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***Government Gazette 40350*, Notice 1275, which was published on 13 October 2016, had errors within the gazette, and is hereby replaced with the following:**

DEPARTMENT OF HEALTH

NO. 1365 **02 NOVEMBER 2016**

NATIONAL HEALTH ACT, 2003

PROCEDURAL REGULATIONS PERTAINING TO THE FUNCTIONING OF THE OFFICE OF HEALTH STANDARDS COMPLIANCE AND HANDLING OF COMPLAINTS BY THE OMBUD

The Minister of Health has, after consultation with the Office, made the regulations contained in the Schedule hereto, in terms of section 90(1*)* of the National Health Act, 2003 (Act No. 61 of 2003).

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CHAPTER 1

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–

"category of health establishment" means the category contemplated in section 35 of the Act;

"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;

"early warning system" means the surveillance systems that collect information on serious user-related incidents that prompt interventions by the health establishment, Office or relevant authority;

"head of the health establishment" means the owner and occupier of a health establishment as contemplated in section 88*(a)* of the Act;

"health care service" includes all services dealing with the diagnosis and treatment of disease, or the promotion, maintenance and restoration of health including personal and non-personal health services provided by public and private health establishments;

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

"person" means a legal person, except where the context indicates otherwise;

"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 a provincial department of health, district health authority, municipal authority or executive management of a private hospital or private hospital group;

"self-assessment" means the information or data resulting from an assessment conducted by the health establishment against a tool or framework published by the Office from time to time;

"serious breach" means a breach in safety procedures which results in the user suffering permanent loss of function or death unrelated to natural causes;

"serious risk" means any risk that could have severe negative effects on public health or result in the death of a user or permanent loss of function;

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

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

2. Purpose of Regulations

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

3. Scope and application

(1) Subject to sub-regulation (2), these Regulations apply to all categories of health establishments referred to in section 35 of the Act,

(2) Despite sub-regulation (1), and with the exception of Chapter 7, these Regulations will come into force in relation to each category of health establishment only once the norms and standards for such category of health establishment have been established.

CHAPTER 2

COLLECTION OF INFORMATION AND DESIGNATION OF PERSON IN CHARGE

4. Collection of or request for information

(1) All health establishments and users that are required by the Office to provide information relating to norms and standards, in terms of section 79(2)*(b)* of the Act, must do so by 31 March of each year.

(2) A request for information from health establishments, referred to in sub-regulation (1), must be in writing, and the required information must be in the form of Form 1 and include, at least, the following:

(a) Name of health establishment;
(b) legal status;
(c) physical address;
(d) contact details, including telephone, fax, email and website details, if any;
(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 days and times; and
(j) results of the most recent annual self-assessment against norms and standards.

(3) The Office may publish the request for information, referred to in sub-regulation (2), in the *Government Gazette* or on its public website.

(4) 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.

(5) 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.

(6) 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, the health department of a municipality or health establishment, as the case may be.

(7) For the purposes of sub-regulation (2) **"legal status"** means the status of the health establishment in law, whether it is a private or public company, partnership, trust, sole proprietorship, cooperative or any other legally recognised form.

5. Indicators of risk

(1) In terms of section 79(1)*(d)* of the Act, the Office must monitor indicators of risk in respect of the early warning system and provide guidance to health establishments on the–

(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 must use the information referred to in sub-regulation (1) to–

(a) identify indicators of significant clinical risks to quality and safety, adverse events and healthcare associated infections as part of an early warning system and report serious breaches of norms and standards to the Minister without delay; or

(b) decide on the need for and conduct an inspection as contemplated in regulation 14 or 15, as the case may be.

6. Designation of person in charge

(1) The Office must request the head of the national or provincial department of health or the health department of a municipality or, in the case of a private health establishment, the head of a health establishment or the executive management of a private hospital group to designate as a person in charge of the health establishment the most senior employee in rank, who will deal with all matters relating to 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 delegatees.

(3) The Office must maintain a database of persons in charge, and any changes to the particulars of the person in charge must be submitted by such person to the Office within 20 working days of such a change occurring.

7. Duties of person in charge

(1) The person in charge contemplated in regulation 6(2) 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 norms and standards and implement remedial measures within specified timeframes;

(f) foster a culture of compliance with 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

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

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

CHAPTER 3

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 issued in the form of Form 2, and include, at a minimum, the following information:

(a) The name and surname of the inspector;
(b) a unique identification number supplied by the Office;
(c) the date of issuance;
(d) the address and contact details of the Office;
(e) the signature of the Chief Executive Officer; and
(f) a form of photographic identification.

9. Skills and experience for inspectors

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

(a) be a qualified health professional, who is registered with the Allied Health Professions Council of South Africa, the Health Professions Council of South Africa, the South African Nursing Council, or the South African Pharmacy Council, referred to in the definition of **"statutory health professional council"** in section 1 of the Act;

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

(c) have experience in the delivery of health care services in a public or private health establishment.

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* within three 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 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 least, the following information:

(a) Name and surname of the person rendering assistance;

(b) a unique identification number;

(c) date of issuance;

(d) contact details of the Office;

(e) signature of the Chief Executive Officer; and

(f) 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 on the Office's public website, and include, at least, the following:

(a) An approach to prioritising, scheduling and conducting inspections; and

(b) resources 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.

13. Notice of inspection to health establishments

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

(2) The notice of inspection referred to in sub-regulation (1), must be in the form of Form 3, and include, at least, 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; and

(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 or his or her delegatee.

(4) Despite sub-regulation (1), the Office may, if it has reasonable grounds to believe that compliance with the notification requirements referred to in regulation (1) may jeopardise user safety or quality of care, conduct an unannounced inspection of a health establishment.

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), if applicable;

(b) a certificate of appointment as an inspector, issued in terms of section 80(3) of the Act; and

(c) an entry and search warrant issued in terms of section 84(5) of the Act, if applicable.

(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) An inspector may question any user, occupant, health care personnel or any person on the premises of a health establishment about any information that is relevant to the inspection, or require the person in charge to produce any document, record or material for inspection.

(4) 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.

(5) Within 20 working days of the completion of the inspection, the inspector must provide his or her preliminary findings to the person in charge in writing.

(6) The preliminary findings must–

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

(b) set out the consequences of non-compliance, contemplated in section 82A(2) and (4) of the Act; and

(c) set out the steps that must be undertaken to achieve compliance and timeframes for corrective action.

(7) The inspector must provide the person in charge not more than 20 working days to respond to the preliminary findings in writing.

(8) Within 20 working days of receipt of the response contemplated in sub-regulation 7, the inspector must consider such response and issue a final report to the person in charge.

(9) After issuing a final report contemplated in sub-regulation 8, 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 norms and standards have not been complied with.

15. Additional inspection

(1) 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 by the health establishment, based on the indicators of risk; or

(d) the Ombud's findings demonstrate that continued exposure to the health care services provided by health establishment may pose a severe risk to users or health care personnel.

(2) The provisions of sub-regulation (1) or (4) of regulation 13 apply, with the necessary changes, to an inspection contemplated in this regulation.

CHAPTER 4

INSPECTION OF HEALTH ESTABLISHMENT

16. Information on approach to carrying out inspections

(1) The Office may, within 2 weeks of the beginning of each financial year, inform the head of the national or provincial department of health, the municipal manager or, in the case of the private health establishment, the head of a health establishment or the executive management of a private hospital group, of its approach to carry out inspections.

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

17. Entry, inspection and search warrant

(1) An inspector may, in terms of section 82(1) of the Act, enter any health establishment, at any reasonable time, for purposes of carrying out an inspection contemplated in section 82(1) of the Act.

(2) Where entry into the health establishment as contemplated in sub-regulation (1) is refused, the Office must apply for a warrant in terms of section 84(1) of the Act.

(3) The application for a warrant must include, at least, the following information:

(a) (the name and address of the health establishment to be inspected, and where possible, the area or areas of the health establishment to which the warrant relates;

(b) the legislative provisions governing the inspection;

(c) the reasons and motivation for the inspection; and

(d) (the most recent inspection results, if the establishment had been inspected previously.

(4) Subject to section 84(3) 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 or any person on the premises his or her legal rights, including their right to remain silent or not to incriminate themselves; and

(b) obtained–

(i) written approval from the user, occupant or any person on the premises for the questioning or recording of the interview; or

(ii) verbal approval from the user, occupant or any or person on the premises for the questioning or recording of the interview, in the presence of a witness.

(5) Despite sub-regulation (2), an inspector may enter, inspect and search the health establishment's 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.

CHAPTER 5

CERTIFICATION

18. Certification of health establishments

(1) Within 15 working days of receipt of the recommendation for certification of a health establishment referred to in regulation 14(9)*(a)* or renewal of certification referred to in regulation 19(1), the Office must issue the health establishment that meets all the compliance requirements with a certificate of compliance.

(2) A certificate of compliance referred to in sub-regulation (1), must–

(a) be signed by the Chief Executive Officer and be placed in the public, visible place within the health establishment and posted on its public website; and

(b) be issued in the form of Form 4, and include, at least, the following information:

(i) the name and physical address of health establishment;

(ii) the category of health establishment;

(iii) the address for the service of legal processes and notices, if that address is not the same as the physical address;

(iv) the date of the last inspection; and

(v) the date of expiry of the certificate.

19. Renewal and extension of certification

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

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

(3) A renewal of a certificate of compliance will be based on a recommendation for certification referred to in regulation 14(9)*(a)*, as well as compliance by the health establishment with the requirements contained in sub-regulation (2).

(4) The Office may extend the certification status of the health establishment that has applied for renewal in terms of regulation 19(1) for a period of not 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 certificate

(1) A certificate of compliance issued in terms of regulation 18(2), remains valid for a period of not 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 that certificate of compliance, 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.

CHAPTER 6

COMPLIANCE NOTICE, ENFORCEMENT AND APPEAL

21. Compliance notice to health establishment

(1) An inspector must–

(a) after issuing a final report, issue a compliance notice in terms of section 82A(1) of the Act, to the person in charge, if any 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 and safety of users.

(2) The compliance notice referred to in sub-regulation (1), must be issued in the form of Form 7, and must 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 the health establishment's quality improvement plan that details–

(a) the actions that will be undertaken to achieve compliance with the norms and standards; and

(b) the 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. Compliance 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 their approval by the Board.

(3) Compliance 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) The nature and severity of non-compliance with the norms and standards and the consequences thereof;

(b) the compliance history of the health establishment;

(c) frequency of transgressions in relation to the norms and standards;

(d) any offences by the health establishment in terms of section 89(1) of the Act; and

(e) any mitigating or aggravating factors.

23. Written warning

(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) A written warning to the person in charge referred to in sub-regulation (1) must be issued in the form of Form 8, and must include, at least, the following information:

(a) The name of the person to whom it is addressed and the date;

(b) the health establishment to which the warning applies;

(c) the norms and standards that have not been complied with;

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

(e) the actions to be undertaken by the health establishment to remedy non-compliance; and

(f) the steps already taken by the Office to ensure compliance, if applicable.

24. Request for response

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

(2) The person in charge must acknowledge receipt of a written warning referred to in sub-regulation (1), in writing.

(3) If the person in charge fails to respond to a request for a response referred to in sub-regulation (1), or provides an unsatisfactory response, the Office may–

(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.

25. Monitoring of recommendations to relevant authority

If a recommendation is made to the relevant authority in terms of regulation 24(3)*(a)*, the Office must monitor and report to the Minister on the implementation of the said recommendation by the relevant authority.

26. Formal hearing

(1) Before revoking a certificate of compliance or imposing a fine, the Office must notify the person in charge of the health establishment and the relevant authority 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.

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

(3) The person contemplated in sub-regulation (2) may appoint not more than 2 persons with technical expertise on the relevant subject as his or her assistants, as may be required.

(4) 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.

(5) The notice of hearing referred to in sub-regulation (1) must be issued in the form of Form 8, and include, at least, the following information:

(a) The date, time and place of the hearing;

(b) the subject matter of the hearing;

(c) the legal rights of the parties and how to exercise them;

(d) the required documents, records, objects or materials, if any; and

(e) the consequences of failure to attend the hearing.

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

(7) The hearing of the matter–

(a) must be conducted expeditiously and in compliance with the principles of administrative justice, set out in the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000);

(b) may be conducted in an informal manner, consistent with paragraph *(a)*; and

(c) must be open to the public: Provided that 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 Court.

(8) 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.

(9) The Office must, within 10 working days after the hearing, make a decision and provide the person in charge of the health establishment and the relevant authority with written reasons for any adverse decision.

(10) For the purposes of this regulation **"suitable person"** means a person who has extensive knowledge and experience in the administration of law and the norms and standards for the health establishments as well as the general laws and regulations applicable to the health care sector.

27. Revocation of certification and recommendation to Minister

(1) If a health establishment fails to comply with the compliance notice referred to in regulation 21(1)*(b)*, the Office may, after complying with regulation 26(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 least, the following information:

(a) the details of non-compliance;

(b) the nature and extent of the risk posed to public health or to users;

(c) the period of non-compliance;

(d) the consequences of continued 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).

28. Fine

(1) Before imposing a fine in terms of section 82A(4)*(e)* of the Act, and after complying with regulation 26(1), the Office must afford the person in charge of 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) the 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 banking account contemplated in sub-regulation (5).

(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).

29. Referral to 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.

30. Appeal against decisions of Office or Ombud

(1) An 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) must be in the form of Form 9, 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 Court.

31. 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* and on its public website;

(b) every six months, publish on its public website and in any other appropriate publication platform, a report which covers all the–

(i) inspections conducted, with the names and location of the health establishments;

(ii) compliance certificates issued, with the names and location of health establishments;

(iii) hearings conducted, with the names and location of health establishments and the outcome of the hearings;

(iv) the recommendations made to the relevant authorities in terms of section 79(1)*(e)*; and

(v) complaints received and resolved by the Ombud, by category.

(c) on an annual basis, publish on its public website and in any other any appropriate publication platform, a report which–

(i) sets out the compliance status of all health establishments; and

(ii) summarises the number and nature of the compliance notices issued.

CHAPTER 7

COMPLAINTS HANDLING AND INVESTIGATION

32. Who may lay complaint

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

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

(3) A complaint may be dealt with by the Ombud despite the death of the person contemplated in sub-regulation (2), if–

(a) a person dies and, if the person were alive, he or she could lay a complaint about a particular matter; or

(b) a person makes a complaint but dies before the complaint is finally dealt with.

(4) If sub-regulation (3)*(a)* applies, a complaint may be laid on behalf of the person.

(5) If sub-regulation (3)*(b)* applies, the Ombud may, at another person's request, permit the other person to be substituted as the complainant.

(6) If a complaint is laid in terms of sub-regulation (2) by a representative on behalf of a person to whom a health care service was provided, other than under the circumstances contemplated in sub-regulation (3), the Ombud may request the person to whom a health care service was provided to confirm the complaint.

33. How to lay complaint

(1) A complaint to the Ombud may be laid–

(a) orally, including by telephone; or

(b) in writing, including by email or other electronic means.

(2) If a complaint is laid 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 lay a complaint, and to take necessary measures to ensure reasonable access to the Ombud by the users of health care services and other concerned persons.

(4) The complaint must contain adequate information regarding the complaint including, at least, the contact details of the complainant or his or her representative, and the evidence or basis for the complaint, and such other particulars as the Ombud may require to deal with the complaint.

34. Acknowledgement of complaint and request for additional information

(1) The Ombud must acknowledge receipt of a complaint within 48 hours of the laying of a complaint, in an appropriate manner.

(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.

35. 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 deal with it further.

(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 34(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;

(d) communication with the complainant or the relevant health establishment; or

(e) consultation with any person or entity with relevant technical knowledge or expertise regarding the subject of the complaint.

36 Submissions regarding complaints

(1) The Ombud may give 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 may not be more than 20 working days from the date of notice.

(3) The Ombud must consider each submission received within the period referred to in regulation 36(1).

37 Period for completing screening

(1) The Ombud must complete the screening within 15 working days of the laying of the complaint or of receiving the additional information in terms of regulation 34(2).

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

(a) the size or complexity of the complaint; or

(b) the time taken to obtain additional information in terms of regulation 34(2) or submissions in terms of regulation 36(1).

38. Decision following screening

Upon completion of the screening, the Ombud must–

(a) make a decision on whether–

(i) to investigate the complaint;

(ii) to refer the complaint to any other statutory authority or other appropriate or suitable body or entity; or

(iii) to take no further action in relation to the complaint;

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

39. Cooperation with other entities

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

40. Referral from other entities and the public

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 consent, deal with the matter as if it were a complaint and the person were the complainant.

41. Decision to take no further action on 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; and

(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; and

(bb) comply with a request from the Ombud for additional information, evidence or submissions the Ombud needs to deal properly 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 from which the complaint arose, and the complainant was aware of the matter, at least 2 years before the complaint was laid; or

(c) a complainant, or other relevant person dies and the Ombud reasonably considers that no further action is necessary.

42. Complaint investigations

The procedure for conducting an investigation must 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 and must be in line with the applicable legislation.

43. Notice to health establishment being investigated

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

44. Progress reports

The Ombud must, every two months, give notice of the progress of an investigation to–

(a) any health establishment being investigated; and

(b) the complainant.

45. Period for completing investigation

(1) The Ombud must complete an investigation referred to in Regulation 42 within a period of 6 months, unless extended in terms of sub-regulation (2), 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 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 the investigation does not exceed 2 years.

46. Investigations register

(1) The Ombud must keep a register, on its public website, of all investigations.

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

(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 person to whom a health care service was provided.

47. Report to Minister

(1) 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) the details of the matter being investigated; and

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

(2) The Minister may make any decision regarding the matter, including a decision to–

(a) close the matter;

(b) extend the investigation for a specified period; or

(c) refer the matter to another statutory authority, body or entity.

48. Notice of decision after investigating complaint and investigation report

Within 10 working days after completing an investigation contemplated in regulation 42, the Ombud must–

(a) inform the complainant and the health establishment of his or her findings and recommendations, in accordance with section 81A (11) of the Act; and

(b) submit a report containing his or her findings and recommendations to the Chief Executive Officer, in accordance with Section 81A(9) of the Act, for appropriate action.

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

(1) When referring the matter, the Ombud must give the relevant statutory authority, or other appropriate and suitable 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 appropriate and suitable body or entity to which the matter was referred must provide the Ombud–

(a) written reports regarding progress on the matter, at regular intervals; and

(b) within 25 working days after completing the investigation, a written report of the results of the action taken regarding the matter.

(3) For the purposes of this regulation **"statutory authority"** means any authority established by or under a provincial or national legislation.

50. Confidentiality of information

(1) Information obtained by the Ombud or persons designated in terms of section 81(3)*(c)* of the Act in the course of or for the purposes of an investigation may not be disclosed to any third party, except for the purposes of the investigation and any report to be made in respect thereof.

(2) A health establishment may, by written notice explaining why the information is confidential, claim any information to be confidential.

(3) The Ombud must, within 10 working days of receipt of the notice referred to in sub-regulation (2), determine whether or not the information is confidential, and if the Ombud finds that the information is confidential, make any appropriate order concerning access to that information.

(4) The health establishment may, within 10 working days of the determination of the Ombud in terms of sub-regulation (3), lodge an appeal against such determination or an order contemplated in sub-regulation (3), to the Minister in terms of section 88A of the Act.

CHAPTER 8

GENERAL PROVISIONS

51. Prescribed forms

(1) The forms prescribed for purposes of these Regulations are set out in the Annexure 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 Handling of Complaints by the Ombud, and come into operation on the date of publication in the *Gazette*.

ANNEXURE

PRESCRIBED FORMS

Form No.	Section No.	Regulation No.	Description
OHSC 1		4(2)	Health establishment information
OHSC 2	80(3)	8(2)	Certificate of appointment as an inspector
OHSC 3		13(2)	Notice of inspection to health establishments
OHSC4		18(1)	Certificate of compliance
OHSC 5	79(1)*(c)*	19(2)	Application for renewal of certification
OHSC 6	82A(1)	21(2)	Compliance notice to health establishments
OHSC 7	82A(4)*(a)*	23(2)	Written warning
OHSC 8		26(5)	Notice of hearing
OHSC 9	88A	30(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 norms and standards, in terms of section 79(2)(b) of the National Health Act,2003 (Act No. 61 of 2003), must do so by 31 March of each year. 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 relevant 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 in accordance with the intervention policy and procedure of the relevant authority.

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 no. e-mail address website details	
Name of the person in charge	
Contact details of the person in charge	
Category of health establishment (according to Policy on Management of Public Hospitals published in *Government Gazette* No 34522 of 12 August 2011);	
Health district in which the health establishment falls	
Services offered by speciality, including number of beds by service or number of consulting rooms	
Operating days and 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 the most recent 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 section 80(2) of the National Health Act, 2003 (Act No. 61 of 2003), read together with regulation 8 of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud

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

OHSC 3

NOTICE OF INSPECTION

Purpose of inspection *In terms of regulation 13 of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud, an inspector must issue a notice of inspection to the health establishment at any time, before commencing with an inspection contemplated in section 82 of the Act. The purpose of inspection is for duly certified inspectors of the Office of Health Standards Compliance to monitor the degree of compliance with the 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 pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud.* ***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 *In terms of section 82(1) of the Act, an inspector may enter any health establishment at any reasonable time, and-* *(a) inspect such a health establishment, as the case may be, in order to ensure compliance with the Act;* *(b) question any person who her or she believes may have information relevant to the inspection;* *(c) require the person in charge of the health establishment to produce, for inspection or for the purpose of obtaining copies or extracts thereof or therefrom, any document, including a health record contemplated in Section 15 of the Act, which such a person is required to maintain in terms of the law.* *(d) take any samples of any substance or photographs relevant to the inspection.*

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 comments	
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

CERTIFICATE OF COMPLIANCE

This certificate of compliance is issued by the Office of Health Standards Compliance in terms of section 82(7) of the National Health Act, 2003 (Act No. 61 of 2003) as read with regulation18(1) of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud (the Regulations) *A Certificate of Compliance is valid for a period of not more than 4 years, before which time the health establishment must apply for renewal. The Office may, however, in terms of regulation 15(1) of the Regulations, 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.*

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

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OHSC 5

APPLICATION FOR RENEWAL AND EXTENSION OF CERTIFICATION

In terms of section 82(7) of the National Health Act, 2003 (Act No. 61 of 2003) as read together with regulation 19 of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud (the Regulations), an application for renewal of a certificate must be submitted to the Office, within a period of not more than six months before the expiration of the certificate of compliance. This certificate will be renewed following an inspection as set out in regulation 14, provided that the Office may extend the certification for up to 1 year pending an inspection. .

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	
Certificate number	
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. Most recent quality improvement plan	

OHSC 6

COMPLIANCE NOTICE

A compliance notice is issued to the person in charge of a health establishment in terms of section 82A(1) of the National Health Act, 2003 (Act No. 61 of 2003), ("the Act") as read together with regulation 21(1) of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud (the Regulations, when the health establishment is found on inspection by the Office of Health Standards Compliance not to be compliant with the norms and standards contemplated in the Act.

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

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. 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 7

WRITTEN WARNING

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") as read together with *regulation 23(1) and (2) of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud (the Regulations, for failure to comply with a compliance notice issued in terms of section 82A of the Act as read with regulation 21(1) of the Regulations*

Name of the health establishment	
Address of the health establishment	
Name of the person in charge	
Contact details of the person in charge	
Annexures: 1. 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 already taken by the Office to ensure compliance.	
Date by which the person in charge must respond to the written warning	
Name and address for response	

OHSC 8

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"), the Office must, in terms of regulation 25 of the Procedural Regulations pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud ("the 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.

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	
Annexures: 1. 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 9

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	