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ENFORCEMENT POLICY

OFFICE OF HEALTH STANDARDS COMPLIANCE

NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)

I Sipiwe Mndaweni hereby publish the Draft Enforcement Policy contained in the Schedule hereto, in terms of regulation 22(2) of the Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud published in *Government Gazette* No. 40396, Notice No. 1365 of 2 November 2016, for consultation.

Interested persons are hereby invited to submit written comments on the draft Policy within ninety (90) working days from the publication date of this notice. Comments may be directed to:

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Director: Certification and Enforcement

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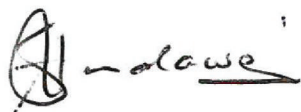
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CHIEF EXECUTIVE OFFICER: OFFICE OF HEALTH STANDARDS COMPLIANCE

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	<h2>OFFICE OF HEALTH STANDARDS COMPLIANCE</h2>		
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Certification and Enforcement Unit			

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1. DEFINITIONS

- 1.1 **“Board”** means the Board of the Office of Health Standards Compliance appointed in terms of Section 79A of the Act;
- 1.2 **“Chief Executive Officer”** means the person appointed as Chief Executive Officer of the Office in terms of Section 79H (1) of the Act;
- 1.3 **“Constitution”** means the Constitution of the Republic of South Africa, 1996;
- 1.4 **“Compliance Enforcement Committee”** means an administrative body established by the Office to adjudicate on formal hearings relating to breaches or non-compliance with the prescribed norms and standards;
- 1.5 **“Early warning system”** means the surveillance systems that collect information of serious user-related incidents that prompt interventions by the health establishment, the Office or relevant authority;
- 1.6 **“Health establishment”** means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services;
- 1.7 **“Inspector”** means a person appointed as an inspector in terms of Section 80(2) of the Act;
- 1.8 **“Minister”** means the Minister responsible for Health;
- 1.9 **“Norms and standards”** mean the norms and standards prescribed by the Minister in terms of Section 90(1)(b) and (c) of the Act;
- 1.10 **“Office”** means the Office of Health Standards Compliance established by Section 77(1) of the Act;
- 1.11 **“Ombud”** means a person appointed as an Ombud in terms of Section 81(1) of the Act;
- 1.12 **“Person-in-charge”** means a person designated by the relevant authority, as a person in charge of a health establishment;
- 1.13 **“Policy”** means this Enforcement Policy of the Office;
- 1.14 **“Regulations”** means the Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud;
- 1.15 **“Relevant Authority”** refers to provincial department of health, district health authority, municipal authority or equivalent authority in the private sector;
- 1.16 **“the Act”** means the National Health Act, 2003 (Act No. 61 of 2003);

1.17 **“User”** means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is:

- a) below the age contemplated in Section 39 (4) of the Child Care Act, 1983 (Act No. 74 of 1983), **“user”** includes the person’s parent or guardian, or another person authorised by law to act on the first mentioned person’s behalf; or
- b) incapable of taking decisions, **“user”** includes the person’s spouse or partner or, in the absence of such spouse or partner, the person’s parent, grandparent, adult child or brother or sister, or another person authorised by law to act on the first mentioned person’s behalf.

2. BACKGROUND

2.1 The Office of Health Standards Compliance was established by section 77(1) of the National Health Act, 2003 (Act No. 61 of 2003), which recognised the need to foster good quality health services. The rationale behind the establishment of the Office was to put in place institutional mechanisms, to advise on how to improve quality of care, monitor, enforce and report on non-compliance with the prescribed norms and standards.

2.2 The norms and standards for different types of health establishments were developed to ensure that health users receive health services at the acceptable standard.

2.3 The following are some of the activities that the Office is enjoined to perform as part of its responsibilities:

- 2.3.1 Inspect health establishments to ensure compliance with the prescribed norms and standards;
- 2.3.2 Certify health establishments found to be compliant with the prescribed norms and standards;
- 2.3.3 Enforce compliance with the prescribed norms and standards;
- 2.3.4 Provide guidance and support on the interpretation and application of the prescribed norms and standards; and
- 2.3.5 Investigate complaints relating to the breaches of the prescribed norms and standards.

3. THE PURPOSE OF THE ENFORCEMENT POLICY

- 3.1 The purpose of the Enforcement Policy is to set out the approach to be followed by the Office in enforcing compliance by health establishments with the prescribed norms and standards, to guide its employees, the Board as well as the categories of health establishments to whom the prescribed norms and standards apply.
- 3.2 This Enforcement Policy also sets out the roles and responsibilities of all the relevant stakeholders.

4. LEGISLATIVE MANDATE

- 4.1 The Constitution of the Republic of South Africa, 1996;
- 4.2 The National Health Act, 2003 (Act No. 61 of 2003), as amended;
- 4.3 Promotion of Access to Information Act, 2000 (Act No. 2 of 2000);
- 4.4 The Protection of Personal Information Act, 2013 (Act No. 4 of 2013);
- 4.5 Promotion of Administrative Justice Act, 2003 (Act No. 3 of 2000);
- 4.6 Criminal Procedure Act, 1977 (Act No. 51 of 1977);
- 4.7 Norms and Standards Regulations applicable to different categories of health establishments, 2016; and
- 4.8 Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud, 2016.

5. PRINCIPLES

In exercising its enforcement powers and to promote the statutory objective of promoting and protecting the health and safety of health users, the Office has adopted the following five (5) principles in its daily operations and regulatory decisions:

PRINCIPLES	
5.1 Accountability	The prescribed norms and standards set explicit benchmarks for health establishments that are objectively assessed and held accountable for compliance.
5.2 Transparency	Clear, specific and explicit obligations are placed on health establishments through the norms and standards,

	assessment tools and procedures. Furthermore, regulatory findings and decisions are published, as required by the Regulations.
5.3 Targeting	Enforcement target those health establishments and components of services which pose the greatest risk and whose levels and persistence of non-compliance with the norms and standards reflect ongoing actual risks to users' health and safety and potential poor outcomes.
5.4 Proportionality	The response as well as the use of enforcement powers must be assessed by the Office to be proportionate to the circumstances of an individual case. Where the health establishment can remedy the breach and the risk to health users is not immediate, the Office provides guidance to the health establishment in remedying the breach before taking enforcement action.
5.5 Consistency	The Office must take a similar approach, in similar cases, to achieve similar outcomes, and ensure that regulatory and enforcement processes are consistent, and decisions are reliable and fair (similar action in similar circumstances to achieve similar results).

6. SCOPE AND APPLICATION

6.1 This policy applies to:

- 6.1.1 The Board;
- 6.1.2 Employees of the Office;
- 6.1.3 Health establishments; and
- 6.1.4 Relevant authorities.

7. COMPLIANCE MONITORING

7.1 The Office monitors compliance with the norms and standards in several ways including, but not limited to: -

- 7.1.1 Inspections and investigations;

- 7.1.2 Incident notifications and complaints; and
- 7.1.3 Early warning system.

8. EDUCATION, ADVICE AND GUIDANCE ON COMPLIANCE

8.1 The purpose of education, advice and guidance is to:

- 8.1.1 Raise awareness of all stakeholders' rights and obligations in relation to the prescribed norms and standards,
- 8.1.2 Guide the persons in charge of the health establishments on how to comply with the norms and standards and other applicable legislation, and
- Empower and capacitate health establishments to timeously address breaches of norms and standards and achieve compliance.

9. INSPECTIONS

9.1 The purpose of inspections is to assess the extent of compliance by health establishments with the prescribed norms and standards.

9.2 Inspectors appointed by the Office must:

- 9.2.1 Inspect health establishments in accordance with the Inspection Strategy of the Office;
- 9.2.2 Interview any person who is believed to have in her or his possession any relevant information;
- 9.2.3 Request documents from the person in charge of a health establishment;
- 9.2.4 Take samples of any substance or relevant photographs; or
- 9.2.5 Issue a compliance notice to the person in charge of a health establishment if the health establishment is found to have breached any norms and standards.

10. RESPONSE TO NON-COMPLIANCE

10.1 The health establishment is responsible for taking timely and appropriate actions to remedy any identified breaches of norms and standards.

10.2 If a health establishment fails to correct any identified breaches of norms and standards a compliance notice shall be issued to the health establishment.

11. COMPLIANCE NOTICE

- 11.1 A compliance notice is issued by an inspector to a health establishment that is found to have breached any prescribed norms and standards.
- 11.2 The health establishment must be given reasonable time to comply with the compliance notice prior to invoking any enforcement action.

12. ENFORCEMENT

12.1 PURPOSE OF ENFORCEMENT

- 12.1.1 The primary purpose of enforcement is:
- 12.1.1.1 To ensure compliance by health establishments with the prescribed norms and standards;
 - 12.1.1.2 To protect health users from harm and the risk of harm caused by non-compliance by health establishments with prescribed norms and standards
 - 12.1.1.3 To ensure that users receive health services of acceptable standard.

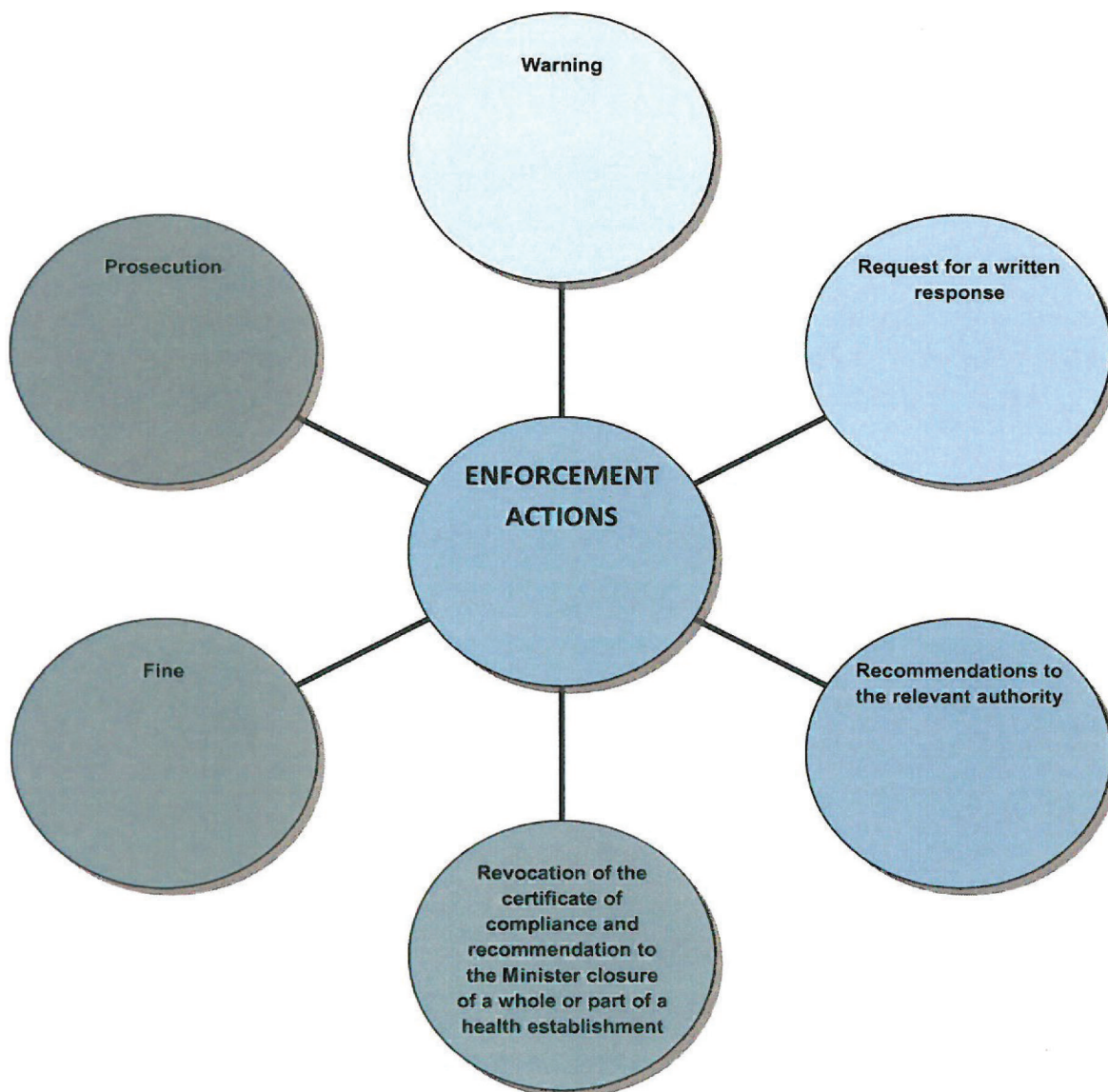
12.2 CRITERIA FOR ENFORCEMENT

- 12.2.1 In deciding the most appropriate action to take, the Office may be guided by the following considerations:
- 12.2.1.1 The severity of the breach and the actual or potential consequences;
 - 12.2.1.2 The extent to which the person in charge or employees of the health establishment contributed to the breach;
 - 12.2.1.3 The compliance history of the health establishment;
 - 12.2.1.4 Any mitigating or aggravating factors, including efforts undertaken by the person in charge of the health establishment to prevent / control the risks;
 - 12.2.1.5 Whether the breach is imminent or immediate.

12.3 ENFORCEMENT ACTIONS

The following diagram outlines the enforcement actions enjoined on the OHSC by the National Health Act, 2003 (Act No. 61 of 2003):

Diagram 1 - Enforcement actions



12.3.1 WARNING AND REQUEST FOR RESPONSE

- 12.3.1.1 If a health establishment fails to comply with a compliance notice issued by an inspector, the Office may issue a written warning to the person in charge of the health establishment, requiring her or him to provide a written response for such failure to comply with the compliance notice.
- 12.3.1.2 A written warning must include a reasonable time frame within which the written response must be provided to the Office and set out the consequences of failure to respond.
- 12.3.1.3 Failure by the person in charge to respond to a written warning within the set time frame would lead to the matter being referred for formal enforcement.

12.3.2 FINE

- 12.3.2.1 The Office shall afford the health establishment an opportunity to submit a request for leniency prior to imposing a fine.
- 12.3.2.2 The fine, if imposed, will be subject to the thresholds determined by the Minister by notice in the *Gazette*.
- 12.3.2.3 The health establishment must pay the imposed fine into a designated account within twenty (20) working days of the decision.
- 12.3.2.4 A separate banking account shall be opened by the Office for the purpose of payment of fines.

12.3.3 REVOCATION OF A COMPLIANCE CERTIFICATE

- 12.3.3.1 If a health establishment fails to comply with a compliance notice issued by an Inspector, the Office may revoke the compliance certificate issued to a health establishment.
- 12.3.1.1 The Office shall afford the health establishment an opportunity to submit a request for leniency prior to revocation of a compliance certificate.

12.3.2 RECOMMENDATION FOR TEMPORARY CLOSURE OF A HEALTH ESTABLISHMENT OR PART THEREOF

- 12.3.2.1 After revoking a certificate of compliance, the Office may make a recommendation to the Minister to temporarily or permanently close a health establishment or a part thereof that constitutes a serious risk to public health or health of the users.
- 12.3.2.2 The recommendation to the Minister must include all the information contained in regulation 27(2) of the Regulations, to enable the Minister to decide.
- 12.3.2.3 Any recommendations to the Minister for temporary or permanent closure of a health establishment or a part thereof must be submitted to the Board for consideration and approval.

12.3.3 FORMAL HEARING

- 12.3.3.1 The Office must notify the health establishment of its intention to revoke the certificate of compliance or to impose a fine and initiate a hearing which must be presided over by a suitable person appointed by the Chief Executive Officer, to allow the health establishment an opportunity to make representations before taking a final decision.
- 12.3.3.2 The person appointed as a presiding officer for the hearings must not have a personal interest in the matter or be in any way associated with any of the parties.
- 12.3.3.3 The hearings must be open to the public, subject to the determination of the presiding officer.
- 12.3.3.4 The Chief Executive Officer must report the recommendations of the presiding officer and the decision of the Compliance Enforcement Committee to the Board for noting.
- 12.3.3.5 The Office must communicate the final decision of the person in charge of a health establishment as well as the relevant authority within the prescribed timeframe.

12.3.4 NOTICE OF HEARING

12.3.4.1 A notice of hearing must be given to both the Office and the health establishment to prepare for the hearing.

12.3.4.2 A notice of hearing or notice of the Office's intention to revoke a certificate of compliance or to impose a fine would be deemed to have been received by the party or parties, as the case may be, if such notice was: -

12.3.4.2.1 sent to the registered postal or physical address of either party and there is enough proof thereof;

12.3.4.2.2 sent to either party's official fax number and there is a fax transmission as proof that the fax was sent or received;

12.3.4.2.3 hand-delivered and signed for at either party's registered business address; or

12.3.4.2.4 sent by e-mail to either party's official email address.

12.3.4.2.5 Where there is proof that the notice of hearing was delivered late, the receiving party may request extension of time or postponement of the hearing, which may not be unreasonably denied.

12.3.5 RECOMMENDATION TO THE RELEVANT AUTHORITY

12.3.5.1 The Office must recommend to the relevant authority any appropriate or suitable action to be taken against the person in charge of a health establishment or the health establishment.

12.3.5.2 The Office must monitor all recommendations sent to the relevant authority and report to the Minister on the implementation thereof.

12.3.6 PROSECUTION

12.3.6.1 Where an alleged breach of prescribed norms and standards is considered to amount to a criminal offence, the Office shall refer the matter to the National Prosecuting Authority for consideration.

12.3.6.2 The decision to prosecute lies solely with the National Prosecuting Authority after considering all the relevant factors relating to the alleged offence or offences.

12.3.7 APPEAL

12.3.7.1 An appeal against any decision of the Office must be in writing and lodged with the Minister within thirty (30) days from the date of gaining knowledge of the decision.

13. PUBLICATION OF TRIBUNAL DECISIONS AND REPORTS

13.1 The Office must publish the decisions of the *ad hoc* tribunal in the *gazette* within twenty-five (25) working days from the date of the decision.

13.2 All other reports relating to the outcome of the hearings conducted and recommendations made to the Minister or other relevant authorities shall be published on the Office's website every six (6) months.

14. ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

Health establishments and the Employees	<ul style="list-style-type: none"> • Familiarise themselves with prescribed norms and standards. • Comply with the prescribed norms and standards. • Cooperate with the Office and its employees.
Relevant Authorities	<ul style="list-style-type: none"> • Ensure that breaches of the prescribed norms and standards are dealt with as and when referred by the Office.

Health Users	<ul style="list-style-type: none"> • Provide inspectors with required information / documentation. • Report breaches of norms and standards / non-compliance by health establishments by way of complaints / whistle blowing.
The Office	<ul style="list-style-type: none"> • Inspect compliance with the norms and standards. • Guide health establishment on compliance with the norms and standards. • Enforce compliance with the norms and standards. • Issue certificate of compliance to compliant health establishments.

15. REVIEW OF THE ENFORCEMENT POLICY

This Policy must be reviewed every five (5) years or earlier, as may be necessary.

16. PUBLICATION OF THE ENFORCEMENT POLICY

A copy of this Policy shall be published in the *Government Gazette* and made available at the Office's official website: <http://www.ohsc.org.za>.