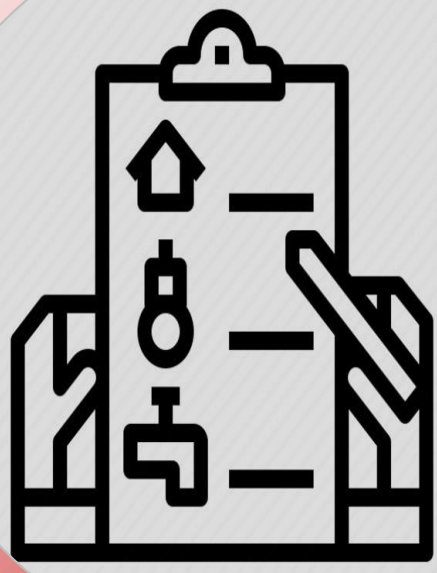
OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care

Regulatory District Hospital Inspection Tool v1.4



Pharmacy

Facility: Date:

- **Tool Name:** Regulatory District Hospital Inspection Tool v1.4 - Final
- **HEs Type:** Hospitals
- **Sector:** Public
- **Specialization:** District
- **Created By:** Health Standards Development and Training

9 Pharmacy

Domain 9.1 USER RIGHTS

Sub Domain 9.1.1 5 Access to care

Standard 9.1.1.1 5(1) The health establishment must ensure that users are attended to in a manner which is consistent with the nature and severity of their health condition.

Criterion 9.1.1.1.1 5(2)(a) The health establishment must implement a system of triage.

9.1.1.1.1.1 The process to fast-track very sick, frail and elderly users to the front of the queue is implemented.

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

It must be evident from observing the activities in the waiting area that there is a process of assessing and determining the order in which patients should be seen, based on their need for care. The criteria used for this process must be explicitly stated either in a written or verbal manner to patients. Evidence of adherence to these criteria must be observed by inspectors.

Not applicable: Where there were no very sick, frail and elderly care users during the time of inspection.

Score	Comment

Sub Domain 9.1.2 22 Waiting times

Standard 9.1.2.1 22 The health establishment must monitor waiting times against the National Core Standards for Health Establishments in South Africa.

Criterion 9.1.2.1.1 22 Waiting times are monitored and improvement plans are implemented.

9.1.2.1.1.1 Compliance with waiting time target(s) in the unit is monitored.

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

Request the previous six months' tools used for monitoring waiting times at the pharmacy.

Not applicable: Never

Score	Comment

Domain 9.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 9.2.1 6 User health records and management

Standard 9.2.1.1 6(1) The health establishment must ensure that health records of health care users are protected, managed and kept confidential in line with section 14, 15 and 17 of the Act.

Criterion 9.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

9.2.1.1.1.1 There is a “No unauthorised entry” sign on the door of the unit.

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

Check if there is a sign that reads 'No unauthorised entry' on the pharmacy/dispensary door. All internal signs must as a minimum be laminated. Text on signs must be typed, no hand written signs will be accepted. Signs do not need to be framed, but laminating must be in good condition with no turned corners or peeling. If frames are not used, posters must be neatly fastened to the wall. Any other sign, e.g., 'Staff only', will be scored non-compliant.
Not applicable: Never

Score	Comment

9.2.1.1.1.2 Access to the unit is controlled at all times.

Assessment type: Observation - **Risk rating:** Vital measure
The unit should have a lockable security gate or access-controlled door to which only pharmacy personnel have access to. Personnel holding the keys/access cards/access codes must always keep it with them and never leave it unattended.
Not applicable: Never

Score	Comment

9.2.1.1.1.3 Confidentiality of health records is maintained.

Assessment type: Observation - **Risk rating:** Vital measure
In line with section 14 of the National Health Act. Observe how user health records are managed in the unit and determine whether unauthorised individuals would be able to access the information in the health records. This includes but not limited to health records being used during dispensing, for clinical audits or other administrative purposes. Such records should be kept in a manner that safeguards against unauthorised access to the content of the health record. Electronic records must be safeguarded with passwords or any other security measures.
Not applicable: Never

Score	Comment

Sub Domain 9.2.2 7 Clinical management
Standard 9.2.2.1 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.
Criterion 9.2.2.1.1 7 Users must be counselled appropriately to ensure adherence to therapy.

9.2.2.1.1.1 Users are informed about their medicines.

Assessment type: Patient interview - **Risk rating:** Vital measure
Interview three users who have received medicines and verify whether they have been informed about the aspects listed below. Score 1 if user was informed and 0 if not informed.

Score	Comment

Unit 1 User 1

Aspects	Score	Comment

1. The user is informed about what each medicine is for.		
2. The user is informed when to take the medicine.		
3. The user is informed whether to take the medicine with or without food.		
4. The user is informed about the most common side-effects they could expect from the medicine.		
5. The user is provided with an opportunity to ask any questions or discuss anything that worries them about their medicine.		

Unit 2 User 2

Aspects	Score	Comment
1. The user is informed about what each medicine is for.		
2. The user is informed when to take the medicine.		
3. The user is informed whether to take the medicine with or without food.		
4. The user is informed about the most common side-effects they could expect from the medicine.		
5. The user is provided with an opportunity to ask any questions or discuss anything that worries them about their medicine.		

Unit 3 User 3

Aspects	Score	Comment
1. The user is informed about what each medicine is for.		
2. The user is informed when to take the medicine.		
3. The user is informed whether to take the medicine with or without food.		
4. The user is informed about the most common side-effects they could expect from the medicine.		
5. The user is provided with an opportunity to ask any questions or discuss anything that worries them about their medicine.		

Criterion 9.2.2.1.3 7 The pharmacy must be licensed by the Director-General of the National Department of Health.

9.2.2.1.3.1 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 displayed.

Not applicable: Never

Score	Comment

Criterion 9.2.2.1.4 7 The pharmacy must be registered with the South African Pharmacy Council.

9.2.2.1.4.1 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 9.2.2.1.5 7 The designated pharmacist must be registered with the South African Pharmacy Council.

9.2.2.1.5.1 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
The current certificate of registration with the South African Pharmacy Council of all pharmacist(s), pharmacist's assistant(s)must be available.
Not applicable: Never

Score	Comment

9.2.2.1.5.2 The current certificate of registration of the responsible pharmacist for the health establishment 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 staff, 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

Criterion 9.2.2.1.6 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.

9.2.2.1.6.1 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 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. The labels of dispensed medicines are clear and legible.		
2. The label affixed to medicine does not obstruct or cover the expiry date.		
3. The label affixed to medicine contains the name of the user.		
4. The label affixed to medicine contains the name of the medicine.		
5. The label affixed to medicine contains the dosage of medicine.		
6. The label affixed to medicine contains the route of administration.		
7. The label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed.		
8. The label affixed to medicine contains date of dispensing.		
9. Reference number or prescription number (where applicable)		
10. Cautionary or advisory or instructions labels (where applicable)		

Unit 2 User 2

Aspects	Score	Comment
1. The labels of dispensed medicines are clear and legible.		
2. The label affixed to medicine does not obstruct or cover the expiry date.		
3. The label affixed to medicine contains the name of the user.		
4. The label affixed to medicine contains the name of the medicine.		
5. The label affixed to medicine contains the dosage of medicine.		
6. The label affixed to medicine contains the route of administration.		
7. The label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed.		
8. The label affixed to medicine contains date of dispensing.		
9. Reference number or prescription number (where applicable)		
10. Cautionary or advisory or instructions labels (where applicable)		

Unit 3 User 3

Aspects	Score	Comment
1. The labels of dispensed medicines are clear and legible.		
2. The label affixed to medicine does not obstruct or cover the expiry date.		
3. The label affixed to medicine contains the name of the user.		
4. The label affixed to medicine contains the name of the medicine.		

5. The label affixed to medicine contains the dosage of medicine.		
6. The label affixed to medicine contains the route of administration.		
7. The label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed.		
8. The label affixed to medicine contains date of dispensing.		
9. Reference number or prescription number (where applicable)		
10. Cautionary or advisory or instructions labels (where applicable)		

Criterion 9.2.2.1.7 7 Users must obtain their medicines from the pharmacy on the day of their visit.

9.2.2.1.7.1 The scripts in the pharmacy are correlated with the medicines dispensed.

Assessment type: Patient record audit - **Risk rating:** Vital measure
Select three user scripts in the pharmacy/dispensary and check whether medicines were dispensed against the scripts. If all medicines as prescribed were dispensed, score 1. If a user has not received all the medicines as prescribed, score 0. Document the unique identifier of the sampled scripts in the comment column

Score	**Comment**

Aspects	**Score**	**Comment**
1. User health record 1		
2. User health record 2		
3. User health record 3		

Criterion 9.2.2.1.8 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.

9.2.2.1.8.1 Pharmacy has functional room thermometer.

Assessment type: Observation - **Risk rating:** Vital measure
A functional room thermometer must be available.
Not applicable: Never

Score	**Comment**

9.2.2.1.8.2 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: This is to assess whether the health establishment consistently monitors the room temperature. Request temperature monitoring sheets from the previous three months.		
2. The temperature of the pharmacy is maintained between 15 and 25 degrees Celsius.		

9.2.2.1.8.3 Procedures to maintain the cold chain for all thermolabile medicines are implemented.

Assessment type: Observation - **Risk rating:** Vital measure
Use the checklist below to verify whether the cold chain for thermolabile medicines and vaccines are maintained. Score 1 if compliant with the aspect below and 0 if not compliant.

Score	**Comment**

Aspects	**Score**	**Comment**
1. The 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. The temperature of refrigerator is recorded twice daily, seven hours apart (check three months' records)		
3. The 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. Ice packs are available for use		
6. There is a functional thermometer in the cooler box.		

Criterion 9.2.2.1.9 7 A system to manage adverse drug reactions must be implemented.

9.2.2.1.9.1 Adverse drug reactions are recorded in the register

Assessment type: Document - **Risk rating:** Vital measure
The register must include the following: name of affected person, date of incident, time of incident, nature of incident.
Not applicable: Where there no adverse drug reactions occurred in the previous twelve months.

Score	**Comment**

9.2.2.1.9.2 Adverse drug reactions are reported to the national pharmacovigilance centre or agency.

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.

Score	**Comment**

9.2.2.1.9.3 Adverse drug reactions are reported to the relevant regulatory bodies.

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.

Score	Comment

Criterion 9.2.2.1.10 7 Designated suppliers and delivery systems for medicines must adhere to their contractual obligations for the supply and delivery of medicines.

9.2.2.1.10.1 A document outlining the ordering and delivery schedule for medicine is available.

Assessment type: Document - **Risk rating:** Essential measure
A document detailing when to place orders and when to expect delivery of orders must be available.
Not applicable: Never

Score	Comment

Criterion 9.2.2.1.11 7 An updated computerised or manual (stock cards) inventory management system for medical supplies must be in place.

9.2.2.1.11.1 The electronic network system for monitoring the availability of medicines is used effectively.

Assessment type: Observation - **Risk rating:** Vital measure
Verify whether the electronic network system for monitoring the availability of medicines is used effectively in terms of the list below. Electronic systems may include, but need not be limited to, the Stock Visibility System, RX Solutions and JAC system. Score 1 if the aspect is compliant and score 0 if not compliant.

Score	Comment

Aspects	Score	Comment
1. The health establishment has a functional electronic network system for monitoring the availability of medicines.		
2. The approved list of medicines to be updated is visible in the electronic network system.		
3. The capturing device and accessories are in a working order		
4. The capturing device stored in a lockable unit (only applicable to SVS)		
5. Accessories, which include batteries and a charger, for the device are stored in a lockable unit (only applicable to SVS)		
6. In the last seven working days or more this health establishment has not been marked as non-reporting (at the point of assessment) * (SVS cell phone will show last reporting date; only applicable to SVS)		

Criterion 9.2.2.1.12 7 The health establishment must have a functional quality management system

9.2.2.1.12.1 Quality improvement plans are developed by health care personnel.

Assessment type: Document - **Risk rating:** Essential measure
Request the quality improvement plan of the unit from the previous six months. Verify whether the aspects listed below are documented. Score if aspect is documented and 0 if not. Score not applicable where no gaps have been identified.

Score	Comment

Aspects	Score	Comment
1. Gaps identified		
2. Activities required to address gaps		
3. Health care personnel responsible		
4. Time frames		

9.2.2.1.12.2 Corrective action has been taken to improve the quality of service provided where gaps are identified.

Assessment type: Document - **Risk rating:** Vital measure
Evidence must be available that the action specified in the quality improvement plan was implemented.
Not applicable: Where there were no gaps identified.

Score	Comment

Sub Domain 9.2.3 8 Infection prevention and control programmes
Standard 9.2.3.1 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 9.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.
9.2.3.1.1.1 Hand washing facilities are available.

Assessment type: Observation - **Risk rating:** Vital measure
Inspect the handwashing facilities for the items listed below. Score 1 If the item is available and 0 if not available.

Score	Comment

Aspects	Score	Comment
1. Functional hand wash basin. Explanatory note: The basin should not be blocked, broken, or have cracks.		
2. Taps are functional and not broken. Explanatory Note: Taps must be elbow or non-touch operated in user care areas.		
3. Plain liquid soap.		

4. Wall mounted soap dispenser.		
5. Paper towel dispenser with disposable hand paper towels.		
6. General waste container. Explanatory note: Containers used for the temporary storage of general waste should be leak proof, intact, corrosive resistant and have a tight-fitting lid. The container must be lined with the appropriate colour coded liner. (Practical Manual: Implementation of the National Infection Prevention and Control Strategic Framework page 82 and page 84).		

9.2.3.1.1.2 Alcohol based hand rub is available.

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

Select three areas and observe whether alcohol-based hand rub is available. Score 1 if available and 0 if not available.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Area 1		
2. Area 2		
3. Area 3		

9.2.3.1.1.3 Posters on hand hygiene are displayed.

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

Select three areas and observe whether posters on hand hygiene are displayed. This could be a single hand hygiene poster or individual posters for hand washing or correct use of alcohol-based hand rub. Score 1 if available and 0 if not available.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Area 1		
2. Area 2		
3. Area 3		

Criterion 9.2.3.1.2 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.

9.2.3.1.2.1 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.

Score	**Comment**

Unit 1 Area 1

Aspects	Score	Comment
1. Gloves non-sterile		
2. Face masks		
3. Protective eyewear (goggles) or face shields		
4. Domestic rubber gloves (for cleaners only)		

Unit 2 Area 2

Aspects	Score	Comment
1. Gloves non-sterile		
2. Face masks		
3. Protective eyewear (goggles) or face shields		
4. Domestic rubber gloves (for cleaners only)		

Unit 3 Area 3

Aspects	Score	Comment
1. Gloves non-sterile		
2. Face masks		
3. Protective eyewear (goggles) or face shields		
4. Domestic rubber gloves (for cleaners only)		

Sub Domain 9.2.4 9 Waste management

Standard 9.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 9.2.4.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

9.2.4.1.1.1 The unit has appropriate containers for disposal 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 health care risk waste from a health facility. Where a particular type of waste is not generated in the unit score not applicable.

Score	Comment

Aspects	Score	Comment
1. Pharmaceutical waste (dark green)		
2. General waste		

Criterion 9.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste. 9.2.4.1.2.1 Sharps are safely managed and discarded in the unit.

Assessment type: Observation - **Risk rating:** Vital measure
Use the checklist below to check whether sharps are safely managed and discarded. Score 1 if the aspect is compliant and 0 if it is not compliant. Score not applicable if there is no sharps waste generated in the unit.

Score	Comment

Aspects	Score	Comment
1. Waste is properly segregated. Explanatory note: Only sharps and vials are discarded into the container; no other waste is observed in the container.		
2. Sharps containers are discarded when they reach the limit mark		
3. Sharps containers are placed on a work surface or in wall mounted brackets		
4. Sharps containers have correctly fitting lids		
5. Needles are not recapped before disposal. Explanatory note: This is not applicable for safety needles and syringes		

9.2.4.1.2.2 Waste is segregated as required by the waste management practices.

Assessment type: Observation - **Risk rating:** Essential measure
Use the checklist below to check if waste is segregated as required by the waste management practices stipulated in the National Environmental Health Norms and Standards. Score 1 if the aspect is compliant and 0 if it is not compliant.

Aspects	Score	Comment
1. General waste is discarded separately in a black or white or transparent plastic bag		
2. Pharmaceutical waste is discarded separately in a green container		

9.2.4.1.2.3 Expired or obsolete medicine is discarded according to prescribed procedures.

Assessment type: Observation - **Risk rating:** Vital measure
Observe if the health establishment complies with the procedure for discarding expired or obsolete medicine. Score 1 if the aspect is compliant and 0 if it is 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 liquid or solid”		
2. The required documentation is attached to the container or available on request. Explanatory note: This includes but is not limited to the 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 for medicines shows minimum and maximum levels and/or reorder levels for medicine.

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

Randomly sample five items held as stock and verify whether minimum, maximum and/or reorder levels are documented. The levels must be recorded on the bin cards or equivalent. The system may be manual or electronic. Score 1 if compliant and 0 if not compliant.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Item 1		
2. Item 2		
3. Item 3		
4. Item 4		
5. Item 5		

9.3.1.1.1.2 Stock levels for medicine on the shelves correspond with recorded stock levels in the stock control system.

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

Randomly sample five items(medicines) 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 compliant and 0 if not compliant.

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 Stock take of medicine was done.

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 detail amongst others expired medicine and its monetary value.
Not applicable: Never

Score	Comment

9.3.1.1.1.4 A system to control and manage schedule 6 medicine is available.

Assessment type: Document - **Risk rating:** Vital measure
Accurate, comprehensive recording of dispensing of Schedule 6 medicines is a legal requirement and must be done in accordance with the applicable legislation. The system may be manual or electronic Verify whether all sections of the register have been completed correctly. Any omitted information noted during the review of the register will result in a non-compliant score. Score 1 if compliant and 0 if not compliant.

Score	Comment

9.3.1.1.1.5 Schedule 6 medicines in stock correspond with the balance recorded in the register.

Assessment type: Observation - **Risk rating:** Vital measure
Randomly sample three medicines from the schedule 6 medicine cupboard and verify whether the quantity available corresponds with the balance recorded in the register. Score 1 if there is correspondence 0 if not.

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 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: Where the pharmacy is open for 24 hours

Score	Comment

9.3.1.1.2.2 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.
Not applicable: Where the pharmacy is open for 24 hours or there is a callout/on call system /Where the emergency cupboard for supply of medicine is not located in the pharmacy.

Score	Comment

9.3.1.1.2.3 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 units 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 the pharmacy is open for 24 hours /Where the emergency cupboard for supply of medicine is not located in the pharmacy.

Score	Comment

9.3.1.1.2.4 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 pharmacy is open for 24 hours /Where the emergency cupboard for supply of medicine is not located in the pharmacy.

Score	Comment

9.3.1.1.2.5 Stock levels of medicine in the emergency cupboard correspond with recorded stock levels in the stock control system.

Assessment type: Observation - **Risk rating:** Essential measure
Randomly sample 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 compliant and o if not compliant. Score not applicable where the pharmacy is open for 24 hours or where the emergency cupboard for supply of medicine is not located in the pharmacy.

Score	Comment

Aspects	Score	Comment

1. Item 1		
2. Item 2		
3. Item 3		
4. Item 4		
5. Item 5		

9.3.1.1.2.6 Medicines in the unit 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. Shelves or cupboards has sufficient space for orderly arrangement of medicines.		
2. Cupboard or medicine trolley or shelves are clean		
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 medicine.		
5. System is in place to ensure packing and issuing of medicine according to ‘first expired, first out’ (FEFO) principle.		
6. System is in place to check expiry dates of medicines.		

9.3.1.1.2.7 Medicines on the tracer or formulary medicine list are available .

Assessment type: Observation - **Risk rating:** Vital measure
Request the tracer medicine list or the formulary of the health establishments and randomly sample thirty items from various categories or groups of medicine. Check whether the selected items are available and not expired. Score 1 if the selected 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 (this could include but is not limited to a letter or memorandum) of the recommended substitute from the District pharmacist or relevant authority is available. Alternatively, where tracer medicine list recommends several medicines as equivalent for treatment, substitutions from this list of recommended medicines will be acceptable without a letter from the district pharmacist.

Score	**Comment**

Aspects	**Score**	**Comment**
1. Sampled medicine 1		

2. Sampled medicine 2		
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30. Sampled medicine 30		

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: Where the hospital has a central air conditioning system. There is no on/off switch in the Pharmacy.

Score	Comment

9.5.1.1.1.2 Pharmacy waiting area 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 waiting 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

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

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 District Hospitals.

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- National Department of Health for their input and comments on the inspection tools.

It is hereby certified that the Regulatory District Hospital Inspection tools version 1.4 was updated by the Office of Health Standards Compliance.

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