

Items which may be inspected by OHSC during a General Practice Inspection (This is an example of their report sheet)

Facility:

Province:

District:

Sub District:

Date of Inspection:

Inspection Type:

1. BACKGROUND

The Office of Health Standards Compliance (OHSC) is established as a juristic person in terms of the National Health Act, 2003 (Act No. 61 of 2003).

The objects of the office are to protect and promote the health and safety of users of health services by:

- Monitoring and enforcing compliance by health establishments with norms and standards prescribed by the minister in relation to the national health system; and
- Ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

The regulations for different categories of health care establishments were promulgated in February 2018 and came into effect in February 2019. Inspections are conducted as a measure contributing to improvement of quality and safety as well as to monitor and enforce compliance with the norms and standards.

2. COMPLIANCE STATUS AND GRADING. (You will be graded on the 4 criteria below)

- Compliance decision:
- Overall health establishment Grading:
- Vitals measures:
- Essential measures:

3. REQUIREMENTS AND RESULTANT SUMMARY OF FINDINGS

FUNCTIONAL AREA	SUMMARY OF REQUIREMENTS /FINDINGS
Administration and Practice Management	<p>Is there a register for complaints.</p> <p>Is there a copy of service level agreement or memorandum of agreement for waste removal.</p> <p>Is there an occupational health and safety risk assessment done in the previous two years.</p> <p>Does the building must comply with safety regulations including fire safety and electrical compliance certificates</p>
Clinical Care and Support	<p>Emergency Trolley and equipment will be checked against the required list.</p> <p>Are Schedule 5 medicine recorded in the register.</p> <p>Is the result of the patient experience of care survey is displayed.</p> <p>Patient Records Analysis: Has erasable been used,</p> <p>Is there a document of next of kin contact details and unique registration number.</p> <p>Staff Interviews will be conducted and health care personnel will be interviewed and asked if they were informed about prophylactic immunizations for high-risk infections.</p>

4. EXAMPLES OF FURTHER STEPS TO BE TAKEN TO ACHIEVE COMPLIANCE

- Is there a documented procedure which describes the information to be collected and discussed during the process to obtain informed consent is implemented, in accordance with Chapter 2 of the National Health Act (Section 7).
- Is there a Decontamination process to provide safe, effective decontamination of medical devices.
- Are medicines 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.
- Is there a process to ensure environmental cleanliness.
- Does the health establishment adhere to a planned schedule for maintaining medical equipment.
- Is there a showing that the health establishment must report information on health care associated infections and notifiable diseases to the appropriate public health agencies.
- Does the practice ensure that medication is dispensed in accordance with legislation to minimise the risk of user harm.
- Does the practice have systems in place to ensure users requiring resuscitation receive an immediate response by health care providers trained in resuscitation.
- Does the practice have systems in place to keep the environment clean by implementing pest control measures in all areas.
- Does the practice implement controls for the management, recording and distribution of medicines listed in Schedules 5 and 6 of the Medicines and Related Substances Act.
- The practice must implement measures and processes to protect users undergoing invasive procedures.
- The practice must manage and maintain the equipment used for decontamination to ensure sustainability of decontamination services.
- The practice must protect the health and safety of employees by implementing the requirements of the Occupational Health and Safety Act, 1993 (Act No.85 of 1993).
- The practice must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.
- The practice must as appropriate for the type of buildings and grounds of the establishment, have all the required compliance certificates in terms of the building regulations.
- The practice must ensure that there are hand washing facilities in every service area.
- The practice must have a health record filing, archiving, disposing, storage and retrieval system which complies with the law.
- The practice must implement and maintain a stock control system for medicine and medical supplies.
- The practice must provide users with information relating to the complaints, compliments and suggestions management system.
- The practice must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.
- The practice must ensure the availability of medicines and medical supplies for the delivery of services.
- The practice must implement procedures for the collection, handling, storage and disposal of waste.
- The practice must provide users with information relating to any fees that are payable for health care services, insofar it being practical to do so before the commencement of the provision of health care services.
- The practice must display the results of user experience of care surveys conducted within the past twelve months.
- The practice must ensure there is clean linen to meet the needs of users.

- The practice must ensure that health care personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations.
- The practice must record the biographical data of the user and the identification and contact information of the user and his or her next of kin.
- The practice must ensure that a copy of the referral document is kept in the user's health record.
- The practice must record information relating to the examination and health care interventions of users.

5. FUNCTIONAL AREAS WHICH WILL BE SCORED BY RISK RATING

FUNCTIONAL AREA	GRADING	NNV	VITAL	ESSENTIAL
Administration and Practice Management				
Clinical Care and Support				

6. DOMAIN SCORE BY RISK RATING

DOMAIN NAME	GRADING	NNV	VITAL	ESSENTIAL
USER RIGHTS				
CLINICAL GOVERNANCE AND CLINICAL CARE				
CLINICAL SUPPORT SERVICES				
GOVERNANCE AND HUMAN RESOURCES				
FACILITIES AND INFRASTRUCTURE				

7. SUB DOMAIN SCORE BY RISK RATING

SUB DOMAIN NAME	GRADING	NNV	VITAL	ESSENTIAL
User information				
Access to care				
User health records and management				
Clinical management				
Infection prevention and control programmes				
Waste management				
Medicines and medical supplies				
Medical equipment				
Management of buildings and grounds				
Engineering services				
Security Services				
Human resource management				

Occupational health and safety				
Adverse events				

8. STANDARD SCORE BY RISK RATING

REGULATION NUMBER	STANDARD NAME	GRADING	NNV	VITAL	ESSENTIAL
	(b) A health establishment must establish and maintain systems, structures and programs to manage clinical risk.				
	Health establishments must ensure that the medical equipment is available and functional in compliance with the law.				
	The health establishment and their grounds must meet the requirements of the building regulations.	●			
	The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.				
	The health establishment must comply with the requirements of the Occupational Health and Safety Act, 1993.				
	The health establishment must create and maintain a system of health records of users in accordance with the requirements of section 13 of the Act.				
	The health establishment must ensure that engineering services are in place.				
	The health establishment must ensure that health records of health care users are protected, managed and kept confidential in line with sections 14, 15 and 17 of the Act.				
	The health establishment must ensure that they have systems in place to manage health care personnel in line with relevant legislation, policies and guidelines.				

	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.				
	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.				
	The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.				
	The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.				
	The health establishment must have a formal process to be followed when obtaining informed consent from the user.				
	The health establishment must have a system to monitor and report all adverse events.				
	The health establishment must have systems to protect users, health care personnel and property from security threats and risks.				
	The health establishment must maintain a system of referral as established by the responsible authority.				

	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.				
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9. CRITERIA SCORE BY RISK RATING

CRITERIA NAME	GRADING	NNV	VITAL	ESSENTIAL
Is there a documented procedure which describes the information to be collected and discussed during the process to obtain informed consent and is this implemented, in accordance with Chapter 2 of the National Health Act (Section 7).				
Is there a Decontamination processes to provide safe, effective decontamination of medical devices.				
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.				
The health establishment must implement processes to ensure environmental cleanliness.				
The health establishment must adhere to a planned schedule of maintaining medical equipment.				
The health establishment must report information on health care associated infections and notifiable diseases to the appropriate public health agencies.				
The practice must ensure that medication is dispensed in accordance with legislation, and to minimize the risk of user harm.				
The practice must have systems in place to ensure users requiring resuscitation receive an immediate response by health care providers trained in resuscitation.				
The practice must have systems in place to keep the environment clean by implementing pest control measures in all areas.				
The practice must implement a system for the referral of users to other service providers.				
The practice must implement controls for the management, recording and distribution of medicines listed in Schedules 5 and 6 of the Medicines and Related Substances Act.				
The practice must implement measures and processes to protect patients undergoing invasive procedures.				
The practice must manage and maintain the equipment used for decontamination to ensure sustainability of decontamination services.				
The practice must provide patients with information on how to access emergency care when the practice is closed.				
The practice must protect the health and safety of employees by implementing the requirements of the Occupational Health and Safety Act, 1993 (Act No.85 of 1993).				
The health establishment must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.				

The health establishment must have all the required compliance certificates in terms of the building regulations, as appropriate, for the type of buildings and grounds of the establishment				
The health establishment must ensure that clinical policies and guidelines for priority health conditions issued by the national department are available and communicated to health care personnel.				
The health establishment must ensure that security staff are capacitated to deal with security incidents, threats and risks.				
The health establishment must ensure that there are hand washing facilities in every service area.				
The health establishment must have a health record filing, archiving, disposing, storage and retrieval system which complies with the law.				
The health establishment must implement a system of triage.				
The health establishment must implement and maintain a stock control system for medicine and medical supplies.				
The health establishment must, as appropriate to the type and size of the establishment, have and implement a human resource plan that meets the needs of the health establishment.				
The health establishment must provide users with information relating to the health care services provided by the health establishment.				
The health establishment must provide users with information relating to service opening and closing times.				
The health establishment must provide users with information relating to the complaints, compliments and suggestions management system.				
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.				
The health establishment must ensure access to emergency medical transport for users requiring urgent transfer to another health establishment, and that they are accompanied by a health care provider.				
The health establishment must ensure confidentiality of health records.				
The health establishment must ensure that equipment is in accordance with the essential equipment list in all clinical service areas.				
The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.				
The health establishment must have systems in place to report adverse incidents to a structure in the health establishment or responsible authority that monitors these events.				
The health establishment must implement procedures for the collection, handling, storage and disposal of waste.				
The health establishment must provide users with information relating to any fees that are payable for health care services, insofar it being practical to do so before the commencement of the provision of health care services.				
The health establishment must display the results of user experience of care surveys conducted within the past twelve months.				

The health establishment must ensure there is clean linen to meet the needs of users.				
The health establishment must, as appropriate to the type and size of the establishment, have a system to monitor that health care personnel maintain their professional registration with the relevant councils on an annual basis.				
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.				
The health establishment must ensure that health care personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations.				
The health establishment must record the biographical data of the user and the identification and contact information of the user and his or her next of kin.				
The health establishment must ensure that a copy of the referral document is kept in the patient's health record.				
The health establishment must record information relating to the examination and health care interventions of users.				

10. COMPLIANT or NOT	GRADING	NNV	VITAL	ESSENTIAL
Administration and Practice Management				

MEASURE NO	Measure	Inspector Comment
1.1.1.1.2	Complaints are logged in a register	
1.1.1.1.3	Complainants are informed about the complaint's resolution	
1.2.1.1.3	Health records are archived and disposed of in line with HPCSA guidelines.	
1.2.3.1.1.1	The practice has determined the linen requirements and meets them.	
1.2.3.1.2.1	Notifiable medical conditions are reported to the relevant authority.	
1.2.3.1.4.1	A standard operating procedure for decontamination processes is available.	
1.2.3.1.4.2	Health care personnel responsible for decontamination of instruments have been trained.	
1.2.3.1.5.1	Decontamination equipment is tested.	
1.2.3.1.6.1	The practice has a pest control programme.	
1.2.4.1.1.2	A copy of service level agreement or memorandum of agreement for waste removal is available.	
1.2.4.1.1.3	Compliance with Service level agreements or memorandum of agreement is monitored.	

1.2.4.1.1.4	Remedial action is taken to rectify the breaches identified.	
1.3.1.1.1.1	A standard operating procedure for management of medicines is available.	
1.3.1.1.2.1	The health care providers have valid dispensing license.	
1.3.2.1.1.1	Maintenance plan for medical equipment is available.	
1.3.2.1.1.2	Equipment is maintained per the maintenance schedule.	
1.4.2.1.1.1	An occupational health and safety risk assessment has been conducted in the practice.	
1.4.2.1.1.2	Mitigation plans are implemented for identified risks.	
1.4.2.1.1.3	A system to manage occupational injuries and diseases is available.	
1.4.2.1.1.4	Health care personnel who experienced exposure to bodily fluids receive post-exposure prophylaxis	
1.5.1.1.1.1	The building(s) complies with safety regulations.	.

FUNCTIONAL AREA	GRADING	NNV	VITAL	ESSENTIAL
Clinical Care and Support				

MEASURE NO	Measure	Inspector Comment
2.1.1.1.4.1	Users are informed of indicative costs related to services provided by the practice prior to these costs being incurred.	
2.1.1.1.5.1	Results of the user experience of care survey are displayed.	
2.1.2.2.1.1	Copies of referral documents are available at the practice making the referral.	
2.2.1.2.2.1	The clinical assessment and management plan for the user is recorded in the user health record.	
2.2.1.3.1.1	Informed consent forms are completed correctly.	
2.2.2.2.2.1	Emergency bag or trolley is stocked with medicines, medical supplies and equipment.	
2.2.2.2.2.3	The emergency bag or emergency trolley are checked.	
2.2.3.1.1.3	Posters on hand hygiene are displayed.	

2.2.3.1.3.1	Health care personnel are informed about prophylactic immunisations for high-risk infections.	
2.3.1.1.1.2	The practice monitors stock levels of medical supplies.	
2.3.1.1.1.3	The practice monitors stock levels of medicine.	
2.3.1.1.2.3	Cold chain for thermolabile medicines is maintained.	
2.3.1.1.2.4	Basic medical supplies (consumables) are available.	
2.3.1.1.3.1	Schedule 5 and 6 medication storage area is kept locked.	
2.3.1.1.3.2	The entries in the schedule 5 and 6 drug register are complete.	
2.3.1.1.3.3	Schedule 5 and 6 medicines in stock correspond with the balance recorded in the register.	
2.3.1.1.4.1	Medicines in the practice are stored and managed in accordance with Good Pharmacy Practice in South Africa. (e.g. evidence that the temperature of the medicine storage area had been maintained between 15 and 25 degrees Celsius.)	
2.5.3.1.1.4	An oxygen cylinder is available in the practice.	
2.5.3.1.1.5	Oxygen concentrator is available and functional.	