No. R. 110 **18 February 2015**

NATIONAL HEALTH ACT, 2003

PROCEDURAL REGULATIONS PERTAINING TO THE FUNCTIONING OF THE OFFICE OF HEALTH STANDARDS COMPLIANCE AND ITS BOARD

The Minister of Health, intends, after consultation with the Office, to make the regulations contained in the Schedule hereto, in terms of section 90(1)(a) of the National Health Act, 2003 (Act No. 61 of 2003) as amended.

Interested persons are invited to submit any substantiated comments or representations in writing on the proposed regulations to the Director General: Health, Private Bag X 828, Pretoria, 0001 (for the attention of the Director: Public Entities Governance), within three months from the date of publication of this notice.

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PART ONE

DEFINITIONS, PURPOSE AND APPLICATION

1. Definitions and interpretation

(1). In these regulations, unless the context indicates otherwise, a word or expression to which a meaning has been assigned in the Act, has the same meaning, and –

"certificate of compliance" means a certificate referred to in regulation 18(2), issued to the health establishment by the Office;

"compliance notice" means a notice referred to in regulation 21(1), issued to the health establishment by an inspector;

"head " means the person in control and responsible for the day to day operations of a health facility;

"inspection" means on site visits to health establishments for the purpose of gathering information and evidence to assess compliance or investigate breaches of prescribed norms and standards;

"person in charge" means a person designated as a person in charge of a health establishment, in terms of regulation 6(1);

"relevant authority" means the provincial department of health, a municipality, or the head of the health establishment or a private hospital group;

"self-assessment" means the report from an assessment of compliance with prescribed norms and standards conducted by the health establishment on the required forms issued by the Office of Health Standards Compliance;

"the Act" means the National Health Act, 2003 (Act No. 61 of 2003) as amended; and

"working day" means any day other than a Saturday, Sunday or public holiday.

2. Purpose of the regulations

The purpose of these regulations is to set out procedures and processes for collection of information from health establishments by the Office, certification of health establishments, conducting of inspections, dealing with non-compliance by health establishments with prescribed norms and standards, as well as the procedures and processes for the consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards, by the Ombud.

3. Scope and application

(1) These regulations apply to all categories of health establishments referred to in section 35 of the Act, subject to sub-section (2).

(2) Despite sub-regulation (1), and with the exception of Part Seven, these regulations will only come into force in relation to each category of health establishment once the norms and standards for such category of health establishment have been prescribed by the Minister.

PART TWO

INFORMATION ABOUT AND GUIDANCE TO HEALTH ESTABLISHMENTS

4. Collection of or request for information

(1) All health establishments and users that are required by the Office to provide information relating to prescribed norms and standards, in terms of section 79(2)(b) of the Act, must do so within a period stated in the specific request for information.

(2) A request for information from health establishments, referred to in sub-regulation (1), must be on Form OHSC 1 and include, at a minimum, the following information:

(a) Name of health establishment;
(b) Legal status;
(c) Physical address;
(d) Contact details, including telephone, email, website details;
(e) Names and contact details of the person in charge;
(f) Category of health establishment;

(g) Health district in which the health establishment falls;
(h) Services offered;
(i) Operating times; and
(j) Results of latest self-assessment against prescribed norms and standards.

(3) The request for information from users, referred to in sub-regulation (1), must be accompanied by details of the required information and the manner in which such information must be submitted.

(4) Any information that may be required by the Office from health establishments or users, in terms of section 79(2)(b) of the Act, may be submitted electronically.

(5) If the person in charge, referred to in regulation 6(1), fails to provide the Office with the required information within the specified period, the Office must refer the matter to the head of the national or provincial department of health or the heath department of a municipality or the head of the health establishment, as the case may be, for intervention.

5. Indicators of risk

(1) In terms of section 79(1)(d) of the Act, the Office must monitor and provide guidance to health establishments on the following:

(a) Indicators of risk by category of health establishment;
(b) Approach to measuring and calculating the indicators of risk;
(c) Frequency of collection of the indicators of risk; and
(d) Reporting to the Office on such indicators.

(2) The Office-

(a) must use the information collected to maintain an early warning system and report serious breaches of norms and standards to the Minister within 5 working days of their occurrence or in the event that the likelihood of re-occurrence is high; or
(b) may conduct an additional inspection as contemplated in regulation 15(1)(c).

6. Designation of a person in charge

(1) The Office must request the head of the national or provincial department of health or the heath department of a municipality or the head of a health establishment to designate as a person in charge of the health establishment the most senior employee, who will deal with all matters relating to prescribed norms and standards.

(2) The designation of a person in charge, referred to in sub-regulation (1), must be in writing and signed by the head of the national or provincial department of health or the health department of a municipality or the head of the health establishment, or their delegates.

(3) The contact details of the person in charge must be submitted to the Office in writing, on an annual basis within 2 weeks of the beginning of the financial year.

(4) Any changes to the particulars of the person in charge must be submitted to the Office within 20 working days of such a change occurring.

7. Responsibilities of a person in charge

(1) The person in charge must –

(a) supply the Office or Ombud with information necessary to discharge its or his or her responsibilities, as the case may be, in terms of the Act;
(b) provide assistance to an inspector in the preparation for and during an inspection contemplated in section 82(1) of the Act;
(c) receive and acknowledge receipt of a compliance notice contemplated in section 82A of the Act and regulation 13;
(d) provide assistance to the Ombud during an investigation contemplated in section 81A(1) of the Act;
(e) consider and respond to any report from the Office regarding compliance by the health establishment with prescribed norms and standards and implement remedial measures within specified timeframes;
(f) Foster a culture of compliance with prescribed norms and standards within the health establishment;
(g) design and implement programmes to improve compliance by health care personnel in the employ of the health establishment;

(h) disseminate information supplied by the Office to the health care personnel in the employ of the health establishment;

(i) Maintain an updated record of inspections by the Office or investigations by the Ombud, and

(k) render any assistance to the Office or Ombud on all matters relating to prescribed norms and standards.

(2) The person in charge may delegate aspects of his or her responsibilities, referred to in sub-regulation (1), to any senior employee within the health establishment.

PART THREE

INSPECTORS AND INSPECTIONS

8. Appointment of inspectors

(1) The Chief Executive Officer must issue a person who has been appointed as an inspector in terms of section 80(2) of the Act with a certificate of appointment as an inspector, in accordance with section 80(3) of the Act, once the person has successfully completed a minimum training programme approved by the Office.

(2) The certificate of appointment as an inspector, referred to in sub-regulation (1), must be on Form OHSC 2, and include, at a minimum, the following information:

(a) Name and surname of the inspector;

(b) A unique identification number supplied by the Office;

(c) Date of issuance;

(d) Date of expiry;

(e) Contact details of the Office;

(f) Signature of the Chief Executive Officer; and

(g) A form of photographic identification.

9. Skills and experience for inspectors

An inspector appointed in terms of section 80(2) of the Act must-

(a) be a qualified health professional, who is registered with the Health Professionals Council of South Africa, the South Africa Nursing Council, or the South Africa

Pharmacy Council, referred to in the definition of statutory health professional council in section 1 of the Act;

(b) maintain the currency of his or her registration status with the relevant statutory health professional council referred to in paragraph (a), for the duration of his or her appointment as an inspector; and

(c) have experience in the delivery of services in hospitals or primary healthcare facilities in the public or private sector.

10. Code of conduct for inspectors

(1) The Chief Executive Officer must develop and enforce a code of conduct for inspectors appointed in terms of section 80(2) of the Act.

(2) The Office must publish the code of conduct for inspectors in the government *gazette* within3 months of the promulgation of these regulations.

(3) A copy of the code of conduct for inspectors referred to in sub-regulation (1), must be signed by all the inspectors prior to the commencement of their duties.

11. Formal credentials for a person rendering assistance

(1) If an inspector is accompanied by any person reasonably required to assist him or her in the conduct of the inspection, as contemplated in section 82(2) of the Act, the Chief Executive Officer must issue such a person with formal credentials.

(2) The formal credentials referred to in sub-regulation (1) must include, at a minimum, the following information:

(a) Name and surname of the person rendering assistance;
(b) A unique identification number;
(c) Date of issuance;
(d) Date of expiry;
(e) Contact details of the Office;
(f) Signature of the Chief Executive Officer; and
(g) A form of photographic identification.

12. Inspection strategy, procedures and plan

(1) The Board must approve an annual inspection strategy to guide the inspection activities of the Office.

(2) The annual inspection strategy referred to in sub-regulation (1), must be published in the government *gazette*, and include, at a minimum, the following:

(a) An approach to prioritising, scheduling and conducting inspections; and
(b) Resources and costs for the implementation of the inspection strategy.

(3) The Office must develop an inspection procedure manual and tools for inspectors to ensure that inspections are carried out in a consistent, fair, equitable and transparent manner.

(4) An inspector must prepare an inspection plan, which sets out a clear approach to carrying out the inspection for each health establishment to be inspected.

(5) The inspection plan referred to in sub-regulation (4) must be appended to the Notice of Inspection referred to in sub-regulation 13(2)(d).

13. Notice of inspection

(1) Before commencing with an inspection contemplated in section 82 of the Act, an inspector must issue a notice of inspection to the health establishment.

(2) The notice of inspection referred to in sub-regulation (1), must be in Form OHSC 3, and include, at a minimum, the following information:

(a) The purpose of the inspection;
(b) The date of the inspection;
(c) The estimated duration;
(d) The inspection plan referred to in sub-regulation 12(4);
(e) The number of authorised personnel expected to take part in the inspection;
(f) The contact details of the inspector primarily responsible for the inspection;
(g) The responsibilities of the health establishment.

(3) The notice of inspection referred to in sub-regulation (1), must be signed by the Chief Executive Officer.

14. Inspection process

(1) Upon arrival at the premises of the health establishment, the inspector must clearly identify himself or herself to the person in charge by presenting –

(a) a notice of inspection, referred to in regulation 13(1);
(b) a certificate of appointment as an inspector, issued in terms of section 80(3) of the Act; and
(c) a letter of consent referred to in regulation 16(3), or
(d) an entry and search warrant issued in terms of section 84(5) of the Act.

(2) During an inspection, the health establishment must make available the necessary staff, resources and space to allow inspectors to complete the inspection in a timely and expeditious manner.

(3) Subject to section 82(1) of the Act, an inspector may question any user, occupant, health care personnel or any person on the premises of a health establishment, provided he or she has -

(a) explained to the said user, occupant, health care personnel or any person on the premises his or her constitutional and legal rights, including the right to refuse to be questioned;
(b) obtained written approval from the user, occupant, health care personnel or any person on the premises for the questioning or recording of the interview; or
(c) obtained verbal approval from the user, occupant, health care personnel or any or person on the premises for the questioning or recording of the interview, in the presence of a witness.

(4) On completion of the inspection, the inspector must present his or her preliminary findings to the person in charge.

(5) The preliminary findings must -

(a) identify the main areas of non-compliance with prescribed norms and standards;

(b) set out the consequences of non-compliance;
(c) set out the steps that must be undertaken to achieve compliance and timeframes for corrective action; and
(d) set out appeal or review mechanisms.

(6) The inspector must provide the person in charge an opportunity to respond to the findings, and the person in charge may provide the inspector with any relevant information, documents, records, objects or materials for the inspector's consideration during the inspection visit.

(7) At the end of the inspection, the inspector-

(a) may recommend to the Office the issuing of a compliance certificate to the health establishment, in terms of regulation 18(2); or
(b) must issue a compliance notice to the health establishment, in terms of section 82A(1) of the Act, if any prescribed norms and standards have not been complied with.

15. Additional inspection

An inspector may, at any time, subject to section 82(1) of the Act, conduct an additional inspection, provided that he or she has reasonable grounds to believe that –

(a) such an inspection is needed to establish whether non-compliance has been remedied within the health establishment;
(b) the health establishment is contravening the Act or any relevant regulations;
(c) there are serious breaches of norms and standards, based on the indicators of risk; or
(d) the Ombud's findings demonstrate that continued exposure to the services provided by health establishment may pose a severe risk to users or health care personnel.

PART FOUR

ENTRY AND SEARCH OF PREMISES

16. Consent to search

(1) Subject to section 86(a) of the Act, the Office must request consent from the head of a national or provincial department of health, the municipal manager or the head of a health

establishment identified as the owner and occupier of the health establishment in terms of section 88(a) of the Act, to carry out inspections.

(2) For the purposes of the consent referred to in sub- regulation (1), the Office may submit to the head of the national or provincial department of health, the municipal manager or the head of the health establishment or private hospital group an annual inspection strategy containing information on the approach to inspections .

(3) Consent must be in the form of a written statement or letter signed by the head of a national or provincial department of health, the municipal manager or the head of a health establishment or private hospital group identified as the owner and occupier of the health establishment in terms of section 88(1)(a) of the Act.

(4) Where the head of a national or provincial department of health, the municipal manager or the head of a health establishment or private hospital group provides such consent, this should be submitted to the Office together with the designation of the person in charge of each health establishment referred to in sub-regulation 6(3) within 2 weeks of the beginning of each financial year.

17. Entry and search warrant

(1) Where consent to enter and search the premises for purposes of carrying out an inspection cannot be obtained, the Office must apply for a warrant in terms of section 84(1) of the Act.

(2) The application for a warrant must be on Form OHSC 4, and include, at a minimum, the following information –

(a) name and address of the health establishment to be inspected;
(b) legislative provisions governing the inspection;
(c) reasons and motivation for the inspection; and
(d) most recent inspection results, if the establishment had been inspected previously.

(3) Despite sub-regulation(1), an inspector may enter and search any premises without the authority of a warrant in terms of section 86(b) of the Act, if there are reasonable grounds to believe that, if applied for, a warrant for entry and search would be issued and that the delay in obtaining the warrant would defeat the object of the warrant.

PART FIVE

CERTIFICATION

18. Certification of health establishments

(1) The office must establish mechanisms to consider and advise on, amongst others, the recommendation for the certification of health establishments referred to in regulation 14(7)(a) and renewal of certification referred to in regulation 19(1).

(2) The office must, within 15 working days, issue any health establishment that meets all the compliance requirements with a certificate of compliance.

(3) A certificate of compliance referred to in sub-regulation(2), must be on Form OHSC 5, and include, at a minimum, the following information:

(a) name of health establishment;
(b) category of health establishment;
(c) physical address;
(d) address for the service of legal processes and notices, if not the same as physical address;
(e) date of last inspection;
(f) date of expiry of certification; and
(g) signature of the Chief Executive Officer.

19. Renewal and extension of certification

(1) The health establishment must, within a period of not more than six months before the expiration of the compliance certificate referred to in regulation 18(2), submit an application to the Office for the renewal of its certificate.

(2) The application for renewal of the certificate of compliance be on Form OHSC 6, and include annual self-assessments of the health establishment's compliance with prescribed norms and standards and its most recent quality improvement plans.

(3) A renewal of a certificate of compliance must be on the basis of a recommendation for certification referred to in regulation 14(7)(a).

(4) The Office may extend the certification status of the health establishment that has applied for renewal in terms of sub-regulation 19(1) for a period of no more than one year from the date of expiry, to afford the Office an opportunity to schedule and conduct an inspection for the purposes of renewal of certification.

20. Suspension of certification

(1) A certificate of compliance issued in terms of regulation 18(2), remains valid for a period of no more than four years, subject to an extension contemplated in regulation 19(4).

(2) Despite sub-regulation (1), a compliance notice referred to in regulation 21(1), suspends the validity of a certificate of compliance referred to in sub-regulation (1), until the conditions set out in the said compliance notice are fulfilled.

(3) The Office must, within 15 working days of the confirmation of fulfilment of the conditions of compliance referred to in sub-regulation (2), reconfirm the compliance status of the health establishment.

PART SIX

COMPLIANCE NOTICE, ENFORCEMENT AND APPEALS

21. Compliance notice

(1) An inspector may –

(a) at the end of the inspection, issue a compliance notice in terms of section 82A(1) of the Act, to the person in charge, if any prescribed norms and standards have not been complied with, or

(b) at any time during an inspection, issue a compliance notice in terms of section 82A(1)of the Act, to the person in charge, if there are reasonable grounds to believe that the health establishment or a part thereof poses a serious risk to public health or the health of users.

(2) The compliance notice referred to in sub-regulation (1), must be on Form OHSC 7, and contain all the information set out in section 82A(2) of the Act.

(3) The person in charge must, within the period specified in the compliance notice, provide the inspector with a health establishment quality improvement plan that details –

(a) the actions that will be undertaken to achieve compliance; and
(b) timeframe for achieving compliance.

(4) If the health establishment fails to comply with the compliance notice issued in terms of section 82A(1) of the Act, the Office may invoke any of the sanctions listed in section 82A(4) of the Act.

22. Enforcement

(1) The Office must develop an enforcement policy which sets out the Office's approach to enforcing compliance.

(2) The Chief Executive Officer must publish the enforcement policy referred to in sub-regulation (1) and any subsequent amendments thereof, in the Government *Gazette,* within 25 working days of approval by the Board.

(3) Enforcement must, as far as possible, be applied in a progressive manner, after taking into account the following, with regards to each health establishment-

(a) nature and severity of non-compliance with prescribed norms and standards and the consequences thereof;
(b) the compliance history of the health establishment;
(c) frequency of transgressions in relation to prescribed norms and standards;
(d) any offences by the health establishment in terms of section 89(1)(a) to (c) of the Act; and
(e) any mitigating or aggravating factors.

23. Warning and request for response

(1) The Office may issue a written warning to the person in charge, in terms of section 82A(4)(a) of the Act, for failure to comply with a compliance notice referred to in regulation 21(1)(a).
(2) The person in charge must acknowledge receipt of a written warning referred to in sub-regulation (1), in writing.

(3) A written warning to the person in charge referred to in sub-regulation (1) must be on Form OHSC 8, and include, at a minimum, the following information–

(a) the health establishment to which the warning applies,
(b) prescribed norms and standards that have not been complied with;
(c) the nature and extent of non-compliance;
(d) actions undertaken by the health establishments to remedy non-compliance; and
(e) steps already taken by the Office to ensure compliance.

(4) If the Office issues a written warning to the person in charge, it must request a written response from the person in charge of health establishment in terms of section 82A (4)(b) of the Act, and set a timeframe within which the health establishment must respond and set out the consequences of any failure to respond.

(5) If the person in charge of the health establishment fails to respond to a request for a response referred to in sub-regulation (4), or provides an unsatisfactory response, the Office may, after considering all the factors listed in sub-regulation (3) –

(a) recommend to the relevant authority any appropriate and suitable action, in terms of section 82A(4)(c) of the Act;
(b) initiate a formal hearing to consider a possible revocation of a certificate of compliance or imposition of a fine, in terms of sections 82A(4)(d) and 82A(4)(e)of the Act, respectively; or
(c) refer the matter to the National Prosecuting Authority for criminal prosecution, in terms of section 82A(4)(f) of the Act.

24. Recommendation to relevant authority

If a recommendation was made to the relevant authority in terms of regulation 23(5)(a), the Office must monitor and report to the Minister on the implementation of the said recommendation by the relevant authority.

25. Formal hearing

(1) Before revoking a certificate of compliance or imposing a fine, the Office must notify a 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 to allow the health establishments an opportunity to make representations, before a final decision is taken.

(2) The Chief Executive Officer must appoint a suitable person to preside over the hearing contemplated in sub-regulation (1).

(3) The presiding officer must provide both the Office and the health establishment with, at least,10 working days' written notice to prepare for the hearing and may –

(a) require written representations from both parties to be submitted to him or her, at least,5 working days prior to the hearing;
(b) allow oral testimony to be presented by the parties or any other interested person, upon application, in relation to the matter.

(4) The notice of hearing referred to in sub-regulation (3)must be on Form OHSC 9, and include, at a minimum, the following information:

(a) date, time and place of hearing;
(b) subject matter of hearing;
(c) legal rights of the parties and how to exercise them;
(d) required documents, records, objects or materials, if any, and
(e) consequences of failure to attend the hearing.

(5) The procedure for the conduct of the hearing contemplated in sub-regulation (1) must be determined by the person presiding at the hearing.

(6) The hearing of the matter-

(a) must be conducted expeditiously and in accordance with the principles of natural justice;
(b) may be conducted as informally as possible, consistent with paragraph (a); and
(c) must be open to the public, but the person presiding at the hearing may exclude members of the public, or specific persons or categories of persons, from attending the proceedings–

(i) if evidence to be presented is confidential information, but only to the extent that the information cannot otherwise be protected;

(ii) if the proper conduct of the hearing requires it; or

(iii) for any other reason that would be justifiable in civil proceedings in a High Court.

(7) At the end of the hearing, the person presiding at the hearing may recommend to the Office to revoke or not to revoke the certificate of compliance of the health establishment, or to impose a fine, as the case may be, but not both.

(8) The Office must, within 10 working days after the hearing, make a decision and provide the health establishment with written reasons for any adverse decision.

26. Revocation of certification and recommendation to the Minister

(1) If the health establishment fails to comply with the compliance notice referred to in regulation 21(1)(b), the Office may, after complying with the regulation 25(1), revoke the certificate of compliance of a health establishment and recommend to the Minister a temporary or permanent closure of the health establishment or a part thereof that constitutes a serious risk to public health or the health of users, in terms of section 82A(4)(d) of the Act.

(2) A recommendation to the Minister in terms of sub-regulation (1) must be in writing and include, at a minimum, the following information:

(a) details of non-compliance;
(b) nature and extent of the risk posed to public health or to users,
(c) consequences of continued non-compliance;
(d) period of non-compliance;
(e) an indication of the part or parts of the heath establishment to be closed, and
(f) any other relevant information.

(3) Before exercising his or her powers in terms of sub-regulation (1), the Minister must comply with the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000).

27. Fine

(1) Before imposing a fine in terms of section 82A(4)(e) of the Act, the Office may afford the health establishment an opportunity to submit a request for leniency.

(2) A fine contemplated in section 82A(4)(e) of the Act may not exceed the thresholds determined by the Minister.

(3) In determining the quantum of the fine, the Office must take into account –

(a) the nature and extent of non-compliance;

(b) actions taken by the health establishment to remedy non-compliance;

(c) any requests for leniency presented by the health establishment; and

(d) the potential impact of the fine on the finances of the health establishment.

(4) If the fine is imposed in terms of section 82A(4)(e) of the Act the health establishment must, within 20 working days of the decision, pay such a fine into a designated account.

(5) The Office must establish and maintain a separate banking account for the payment of fines in accordance with the provisions of the Public Finance Management Act, 1999 (Act No. 1 of 1999).

28. Referral to the National Prosecuting Authority

(1) Despite regulation 23, the Office may, at any time, refer the matter to the National Prosecuting Authority for criminal prosecution, in terms of section 82A(4)(f) of the Act, if any failure to comply with a compliance notice issued in terms of the Act is considered to amount to a criminal offence in terms of section 89(1) of the Act.

(2) For the purposes of sub-regulation (1), the Office must prepare and hand over any and all evidence that may be relevant to the prosecution of the health establishment to the National Prosecuting Authority.

29. Appeals

(1) A written appeal to the Minister in terms of section 88A(1)of the Act must be lodged by written notice.

(2) The notice referred to in sub-regulation (1) above must be on Form OHSC 10, and must set out the grounds for the appeal and sufficient information or documentation to support the application for appeal.

(3) The *ad hoc* tribunal contemplated in section 88A(2) of the Act must determine the rules and procedure for the conduct of its proceedings.

(4) The proceedings of the tribunal must be open to the public, but the chairperson of the tribunal may exclude members of the public, or specific persons or categories of persons, from attending the proceedings–

(a) if evidence to be presented is confidential information, but only to the extent that the information cannot otherwise be protected;
(b) if the proper conduct of the hearing requires it; or
(c) for any other reason that would be justifiable in civil proceedings in a High Court.

30. Publication of reports and tribunal decisions

(1) The Office must–

(a) within 25 working days of the issue of the decision, publish the decision of the *ad hoc* tribunal in the government *gazette*;
(b) on a quarterly basis, publish on its website or in any other publication a report covering
(i) inspections conducted with name and location of establishments;
(ii) compliance certificates issued with name and location of establishments;
(iii) hearings conducted with name and location of establishments and outcome;
(iv) recommendations made to relevant authorities in terms of section 79(1)(e);
(v) complaints received and resolved, by category
(c) on an annual basis, publish on its website or in any other publication a report covering
(i) the compliance status of all health establishments; and
(ii) compliance notices achievement record.

PART SEVEN

COMPLAINTS HANDLING AND INVESTIGATION

31. Who can lodge a complaint

(1) Any person may lodge a complaint to the Ombud, in terms of section 81A(1)of the Act, for breach by a health establishment of any prescribe norms or standards.

(2) Any person, a guardian or representative of a person to whom a health service was provided, can lodge a complaint to the Ombud.

(3) A complaint may be lodged in relation to an entity's conduct while the entity was a health establishment, or be dealt with under these regulations as if the entity were still a health establishment.

(4) A complaint may be dealt with by the Ombud despite the death of the relevant person if-

(a) a person dies and, if the person were alive, he or she could make a complaint about a particular matter; or
(b) a person makes a complaint but dies before the complaint is finally dealt with.

(5) If sub-regulation (4)(a) applies, a complaint may be made on behalf of the person.

(6) If sub-regulation (4)(b) applies, the Ombud may, at another person's request, permit the other person to be substituted as the complainant.

(7) If a complaint was lodged in terms of sub-regulation (2) by a representative on behalf of a person to whom a health service was provided, other than under the circumstances contemplated in sub-regulation (4), the Ombud may request the person to whom a health service was provided to confirm the complaint.

32. How to lodge a complaint

(1) A complaint to the Ombud may be lodged-

(a) orally, including by telephone; or
(b) in writing, including by email or other electronic means.

(2) If a complaint is lodged orally, the Ombud must -

(a) make a record of the complaint; and
(b) request the complainant to confirm the accuracy of the recording.

(3) The Ombud must give a complainant reasonable assistance to lodge a complaint, and take necessary measures to ensure reasonable access to the Ombud by the users of health services and other concerned persons.

(4) The complaint must contain adequate information regarding the complaint and the complainant, including the evidence or basis for the complaint, and such other particulars as the Ombud may need to deal with the complaint.

33. Acknowledgement of complaint and request for additional information

(1) The Ombud must acknowledge receipt of a complaint within 48 hours of lodgement of a complaint.

(2) The Ombud may request any additional information from the complainant, to be provided within a reasonable period stated in the request.

(3) The Ombud may not deal with the complaint, or deal further with the complaint, until the complainant complies with a request contemplated in sub-regulation (2), to the extent the complainant is reasonably able to comply therewith.

(4) A complainant's non-compliance with a request may be a ground for a decision to take no further action on the complaint.

34. Screening of complaints

(1) The purpose of the screening is to obtain and analyse information relevant to the complaint and decide the most appropriate way to further deal with it.

(2) The screening may be undertaken in any manner the Ombud considers appropriate, including-

(a) analysing information provided by the complaint;
(b) analysing information obtained in terms of regulation 33(2) from the complainant;
(c) considering submissions received in terms of regulation 36(1) from the complainant or the relevant health establishment or any other person or entity;
(d) communication with the complainant or the relevant health establishment; or
(e) consultation with any person or entity with relevant technical expertise regarding the subject of the complaint.

35 Submissions regarding complaints

(1) The Ombud may give a notice to the complainant or the relevant health establishment, inviting submissions regarding a complaint, to be provided to the Ombud within a stated period.

(2) The period for providing submissions must be reasonable, but must not be more than 10 working days from the date of notice.

(3) The Ombud must consider each submission received within the period referred to in regulation 37(1).

36 Period for completing screening

(1) The Ombud must complete the screening within 15 working days of the lodgement of the complaint or of receiving the additional information terms of regulation 33(2).

(2) The Ombud may extend the period for screening the complaint by a further period of up to 15 working days if necessary due to-

(a) the size or complexity of the complaint; or
(b) the time taken to obtain additional information in terms of regulation 33(2)or submissions in terms of regulation 36(1).

37 Decision following screening

(1) After completing the screening, the Ombud must-

(a) make a decision on whether-
(i) to investigate the complaint;
(ii) refer the complaint to any other statutory authority or other appropriate or suitable body or entity; or
(ii) to take no further action in relation to the complaint; and

(b) give notice of the decision to the complainant and the relevant health establishment, and reasons for the decisions.

38 Cooperation with other entities and reports from health establishments

(1) The Ombud must consult and cooperate with other public entities with functions that are relevant to, or may impact on, the Ombud's functions.

(2) All health establishments must, on an annual basis, submit a report of all complaints they received to the Ombud.

39 Referral from other entities and the public

(1) If the Ombud becomes aware of a particular matter, other than through a formal complaint, by way of a referral from-

(a) a health establishment;
(b) other statutory authority or any other appropriate or suitable body or entity, including the Office; or
(c) in any other manner,

and decides to deal with the matter, the Ombud may, with the relevant person's agreement, deal with the matter as if it were a complaint and the person were the complainant.

40 Decision to take no further action on a complaint

(1) At any time, the Ombud may decide to take no further action on a complaint if the Ombud reasonably considers that-

(a) the complaint-
  (i) is frivolous, vexatious, trivial or not made in good faith;
  (ii) is misconceived or lacking in substance;
  (iii) is being adequately dealt with by another appropriate entity;
  (iv) has been resolved or otherwise appropriately finalised by the Ombud or another appropriate entity;
  (v) despite reasonable efforts by the Ombud or another appropriate entity, cannot be resolved; or
(b) the complainant-
  (i) has failed, without reasonable excuse, to-
    (aa) satisfactorily cooperate with the Ombud to resolve the complaint;

(bb) comply with a request from the Ombud for additional information, evidence or submissions the Ombud needs to properly deal with the complaint.

(2) The Ombud may decide to take no further action on a matter if -

(a) the complaint is withdrawn;

(b) the matter of the complaint arose, and the complainant was aware of the matter, at least 2 years before the complaint was made; or

(c) a complainant, or other relevant person dies and the Ombud reasonably considers it would be appropriate to take no further action.

41 Complaint investigations

(1) The Ombud may decide to investigate-

(a) a matter relating to the breach of norms and standards; or

(c) any other matter, if the Ombud considers an investigation of the matter relevant to achieving the objects of this Act.

(2) The procedure for conducting an investigation shall be such as the Ombud considers appropriate in the circumstances of the case, and in particular, he or she may make such inquiries, as he or she deems fit.

(3) For the purposes of an investigation in terms of these regulations, the Ombud may require any person who in his or her opinion has or is able to supply information, evidence or produce documents relevant to the investigation, to supply any such information, evidence or produce any such document, at a time and place determined by the Ombud.

(4) For the purposes of an investigation contemplated in sub-regulation (1), the Ombud has all powers provided for in section 81A(3) of the Act in respect of the attendance and examination of witnesses, including-

(a) the administration of oaths and affirmations;

(b) the examination of witnesses, and

(b) the production of documents.

42. Notice to health establishment being investigated

The Ombud must notify the relevant health establishment regarding the investigation, before or when the investigation has been started.

43. Progress reports

The Ombud must, at monthly intervals, give notice of the progress of an investigation to-

(a) any health establishment being investigated; and
(b) the complainant.

44. When must an investigation be completed

(1) The Ombud must complete an investigation referred to in regulation 42(1) within a period of 6 months, unless extended, after the decision to carry out the investigation.

(2) The Ombud may extend the period for completing an investigation if the Ombud reasonably considers that, in view of all the circumstances, including the size and complexity of the matters being investigated, it is not possible to properly complete the investigation by the due date.

(3) The period for completing an investigation may be extended more than once, but each extension may not be more than 3 months, provided the total period of investigation does not exceed a maximum of 2 years.

45. Investigations register

(1) The Ombud must keep a register, on a publicly accessible website of the Ombud, of all investigations.

(2) The register must list the following matters for each of the investigations-

(a) type of norm or standard breached;
(b) general nature of the matter being investigated;
(c) date on which it was decided to carry out the investigation;
(d) current due date for completing the investigation;

(e) current status of the investigation; and

(f) reason for each extension of the period of investigation.

(3) The register must not include information that identifies or puts at risk a complainant, health establishment or individual to whom a health service was provided.

46. Report to the Minister

If an investigation is not completed within 2 years after the decision to conduct it, the Ombud must give notice to the Minister stating—

(a) details of the matter being investigated; and

(b) reasons why the investigation has not been completed.

47. Investigation reports

(1) After completing an investigation, the Ombud must prepare a report on the investigation containing his or her findings or recommendations for action.

(2) An investigation report contemplated in sub-regulation (1) must be given to the Chief Executive Officer for appropriate action.

48. Notice of decision after investigating complaint

Within 10 working days after completing an investigation of a matter, the Ombud must inform the complainant and the health establishment of his or her findings and recommendations.

49. Referral to and reports from other statutory authority or other suitable body or entity

(1) When referring the matter, the Ombud must give the relevant authority, body or entity all relevant information that the Ombud has regarding the matter, including, details of the complaint, the complainant and the relevant health establishment.

(2) The statutory authority or other suitable body or entity to which the matter was referred must provide the Ombud –

(c) reports regarding the progress and results of the action taken by the entity regarding the matter;

(d) as soon as practicable and within 25 working days after completing the investigation, a written report of the results of the action taken regarding the matter.

50. Confidentiality of information

Information obtained by the Ombud or his or her officers or agents in the course of or for the purposes of an investigation must not be disclosed, except for the purposes of the investigation and any report to be made in respect of it.

PART EIGHT

GENERAL PROVISIONS

51. Prescribed forms

(1) The forms prescribed for purposes of these regulations are set out in Schedule 1 to these regulations.

(2) Any form that must or may be submitted by any health establishment or user to the Office in terms of these regulations may be submitted electronically.

52. Short title and commencement

These Regulations are called the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and its Board, and come into operation on the date of publication in the *Gazette*.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 12/1/2015

SCHEDULE1

PRESCRIBED FORMS

Form No.	Section No.	Regulation No.	Description
OHSC 1		4(2)	Information about the health establishment
OHSC 2	s80(3)	8(2)	Certificate of appointment as an inspector
OHSC 3		13(2)	Notice of inspection to health establishments
OHSC 4	s84(1)	17(2)	Application for a warrant
OHSC 5	s82A(1)	18(2)	Certificate of compliance
OHSC 6	S79(1)(c)	19(2)	Application for renewal of certification
OHSC 7		21(2)	Compliance notice to health establishments
OHSC 8	S82A(4)(a)	23(3)	Written warning
OHSC 9		25(4)	Notice of hearing
OHSC 10	s88A	29(2)	Notice of appeal

OHSC 1

INFORMATION ABOUT THE HEALTH ESTABLISHMENT

All health establishments and users that are required by the Office to provide information relating to prescribed norms and standards, in terms of section 79(2)(b) of the Act, must do so within a period stated in the specific request for information. If the person in charge, referred to in regulation 6(1), fails to provide the Office with the required information within the specified period, the Office must refer the matter to the head of the national or provincial department of health or the heath department of a municipality or the head of the health establishment, as the case may be, for intervention.

Name of health establishment	
Legal Status	
Details of relevant authority (head of national, provincial or municipal health department, head of the health establishment or private hospital group)	
Physical Address of health establishment	
GPS coordinates - latitude and longitude	
Contact details of the Health Establishment including: telephone email website details	
Name of the person in charge	
Contact details of the person in charge	
Category of health establishment (according to Gazette No 34522) Policy on management of Public Hospitals);	
Health district in which the health establishment falls;	
Services offered by speciality including number of beds by service or number of consulting rooms	

Operating times: In patient unit Outpatient unit Emergency unit Pharmacy	
Human resources. Number of staff by category: Health care professionals Management Administrative Clinical support services	
Results of latest self-assessment against norms and standards	
Chief Executive Officer (*signature*)	Date _____

OHSC 2

CERTIFICATE OF APPOINTMENT AS AN INSPECTOR

This certificate of appointment as an inspector of the Office of Health Standards Compliance is hereby issued in terms of Sections 80 (2) and 80 (3) of the National Health Act,2003 (Act No. 61 of 2003), and Regulations 8, 9 and 10 of the Procedural Regulations pertaining thereto and confirms that the bearer of this certificate meets the minimum requirements set out in Regulation 11 of the Regulations in that he/she is a registered health professional with experience in the delivery of services in hospitals or primary healthcare facilities in the public or private sector and has successfully completed the inspector training programme prescribed by the Office as set out in Regulation 8 of the Regulations.

Name and surname _____ _ _____ _ OHSC Number: _____	*(photograph)*	Date of issued _____ Date of expiry _____ _
Chief Executive Officer *(signature)*	OHSC contact telephone _____ _	OHSC address _____

OHSC 3

NOTICE OF INSPECTION

Purpose of inspection

In terms of Section 82 of the National Health Act, 2003 (Act No. 61 of 2003) and Regulation 13 of the Procedural Regulations, an inspector must issue a notice of inspection to the health establishment at the start of an inspection visit. This inspection is to be carried out in order for duly certified inspectors of the Office of Health Standards Compliance to monitor the degree of compliance with the regulated norms and standards for quality of healthcare as mandated by the National Health Act, 2003 (Act No. 61 of 2003) ("the Act") and the Regulations promulgated to this effect by the Minister of Health on the advice of the Office of Health Standards Compliance.

Responsibilities of the health establishment

The responsibilities of the health establishment during this visit are to make available the necessary staff, resources and space to allow inspectors to complete the inspection in a timely and expeditious manner.

Powers of inspectors

An inspector has powers to collect evidence of compliance in accordance with Section 84 of the Act (set out below for information)

1) *A health officer or inspector may, where necessary, subject to Sections 85 and 86A, enter any premises, including a private dwelling, or health establishment, as the case may be, and—*
   a) *inspect, photograph, copy, test and examine any document, record, object or material, or cause it to be inspected, photographed, copied, tested and examined;*
   b) *seize any document, record, object or material if he or she has reason to suspect that it might be used as evidence in a criminal trial; and*
   c) *examine any activity, operation or process carried out on the premises or health establishment.*
2) *A health officer or an inspector who removes anything from the premises or health establishment being searched, as the case may be, must—*
   a) *issue a receipt for it to the owner or person in control of the premises or health establishment; and*
   b) *unless it is an item prohibited in terms of this Act, return it as soon as practicable after achieving the purpose for which it was removed.*
3) *Upon the request of a health officer or an inspector acting in terms of a warrant issued in terms of Subsection (5), the occupant and any other person present on the premises or*

health establishment, as the case may be, must— *a) make available or accessible or deliver to the health officer or inspector any document, record, object or material which pertains to an investigation or inspection contemplated in Subsection (1) and which is in the possession or under the control of the occupant or other person;* *b) furnish such information as he or she has with regard to the matter under investigation or inspection; and* *c) render such reasonable assistance as the health officer or inspector may require to perform his or her functions efficiently in terms of this Act.* *4) Before questioning any person at the premises or health establishment in question, the health officer, inspector or police official must advise that person of his or her right to be assisted at the time by an advocate or attorney, and allow that person to exercise that right.* According to the above and Regulation 14 (3) of the Regulations, an inspector may, with due regard for the rights of those thus questioned, question any user occupant, health care personnel or any person on the premises.
Right to entry An inspector may, in terms of Section 85 of the Act, enter any health establishment with a warrant, or, in terms of Section 86 of the Act and Regulation 16 of the Procedural Regulations, enter if the head of a national or provincial department of health, the municipal manager or the head of a health establishment or private hospital group identified as the owner and occupier of the health establishment in terms of Section 88(a) of the Act consents to this.

Name of health establishment	
Address of health establishment	
Consent for inspection OR warrant to enter (specify)	
Date of inspection	
Estimated duration of inspection	
Date for reporting and comment	
Number of authorised personnel taking part in the inspection	
Contact details of the inspector primarily	

responsible for the inspection	
The responsibilities of the health establishment.	
Chief Executive Officer (*signature*)	Date _____

OHSC 4

APPLICATION FOR A WARRANT

This warrant for entry and search is applied for in terms of Section 84 (5) of the National Health Act, 2003 (Act No. 61 of 2003) and Regulation17 of the Procedural Regulations issued in terms of this Act. The governing legislation provides in Section 86 for inspection to be authorised by a person competent to do so, but the Office of Standard Compliance hereby seeks a warrant for its certified inspectors to enter the health establishment listed below because such consent has not been obtained in this case.

Name of the health establishment to be inspected	
Address of health establishment to be inspected	
Reasons and motivation for the inspection for which this warrant is sought	
Most recent inspection results available	
Chief Executive Officer *(signature)*	Date _____

OHSC 5

CERTIFICATE OF COMPLIANCE

This certificate of compliance is issued by the Office of Health Standards Compliance in terms of Section 79 (1)(c) and Section 82 (7) of the National Health Act, 2003 (Act No. 61of 2003) and Regulation18 (2) of the Procedural Regulations issued in terms of this Act, whereby the Office must issue such a certificate of compliance to a health establishment that meets all compliance requirements. A Certificate of Compliance remains valid for a period of not more than 4 years before which time the health establishment must apply for renewal, however, the Office may, in terms of Regulation 5 (2)(b) and Regulation 15 of the Procedural Regulations referred to above conduct an additional inspection at any time if it has reason to believe that the establishment is failing to comply with the provisions of the Act. As contemplated in Section 79 (2) (b) of the Act, certified health establishments remain obliged to submit the required reports, information on indicators of risk, and information on changes with respect to the person in charge of the health establishment as specified in Regulations 4,5 and 6 of the Procedural Regulations issued in terms of the Act.

Name of health establishment certified as compliant	
Category of health establishment	
Physical address	
Address for the service of legal processes and notices, (if not the same as physical address)	
Date of inspection	
Chief Executive Officer (*Signature*)	Date of certification Date of expiry of certification

OHSC 6

APPLICATION FOR RENEWAL AND EXTENSION OF CERTIFICATION

Name of health establishment applying for extension of certification	
Address	
Name of person in charge	
Date of last inspection	
Date of certification	
Date of expiry of certification	
Number of certificate	
Person in charge of health establishment *(Signature)*	Date _____
Attachments: 1. Most recent report submitted 2. Last 6 months of reporting on indicators of risk 3. Annual self assessment reports since last inspection 4. Latest quality improvement plan	

OHSC 7

COMPLIANCE NOTICE

A compliance notice is issued to the person in charge of a health establishment in terms of section 82A (1) and (2) of the National Health Act, 2003 (Act No. 61 of 2003), ("the Act") and Regulations 14(7) and 21 of the Procedural Regulations issued in terms of this Act, when the health establishment is found on inspection by the Office of Health Standards Compliance not to be compliant with the prescribed norms and standards contemplated in the Act.

Following an inspection as outlined in Regulation 14 of the Procedural Regulations, the person in charge is given an opportunity to respond to the preliminary findings, after which a compliance notice is issued setting out the details of non-compliance and the requirements and time frames for (a) submission of a quality improvement plan and (b) correction of areas of non-compliance identified.

The penalties that may be imposed by the Office of Health Standards Compliance in the event of continued non-compliance and in terms of Section 82A(4) of the Act are to:

a) issue a written warning to achieve compliance within a set period of time in a manner prescribed;
b) require a written response from the health establishment regarding the continued non-compliance;
c) recommend to the relevant authority any appropriate and suitable action to be undertaken, including the institution of disciplinary proceedings against persons responsible for the non-compliance or continued non-compliance;
d) revoke the compliance certificate and recommend to the Minister the temporary or permanent closure of the health establishment or part thereof that constitutes a serious risk to public health or to health service users;
e) impose upon that person or health establishment a fine as determined by the Minister in the Gazette from time to time; or
f) refer the matter to the National Prosecuting Authority for prosecution.

Name of health establishment	
Address of health establishment	
Name of person in charge	

Contact information of person in charge	
Overall score and compliance status	
Requirements for corrective action	
Name of contact person in OHSC for submission of documentation	
Annexures: 1) Prescribed norms and standards that have not been complied with; 2) details of the nature and extent of non-compliance; 3) steps that are required to be taken and the period over which such steps must be taken	

OHSC 8

WARNING AND REQUEST FOR RESPONSE

The Office of Health Standards Compliance may issue a written warning to the person in charge, in terms of Section 82A(4)(a) of the National Health Act, 2003 (Act No. 61 of 2003), ("the Act") and Regulation 23 (1) and (2) of the Procedural Regulations issued in terms of the Act, for failure to comply with a compliance notice issued in terms of Section 82A of the Act and Regulation 21(1)(a); and the person in charge must in terms of Sub-regulation 23 (2) acknowledge receipt of such written warning in writing.

The Office must furthermore in terms of Section 82A (4)(b) of the Act and Regulation 23 (4) of the Procedural Regulations request a written response from the person in charge of the health establishment, within a specified timeframe set out the consequences of any failure to respond as listed in Section 82A(4) of the Act whereby the Office may:

a) issue a written warning to achieve compliance within a set period of time in a manner prescribed;
b) require a written response from the health establishment regarding the continued non-compliance;
c) recommend to the relevant authority any appropriate and suitable action to be undertaken, including the institution of disciplinary proceedings against persons responsible for the non-compliance or continued non-compliance;
d) revoke the compliance certificate and recommend to the Minister the temporary or permanent closure of the health establishment or part thereof that constitutes a serious risk to public health or to health service users;
e) impose upon that person or health establishment a fine as determined by the Minister in the Gazette from time to time; or
f) refer the matter to the National Prosecuting Authority for prosecution.

Before revoking a certificate of compliance or imposing a fine, the Office must in terms of Regulation 25(1) of the Procedural Regulations notify a health establishment of its intention to revoke the certificate of compliance or to impose a fine, and initiate a hearing to allow the health establishments an opportunity to make representations, before a final decision is taken.

Name of the health establishment	
Address of the health establishment	
Name of the person in charge	

Contact details of the person in charge	
In annexure: 1. Prescribed norms and standards that have not been complied with 2. The nature and extent of non-compliance 3. Actions undertaken by the health establishment to remedy non-compliance	
Steps taken by the Office to enforce compliance.	
Date by which the person in charge must respond to the written warning	
Name and address for response	

OHSC 9

NOTICE OF FORMAL HEARING

Before revoking a certificate of compliance or imposing a fine in terms of Section 82A(4) of the National Health Act, 2003 (Act No. 61 of 2003), ("the Act") and taking into account the nature, extent, gravity and severity of the contravention, the Office must in terms of Regulation 25 of the Procedural Regulations notify a 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 to allow the health establishment an opportunity to make representations, before a final decision is taken. The Chief Executive Officer must appoint a suitable person to preside over the hearing who must provide both the Office and the health establishment with at least 10 working days' written notice to prepare for the hearing, may require written representations from both parties to be submitted to him or her at least 5 working days prior to the hearing; and may allow oral testimony to be presented by the parties or any other interested person, upon application, in relation to the matter.

The hearing in terms of Regulation 25 (6) must be conducted expeditiously and in accordance with the principles of natural justice, and as informally as possible. It must be open to the public unless the person presiding at the hearing determines otherwise based on Regulation 25 (6) (c) of the Procedural Regulations.

Each party shall have the right to legal representation.

In relation to such a hearing, the person in charge of the health establishment has the right to call on any person who may have material information related to the matter to assist in preparing or making a representation in this respect; and to be informed of the permission granted to other interested parties or persons to make representations.

Name of health establishment	
Address of health establishment	
Name of person in charge	
Contact information of person in charge	
Name of relevant authority	
Contact information for relevant authority	
Date, time and place of hearing	
Name and position of presiding officer	
Subject matter of hearing	
Required documents, records, objects or materials	
Date for submission of above	

In annexure: 1. Prescribed norms and standards that have not been complied with 2. The nature and extent of non-compliance 3. Actions undertaken by the health establishment to remedy non-compliance 4. Actions taken by the Office to ensure compliance	

OHSC 10

NOTICE OF APPEAL

In terms of Section 88A of the National Health Act, 2003 (Act No. 61 of 2003), any person aggrieved by any decision of the Office or any finding and recommendation of the Ombud in relation to a matter regulated by this Act, or a person acting on his or her behalf, may within 30 days of gaining knowledge of that decision, lodge a written appeal with the Minister, who must appoint an independent *ad hoc* tribunal to whom the appeal received must be submitted.

Name of establishment	
Address of establishment	
Name of person lodging appeal	
Contact information of person lodging the appeal	
Decision, finding or recommendation against which appeal is being lodged	
Date of such finding, appeal or recommendation	
Grounds for appeal	
In annexure: Any documentation or representations relevant to the appeal	