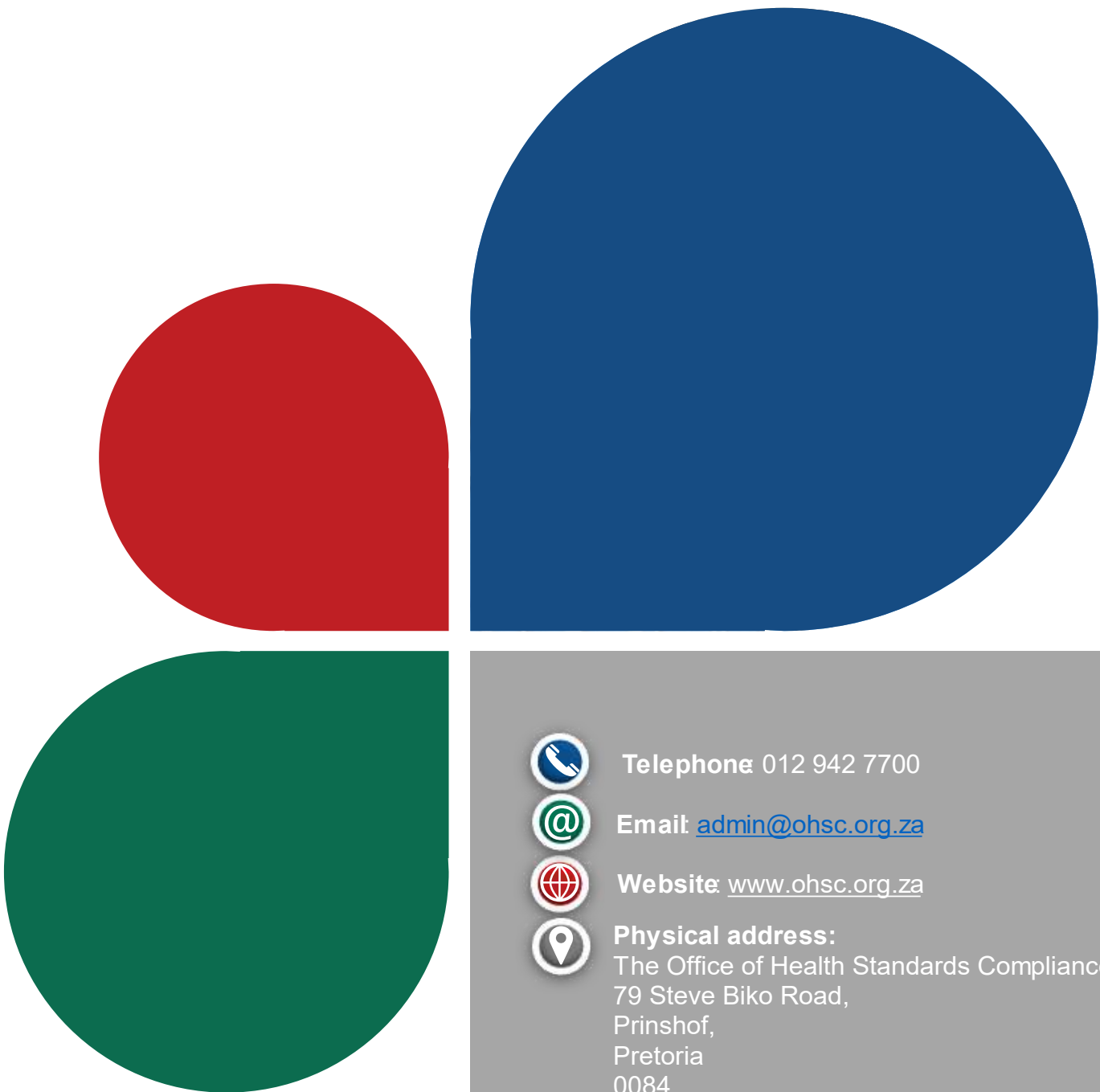
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