

## NON-GOVERNMENTAL ORGANIZATION

NO. 1286


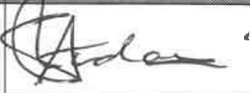
04 DECEMBER 2020

**OFFICE OF HEALTH STANDARDS COMPLIANCE**

I Sipiwe Mndaweni hereby publish the 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.

**DR SIPHIWE MNDAWENI****CHIEF EXECUTIVE OFFICER: OFFICE OF HEALTH STANDARDS COMPLIANCE**

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	<b>OFFICE OF HEALTH STANDARDS COMPLIANCE</b>		
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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, Act 108 of 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 breaches of norms and standards 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”** means the norms and standards prescribed by the Minister in terms of Section 90(1)(b) and (c) of the Act;
- 1.10. **“Office / OHSC”** 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. **“Reasonable time”** means refers to the amount of time that is fairly required to do whatever is required to be done, conveniently under the permitted circumstances. For the purpose of the Office, reasonable time shall be any time frame within which a health establishment is required to perform a specific action and communicated accordingly;
- 1.15. **“Regulations”** means the Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud;
- 1.16. **“Relevant Authority”** refers to provincial department of health, district health authority, municipal authority or executive management authority in the private sector;
- 1.17. **“the Act”** means the National Health Act, 2003 (Act No. 61 of 2003); and
- 1.18. **“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 129 of the Children’s Act 38 of 2005, **“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 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—
- a. Inspect health establishments to ensure compliance with the prescribed norms and standards;
  - b. Certify health establishments found to be compliant with the prescribed norms and standards;
  - c. Enforce compliance with the prescribed norms and standards;
  - d. Provide guidance and support on the interpretation and application of the prescribed norms and standards; and
  - e. 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 the stakeholders.

#### 4. APPLICABLE LEGISLATION

- 4.1 The Constitution of the Republic of South Africa, Act 108 of 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 OF ENFORCEMENT

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

PRINCIPLE	DEFINITION
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 shall target health establishments and part thereof which poses a risk to users of health care services.
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 users is not immediate, the Office shall give the health establishment an opportunity to remedy 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 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 shall be applicable to—

- 6.1.1 The OHSC Board;
- 6.1.2 Employees of the OHSC;
- 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;
- 7.1.2 Complaints investigations; 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;
- 8.1.1 support the person in charge of the health establishments on how to comply with the norms and standards and other applicable legislation; and
- 8.1.3 empower and capacitate health establishments to address breaches of norms and standards within a reasonable time 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 and to provide support where necessary.



## 9.2 Inspectors appointed by the Office may—

- 9.2.1 Inspect health establishments in accordance with the Inspection Strategy of the Office;
- 9.2.2 Question 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; and
- 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

The health establishment is responsible to take reasonable time and appropriate action to remedy any identified breaches of norms and standards. If a health establishment fails to correct any identified breaches of norms and standards, a compliance notice will be issued to a health establishment.

## 11. COMPLIANCE NOTICE

- 11.1 A compliance notice shall be issued by an inspector to a health establishment that is found to have breached the prescribed norms and standards.
- 11.2 The health establishment will be expected to comply with the conditions set out in the compliance notice prior to the Office taking any enforcement action.
- 11.3 A compliance notice shall stipulate the time frame within which remedial action must be taken to correct the identified breaches to the norms and standards.

## 12. ENFORCEMENT

### 12.1 PURPOSE OF ENFORCEMENT

#### 12.1.1 The primary purpose of enforcement is to—

- a) enforce compliance by health establishments with the prescribed norms and standards;
- b) protect users and health care personnel from harm and the risk of harm caused by non-compliance by health establishments with prescribed norms and standards;
- c) ensure that users receive health services of acceptable standard and that health care personnel work in a safe environment.

## 12.2 CRITERIA FOR ENFORCEMENT

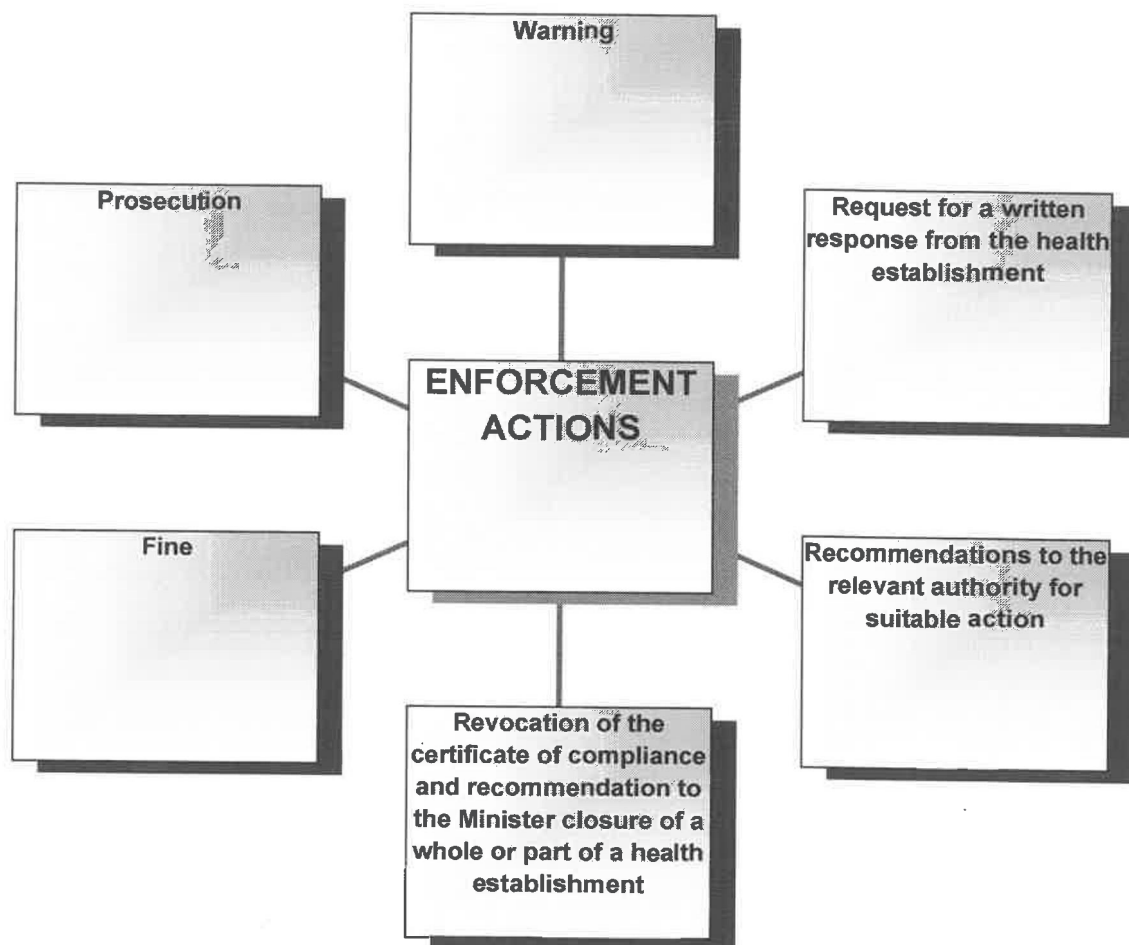
12.2.1 In deciding the most appropriate action to take, the Office may be guided by the following considerations—

- a) The impact of the breach on the provision of health care service delivery;
- b) Any injury, loss, damage or death resulting from the breach;
- c) The health establishment or person in charge blameworthiness or the degree within which they should be held accountable for the breach;
- d) The compliance history of the health establishment;
- e) Any mitigating or aggravating factors, including efforts undertaken by the person in charge of the health establishment to prevent / control the risk;
- f) Whether the breach is imminent.

## 13. ENFORCEMENT ACTIONS

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

### Diagram 1 - Enforcement actions



### 13.1 WRITTEN WARNING

- 13.1.1 If a health establishment fails to comply with a Compliance Notice issued by an inspector, the Office shall issue a written warning to the person in charge of the health establishment.
- 13.1.2 The written warning shall include a time frame within which compliance must be achieved.
- 13.1.2 Failure by the person in charge to respond to a written warning within the reasonable time would lead to the matter being referred for other enforcement processes.

### **13.2 REQUEST FOR A WRITTEN RESPONSE FROM A HEALTH ESTABLISHMENT**

13.2.1 Where appropriate, the Office shall request for a written response from the health establishment, providing reasons for the continued non-compliance.

13.2.2 The request for a written response from the Office will also set out the consequences of failure to respond.

### **13.3 RECOMMENDATION TO THE RELEVANT AUTHORITY FOR SUITABLE ACTION**

13.3.1 The Office shall 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.

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

### **13.4 REVOCATION OF A COMPLIANCE CERTIFICATE AND RECOMMENDATION FOR TEMPORARY OR PERMANENT CLOSURE OF A HEALTH ESTABLISHMENT OR PART THEREOF.**

13.4.1 Where a health establishment fails to comply with a Compliance Notice issued by an Inspector, the Office may revoke the certificate of compliance issued to a health establishment and recommend to the Minister to temporarily or permanently close a health establishment or a part thereof that constitutes a serious risk to the users.

13.4.2 Health establishments shall be afforded an opportunity to be heard prior to revocation of a compliance certificate or recommendation to the Minister for temporary or permanent closure of a health establishment of part thereof, that poses a risk to the users.

13.4.3 The recommendation to the Minister shall include all the information contained in regulation 27(2) of the Regulations, to enable the Minister to make a decision.

### **13.5 FINE**

13.5.1 Prior to imposing a fine, the Office shall afford the health establishment an opportunity to submit a request for leniency.

13.5.2 The fine, if imposed, will be subject to the thresholds determined by the Minister by notice in the *Government Gazette*.

13.5.3 The health establishment shall pay the imposed fine into a designated account within twenty (20) working days of the decision.

13.5.4 Banking details for payment of fines shall be provided by the Office.

### **13.6 PROSECUTION**

13.6.1 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 and possible criminal prosecution.

13.6.2 The Office shall also refer for prosecution any offences in terms of the Act.

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

### **14. FORMAL HEARING**

14.1 The Office shall notify the health establishment of its intention to revoke the certificate of compliance or to impose a fine, as the case may be, and initiate a hearing which must be presided 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.

14.1.1 The person appointed as a presiding officer for the hearings shall not have a personal interest in the matter or be in any way associated with any of the parties.

14.1.2 The hearings shall be open to the public, subject to the determination of the presiding officer.

14.1.3 The presiding officer shall communicate the decision on the hearing to the Office, person in charge of a health establishment as well as the relevant authority within the prescribed timeframe.

14.1.4 Notice of hearing—

- a) notice of hearing shall be given to both the Office and the health establishment to prepare for the hearing.
- b) 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—
  - i. sent to the registered postal or physical address of either party and there is sufficient proof thereof;
  - ii. sent to either party's official fax number and there is a fax transmission as proof that the fax was sent or received;
  - iii. hand-delivered and signed for at either party's registered business address; or
  - iv. sent by e-mail to either party's official email address.
- c) 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.

## 15. APPEAL

15.1 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.

15.2 The Minister shall, upon receipt of the notice of appeal, appoint an *ad hoc* tribunal to hear the appeal.

15.3 The procedure and conduct of the appeal must be determined by the *ad hoc* tribunal.

15.4 There is no right of appeal to the Minister in relation to a conviction for an offence, if prosecuted.

## 16. PUBLICATION OF TRIBUNAL DECISIONS AND REPORTS

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

16.2 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 months.

## 17. ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

17.1 Health establishments, person-in-charge, and employees	<ul style="list-style-type: none"> <li>• Familiarise themselves with prescribed norms and standards.</li> <li>• Comply with the prescribed norms and standards.</li> <li>• Cooperate with the Office and its employees.</li> </ul>
17.2 Relevant Authorities	<ul style="list-style-type: none"> <li>• Ensure that breaches of the prescribed norms and standards are dealt with as and when referred by the Office.</li> </ul>
17.3 Users	<ul style="list-style-type: none"> <li>• Provide inspectors with required information.</li> <li>• Report breaches of norms and standards / non-compliance by health establishments.</li> </ul>
17.4 The Office	<ul style="list-style-type: none"> <li>• Inspect compliance with the norms and standards.</li> <li>• Guide health establishment on compliance with the norms and standards.</li> <li>• Enforce compliance with the norms and standards.</li> <li>• Issue certificate of compliance to compliant health establishments.</li> </ul>

## 18. REVIEW OF THE ENFORCEMENT POLICY

This Policy shall be reviewed as and when necessary.

## 19. PUBLICATION OF THE ENFORCEMENT POLICY

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