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DEPARTMENT OF HEALTH

No. R. 109 **18 February 2015**

NATIONAL HEALTH ACT, 2003

NORMS AND STANDARDS REGULATIONS IN TERMS OF SECTION 90 (1)(b) AND (c) OF THE NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003), APPLICABLE TO CERTAIN CATEGORIES OF HEALTH ESTABLISHMENTS

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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CHAPTER 1

Definitions, Purpose and Application

Definitions

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 –

"adverse event" means an incident in which harm resulted to a person receiving health care consequent on the care provided and not due to the underlying health condition;

"catchment area" meansthe delineated areas which the health establishment serves;

"Antimicrobial Stewardship Programme" means a programme implemented in a health service organisation to reduce the risks associated with increasing microbial resistance and to extend the effectiveness of antimicrobial treatments;

"clinical risks" means the chance of an adverse outcome resulting from clinical investigations, treatment or patient care;

"clinical outcome" means the end result of a medical intervention, such as survival or improved health;

"environmental hazards" means the source of or exposure to danger within the surroundings within which humans exist;

"executive management" includes the chief executive officer, human resource manager, financial manager, nursing service manager, information manager and clinical director or their equivalent;

"Hazardous Substances Act" means the Hazardous Substances Act, 1973 (Act No. 15 of 1973);

"high risk users" include vulnerable and high clinical risk users such as pregnant women, newborns, infants and children, patients with Tuberculosis, HIV, Trauma and emergency and critically ill patients in intensive care;

"Human Tissue Act" means the Human Tissue Act, 1983 (Act No. 65 of 1983);

"management" refers to executive management and all heads of departments, including clinical and non clinical service areas of a health establishment;

"National Environmental Management: Waste Act" means the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008);

"notifiable conditions" means those conditions that are required by law to be reported to relevant authorities for purposes of disease control;

"outreach services"means clinical services provided from higher levels of care to lower levels of care and may include specialists providing services at clinic level or professional nurses providing services to satellite clinics or with community based workers;

package of services" includes clinical services as approved by the relevant authority, in line with the category of health establishment as contemplated in section 35 of the Act.

"person-in charge" means a person designated by the relevant authority, as a person in charge of a health establishment;

"public health" means the science and practice of protecting and improving the health of a community by preventive medicine, health education, control of communicable diseases, application of sanitary measures, and monitoring of environmental hazards;

"priority health conditions" means conditions designated by the Minister as high priority for focus, including mother and child health, Tuberculosis, HIV, Trauma and chronic diseases;

"quality improvement" means the combined and continuousefforts of health care providers to make the changes that will lead to better patient outcomes and experience, better system performance and better health provider development;

"quality forum" means a platform or structure for meetings and discussions of issues of common interest relating to quality;

"relevant authority" refers to provincial department of health, district health authority, municipal authority or other equivalent authority in the private sector;

"scope of practice" means the procedures, actions, and processes that are permitted by the relevant health professional councilfor that category of health care provider;

"services areas" means areas where users receive care such as medical ward, outpatients department or clinical support service areas such as radiology or physiotherapy;

"standard precautions" means a group of infection prevention practices that all health care personnel have to employ in the management of all users so as to protect themselves and the users from acquiring infections;

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

"vulnerable users" include the disabled, mentally disabled, orphans, elderly, reduced mobility, frail, terminally ill, HIV infected, foreignersand refugees.

Scope and Application

2. These regulations apply to the following health establishments, subject to the limitations and alternative requirements set out in Schedule 1 to these regulations:
   (a) Public hospitals;
   (b) Public clinics;
   (c) Public Community health centres;
   (d) Private acute hospitals; and
   (e) Private primary health clinics.

3. These regulations will apply to other categories of health establishments contemplated in section 35 of the Act, once the Minister has prescribed specific norms and standards for such categories.

Purpose of the regulations

4. The purpose of these regulations is to guide, monitor and enforce the control of critical risks to the health and safety of users by means of the required systems and relevant supportive structures within different categories of health establishments, in order to provide safe quality services to the citizens.

Chapter 2

Patient Rights

Respect, Dignity and Caring attitudes

5.(1) Thehealth establishment must protect the rights of users and ensure that they are treated with respect and dignity as espoused in the South African Patients Rights Charter.

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(2) For the purposes of sub-regulation (1), the health establishment must ensure that its health care personnel:

(a) Demonstrate caring attitudes and treat users and their families with courtesy and empathy;
(b) Dress in a manner that allows the user to identify the health care personnel;
(c) Display their institutional name tags at all times;
(d) Care for users in a manner that promotes their privacy and dignity; and
(e) Provide users with information on their rights and responsibilities.

Information for users

6.(1) The health establishment must ensure that users are provided with information on how to access the facility and for which services they can seek care, to prevent unnecessary delays in care.

(2) For the purposes of sub-regulation (1), the health establishment must provide -

(a) users with information relating to the services, service operating times and visiting hours of the health establishment;
(b) users with information on the result of patient satisfaction surveys and waiting times;
(c) users with information on the policies from the relevant authority for admission to inpatient services or entry to outpatients services;
(d) clear signage to the facility from major access points outside the premises of the health establishment;
(e) clear signage and direction to the services or areas within the health establishment; and
(f) a clearly identifiable person/s to assist users to access the services.

7.(1) The health establishment must ensure that users, including vulnerable users, are informed of their health status and treatment plans in a respectful manner to promote the users' active participation and responsibility for their care.

(2) For the purposes of sub-regulation (1), the health establishment must document that it has -

(a) provided users and their families with information on their rights and responsibilities;
(b) provided users and their families with information relating to their treatment, on-going care or referral;
(c) documented the users' and their families' preferences and choices for care which takes into account their cultural and religious preferences;

(d) provided users with the necessary discharge report containing such information as prescribed in terms of section 10 of the Act; and

(e) provided users with the information they need to-

(i) understand the risks of the treatment or procedure they are to undergo;

(ii) understand they have the right to refuse treatment and the consequences of that refusal; and

(ii) protect their rights if they participate in research.

Healthy, safe, and clean environment

8.(1) The health establishment must ensure that users are treated in a healthy, safe, and clean environment that promotes confidence in the care provided.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that public areas, buildings and grounds are kept clean and well maintained;

(b) On a quarterly basis, monitor user satisfaction regarding the safety and cleanliness of the health establishment;

(c) Provide functional and clean ablution and hand washing facilities for in-patients and outpatients,to maintain their personal hygiene and dignity; and

(d) Ensure that the buildings and grounds that the users need to access are easy and safe to access.

Continuity of care

9.(1) The health establishment must maintain a system of referral and discharge planning for further care which protects users from unnecessary costs and promotes continuity of care.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Develop and implement a system for referral and discharge planning based on the policies of the relevant authority;

(b) Provide users with information to enable continued care in the referral health establishment;

(c) Monitor referrals to identify trends and gaps in the system and suggest improvements to the relevant authority;

(d) Ensure that users are referred to a named healthcare provider or department within a health establishment; and

(e) Ensure that the discharge of users is planned in conjunction with referral Health Establishmentor other health service providers or other sectors.

Reducing delays in care

10.(1) The health establishment must ensure that users are attended to in accordance with the nature and severity of their condition, to reduce delays in accessing care.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Manage queues in waiting areas and report waiting times to users on a daily basis;

(b) Implement a system of retrieving health records;

(c) Provide users with information on how to report delays in accessing services;

(d) Monitor and analyse trends in waiting times on a monthly basis, and report to management structures or quality forum; and

(e) Implement improvements in waiting times.

(3) For the purposes of this regulation "waiting time" means time from the arrival of a user in the health establishment to-

(a) retrieving their health records;

(b) being triaged in emergency room;

(c) seeing the health care provider in outpatients or emergency room;

(d) receiving their medication; and

(e) being admitted to the health establishment.

11.(1) The health establishment must ensure that users booked for procedures, surgery or outpatient services receive these services within agreed timeframes to prevent delays in treatment and to protect users from morbidity and mortality.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Monitor and manage waiting lists for elective procedures;

(b) Monitor and manage waiting lists for users who are accessing outpatient services at higher levels of care;

(c) implement measures to reduce waiting lists; and

(d) Monitor and manage that in-patients referred for specialist care receive the needed service.

(3) For the purposes of this regulation-

(a) "waiting lists"means lists of names of users requiring elective procedures or outpatient services; and

(b) "elective procedures" means non emergency procedures where the user has a choice or option to have the procedure performed or not.

Users with disabilities

12.(1) The health establishment must ensure that users with disabilities are able to access services in the health establishment.

(2) For the purposes of sub-regulation (1), the health establishment must ensure that -

(a) the health establishment is easy to access for patients with physical, sight and hearing disabilities;

(b) there are functional ablution and hand washing facilities for all in-patients and outpatients with disabilities to maintain their personal hygiene and dignity; and

(c) it provides information, in an accessible manner to users with sight or hearing disabilities.

Access to range of services including emergency care

13.(1) The health establishment must provide emergency services at its designated level of care to prevent harm to users.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that-

(i) it can access emergency patient transport for users requiring urgent transfer;

(ii) users presenting in an emergency and requiring referral out of the health establishment are stabilised first ;

(iii) it receives information regarding the non availability of referral level services in order to ensure availability of resources to cater for the potential extra workload;

(b) Communicate with the relevant authority if it fulfils the criteria for diversion of a serviceas applicable to the category of health establishment; and

(c) Implement plans and protocolsto ensure that users can access emergency services they require through agreements with other establishments, if the health establishment is unable to provide the service.

14.(1) The health establishment must provide services that are appropriate to the category of the health establishmentas contemplated in section 35 of theAct, to ensure availability of services.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Provide services that are appropriate to the category of the health establishment within the stated service hours;

(b) Provide essential equipment to deliver the services that are appropriate to the category of the health establishment;

(c) Ensure provision of the essential medicines in accordance with the essential medicines list or formulary to deliver the services that are appropriate to the category of the health establishment;

(d) implement plans and protocols to ensure that users can access the stipulated services through agreements with other establishments if the health establishment is unable to provide the service;

(e) Monitor the–

(i) availability of services annually;
(ii) utilisation of services annually;and

(f) Develop plans to adjust services to meet the needs of the population.

User experience

15.(1) The health establishment must monitor user satisfaction on a quarterly basis to ensure that safety and quality of health services meets the requirements set out in these regulations and that users needs for a safe, quality healthcare service are met.

(2) For the purposes of sub-regulation (1), the health establishment must

(a) Establish and maintain systems that allow users to provide feedback or suggestions;
(b) Ensure that users are provided with information on how to give feedback or suggestions;
(c) On a quarterly basis, obtain and utilise user and health care personnel feedback from satisfaction surveys, compliments and suggestions for improvement of services; and
(d) Display the results of user and health care personnel feedback on a quarterly basis.

16.(1) The health establishment must ensure that users and their families are able to contribute to an improvement in the acceptability, quality and safety of their care and services through the lodging of complaints.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that users, and their families-

(i) are provided with information on how to lodge a complaint, and

(ii) are provided with the means to lodge a complaint, and

(b) Maintain a forum or structure that investigates, analyses, monitors and acts upon complaints to improve care and services.

17.(1) The health establishment must ensure that all complaints are managed in accordance with the complaints management protocol, and feedback is given to the complainant upon resolution of the matter.

(2) For the purposes of sub-regulation (1) the health establishment must:

(a) Ensure that complaints are-

(i) recorded in a formal manner;

(ii) classified according to severity;

(b) Ensure that clinical adverse events are identified and dealt with urgently by the health care personnel;

(c) Provide users ortheir families with acknowledgement of receipt of their complaint within specified timeframes;

(d) Investigate complaints to determine the root causes and corrective actions required; and

(e) Provide users with information regarding progress in the resolution of their complaint within specified timeframes, according to the severity.

Chapter 3

Clinical Governance and Clinical Care

User Health records

18.(1) The health establishment must maintain health records of the care provided to users in order to protect them against the risks of unsafe or inappropriate care and promote the continuity and effectiveness of care.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Record necessary registration, identification and contact information about the user and their next of kin;

(b) Ensure that-

(i) all contacts with the health establishment are recorded;

(ii) user admissions are coded and billed according to the relevant tariff; and

(iii) Health records areaccessible, and kept strictly confidentialand secure in the service areas;

(c) Ensure that the initial and subsequent assessments of the user are performed by the relevant health care provider in accordance with the assessment policy of the health establishmentand the respective service area;

(d) Record the clinical assessment and diagnosis in the user's health record when they present at the health establishment;

(e) Ensure that health records contain-
  (i) details of the user's care plan, desired results of treatment and implementation thereof, including the monitoring of responses to treatment;
  (ii) all documentation relating to the user's care, diagnostic investigations, treatment and progress reports;
  (iii) a documentation of the name of the mainhealth care provider responsible for the treatment of the user;
(f) Obtain and record, in accordance with the health establishment's protocols-
  (i) informed consent from the user or in the case of a minorfrom a guardian, parent or caregiver of the user;
  (ii) users and their families instructions in relation to resuscitation and end of life care;
(g) Issue a discharge report to users in accordance with section 10 of the Act;
(h) Ensure that a referral note is issued to the user, if necessary; and
(i) Correctly identify users and their health records, including in circumstances when the user is unable to confirm his or her identity.

Reliability of clinical management of national priority health conditions

19.(1) The health establishment must improve the consistency and reliability by which patients receive care that promotes optimal clinical outcomes.

(2) For the purposes of sub-regulation (1) the health establishment must:

(a) Ensure that clinical guidelines for priority health conditions are available and communicated to health care personnel including provision of in-service training on the guidelines to maintain staff proficiency
(b) Ensure that the delivery of care follows best practice by auditing the health records of users on a quarterly basis to establish whether-
  (i) diagnostic investigations and treatment planned follows the condition-specific guidelines;
  (ii) the progress of the users towards the desired outcomes is monitored and reassessed if needed
  (iii) escalations in care or revisions to care plansoccurred according to the condition–specific guidelines;
(c) Ensure that users at risk of non communicable diseases and communicable diseases are screened and diagnosed to detect disease early;

(d) Ensure that users with non communicable diseases and communicable diseases are monitored and supported to successfully complete their treatment regimen; and

(e) Monitor the clinical outcomes of the national priority health conditions and implement improvement initiatives to optimiseoutcomes

Clinical leadership and clinical risk

20.(1) The health establishment must design, implement and monitor quality and safety programmes in the clinical areas to protect and promote the health and safety of users.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that the clinical leadership team is functional with clear roles and responsibilities for ensuring quality care and user safety;

(b) Perform clinical audits of users health records on a quarterly basis to –

(i) ensure that care was administered in accordance with the nursing care plan and doctors instructions;

(ii) establish whether diagnostic investigations and treatment planned were provided according to instructions;

(iii) develop quality improvement plans to address shortcomings or improve competency of health care providers

(c) Maintain multidisciplinary fora and peer review structures that-

(i) analyse, monitor and act upon general quality and user safety data;

(ii) monitor and oversee interventions to improve the use of antimicrobials as part of an Antimicrobial Stewardship Programme;

(iii) oversee the selection, prescribing, dispensing, administration and use of medicines as part of an Pharmaceutical and Therapeutics Programme;

(iv) resolve ethical dilemmas relating to withdrawal of treatment, end of life care and treatment of patients against their wishes;

(d) Report indicators of significant clinical risks to quality and safety to the relevant authority;

(e) Develop and implement quality improvement plans in response to quality and user safety data;

(f) Monitor quality improvement plans against service delivery targets and communicate improvements and compliance to health care personnel;

(g) Implement a formal supervision programme for health care providers aimed at improving patient safety in the service areas;

(h) Provide health care personnel with an orientation, training and formal supervision programme on quality improvement; and
(i) Ensure that research conducted follows ethical guidelines.

21.(1) The health establishment must identify reasonably foreseeable hazards that could give rise to risks to the health and safety of users and health care personnel and establish and maintain safety procedures to minimise these risks.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Disseminate and implement a clinical risk management policy from the relevant authority which directs the context and scope of clinical risk and the roles and responsibilities for management of risk;
(b) Identify and analyse user and health care personnel safety hazards in every service area and grade them based on severity;
(c) Implement a risk management plan for each identified risk and monitor controls; and
(d) Provide health care personnel with an orientation, training and formal supervision programme on user safety, risk identification and mitigation strategies.

22.(1) The health establishment must prevent or reduce adverse events, to safeguard users against the risks associated with unsafe and inappropriate care.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Develop a protocol that outlines its approach to identifying and monitoring adverse events and near misses;
(b) Maintain a surveillance system to collect, categorise and analyse;
(c) Report on adverse events to the relevant authorities;
(d) Investigate adverse events to determine the root causes and corrective actions required within specified timeframes according to the severity;
(e) Implement protocols for informing users if they have been involved in an adverse event; and
(f) Use the information relating to adverse events to make changes to processes, systems and behaviours to minimise or mitigate against adverse events.

23.(1) In addition to the criteria in regulations 21(2) and 22(2) the health establishment must, for the purposes of regulations 21 and 22 undertake the following further processes:

(2) Maintain and implement processes for the identification, assessment and treatment of high risk and vulnerable users, including processes-

(a) for the handover of users between shifts;
(b) for monitoring and supervision of users being transferred to the health establishment and within thehealth establishment;
(c) for assessing users in intensive care, trauma and specialised units and implementing treatment;
(d) for assessing acutely ill and injured users and implementing treatment;
(e) to identify clinical deterioration in users and implementing treatment;
(f) to protect high risk maternity users and their babies;
(g) to protect mental health care users from abuse or injury;
(h) to protect vulnerable users from the risk of injury, neglect or abuse; and
(i) to train health care personnel, users and their families on how to identify risk, report abuse and prevent harm in vulnerable patients.

(3) For the purposes of sub-regulation (2)-

(a) "abuse" includes-
(i) sexual abuse;
(ii) physical or psychological ill-treatment; and

(b) "neglect" includes acts of omission which cause harm to a user or place the user at risk of harm.

(4) Maintain measures and processes to protect users undergoing high risk procedures, including-
(a) processes to guide the safe-
(i) administration of medication;
(iii) injection practices;
(b) safety measures which are carried out before, during and after surgery;
(c) processesthat guide the safe execution of invasive procedures;
(d) process that ensure users requiring resuscitation receive an immediate response by life-support trained health care personnel; and
(e) processes to ensure that blood and blood products are ordered, handled and administered safely.

(5) For the purposes of sub-regulation (3):

(a) "surgery" refers to a procedure that takes place in an operating room, where the surgeon makes at least one incision through the skin or mucous membranes and the incision is closed before the patient leaves the operating room;
(b) "invasive procedure" refers to a medical procedure in which a part of the body is entered, as by puncture or incision, such as repairing of cuts, insertion of tubes or drains; and
(c) "incision" means a cut.

Prevention and control of infections

24.(1) The health establishment must implement an infection prevention and control programme to reduce health care associated infections.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Develop a protocol and plan that outlines its approach to the monitoring and management of health care associated infection;
(b) establish an infection prevention and control forum which oversees all aspects of infection prevention and control and follows up thatappropriate actions are taken to reduce infection rates;
(c) appoint a trained health care provider to oversee the infection control programme;
(d) Assign infection, prevention and control duties to teams or individuals responsible for the daily infection, prevention and control activities in the service areas;
(e) Maintain a formal surveillance and reporting system to identify and track infections;
(f) Report information on health care associated infections to the relevant authority; and
(g) Plan and deliver formal education and in service training programmes on infection prevention and control to the health care personnel, health care providers, users and their families.

25.(1) The health establishment must prevent or reduce the transmission of health care associated infections.

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(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that health care personnel -
  (i) use standard precautions;
  (ii) use personal protective equipment when providing care to users;
  (iii) practise effective hand hygiene;and
(b) Implement procedures for the management of users with hazardous infections.

26.(1) The health establishment must prevent or reduce the transmission of airborne infections.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Conduct bi-annual respiratory risk assessments in all service areas and public areas;
(b) Develop and implement an infection control plan for all high risk areas based upon the respiratory risk assessment;
(c) Educate health care personnel, users and their families on respiratory hygiene and coughetiquette;
(d) Install or provide ventilation systems in the required service areas;
(e) Ensure that health care personnel implement precautions during the transportation or movement of infectious users; and
(f) Segregate in-patients diagnosed with contagious respiratory conditions from non-infected users or users vulnerable to infections, until the risk of infection is reduced.

27.(1) The health establishment must prevent the spread of infections through a decontamination and sterilisation process.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Implement a decontamination and sterilisation protocol;
(b) Appoint trained health care personnel to manage or perform the functions of decontamination and sterilisation, with clear roles and responsibilities;
(c) Train health care personnel responsible for sterilisation on the use of the equipment and the disinfection process;

(d) Ensure that the equipment for sterilisation is procured, licensed and maintained according to guidelines of the manufacturer; and

(e) Report, investigate and take actions to mitigate the risk of recurrence of incidents of failure of sterilisation processes.

28.(1) The health establishment must ensure that the clinical environment is hygienic and clean, in order to limit the spread of infections.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that-

(i) cleaning is performed in all service areas, according to a routine schedule and protocol;

(ii) cleaning agents and equipment for cleaning personnel are available;

(iii) cleaning personnel are trained to perform environmental cleaning and surface disinfecting of service areas and isolation rooms;

(iv) terminal decontamination of equipment and rooms used by infected users is performed according to protocol;

(v) cleaning personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations; and

(b) Monitor the service level agreements of the outsourced cleaning suppliers, where relevant and report any contractual breaches to the relevant authority.

29.(1) The health establishment must ensure that health care risk waste is handled, stored, and disposed of safely, to reduce potential health risks and to protect the environment.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Develop annual plans for dealing with risks based on a risk assessment conducted to identify hazardous waste;

(b) Implement procedures for the collection, handling, segregation, storage and disposal of health care risk waste in line with the Hazardous Substances Act, 1973 (Act No. 15 of 1973) or the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008);

(c) Monitor the service level agreement of the waste removal service provider and report any contractual breaches to the relevant authority;

(d) Ensure the availability and suitability of waste containers appropriate to the type of waste generated, to health care personnel and users, in all relevant areas of the health establishment; and

(e) Ensure that sharps are managed and disposed of according to relevant legislation.

(3) For the purposes of this regulation-

(a) "health care risk waste" includes infectious waste or waste which is suspected to contain pathogens, and which contributes a risk to the health and safety or users and heath care personnel ; and

(b) "sharps" include medical needles and other sharp medical instruments, such as intravenous catheters.

Chapter 3

Clinical support services

Definitions applicable to this Chapter

30. In this Chapter-

"**administer**" means the giving of a prescribed dose of medication to an individual user at the prescribed time and through the prescribed route;

"**dispense**" means the interpretation and evaluation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container according to applicable legislation and the provision of information and instructions by a pharmacist or health care provider to ensure safe and effective use of medicine by a user;

"**essential medicines list**" means a list of medicines that satisfy the priority health care needs of the population whichshould be available within the context of functioning health system at all times in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford;

"**formulary**" means a list of medicines approved to be prescribed within a particular health establishment;

"medicines" means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in a person; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in person,

and includes any veterinary medicine;

"Medicines and Related Substances Act" means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

"medical supplies" means products and devices other than medicines that are used for therapeutic purposes;

"medical supplies list" means a list of supplies that are accepted for use within the health establishment;

"obsolete medicines" means expired, damaged or quarantined medicines;

"Pharmacy Act"means the Pharmacy Act,1974 (Act No. 53 of 1974);

"prescribe" means the act performed by an authorised prescriber of initiating a medicine order,usually written, for a scheduled medication to be dispensed or administered to a particular user;

"scheduled medicine" means any medicine or other substance prescribed by the Minister under section 22A of the Medicines and Related Substances Act;

"terminal decontamination"refers to the process of rendering a user's room free from the possibility of transmitting infection after a user has left the room;and

"therapeutic support services"means professional persons whose work relates to therapeutics or to treating, remediating, or curing a disorder or disease such as occupational therapy, physiotherapy, dietetics or optometry.

Medicines and Medical Supplies

31.(1) The Health Establishment must manage pharmaceutical services and oversee operations throughout the service areas to ensure the availability and appropriate use of medicines.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that the pharmacy is-

(i) licensed and that its premises are recorded by the relevant authority; and

(ii) managed by a pharmacist, whose role and responsibilities are defined;

(b) Ensure that pharmacy staff work with health care providers in the health establishment to ensure that the ordering, safe prescribing, storage, preparation, prescribing, dispensing and administration of medicines follows good pharmacy practice; and

(c) Implement all policies and procedures that guide health care provider in the management of medicines in accordance with the Medicines and Related Substances Act.

32.(1) The health establishment must ensure that medicines are accessible and available for users when they are prescribed, to promote optimal clinical outcomes.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Provide access to all medicines, including those needed for emergencies, during the health establishment's operating hours and after hours;

(b) Ensure that all medicines are in stock, in accordance with the essential medicines list or applicable formulary;

(c) Monitor that the ordering, supply and delivery of medicines is in accordance with applicable policies and contractual obligations;

(d) Implement stock control and inventory procedures in compliance with relevant legislation and best practice;

(e) Store medicines in accordance with storage conditions specified by the manufacturer;

(f) Implement appropriate controls for the management and distribution of Schedule 5, 6 and 7 medicines in accordance with Medicines and Related Substances Act;

(g) Monitor that users receive all medicines prescribed in accordancewith applicable essential medicines list or formulary during their stay and upon discharge;

(h) Implement contingency measures when medicines are not available; and

(i) Prevent or manage obsolete medicines according to the Medicines and Related Substances Act, Pharmacy Act and best practice.

33.(1) The health establishment must ensure that medicines are prescribed and dispensed in accordance with the Pharmacy Actand the Medicines and Related Substances Act, to promote clinical outcomes and protect users from harm.

(2) For the purposes of sub-regulation (1), the health establishment must ensure that-

(a) prescribing, dispensing and administration of medicines complies with applicable legislation, policies and guidelines across all service areas;

(b) health care providers advise users or caregivers on the appropriate way to take medicines and caution users against potential side effects.

34.(1) The health establishment must manage medical supplies to ensure that they are accessible, available and appropriately used to promote optimal clinical outcomes.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Monitor that the ordering, supply and delivery of medical supplies is in accordance with contractual obligations;

(b) Implement stock control and inventory procedures in compliance with relevant legislation and best practice;

(c) Provide access to medical supplies, including those needed for emergencies, during the health establishment's operating hours; and

(d) Ensure that all medical supplies required for the care of users are in stock in accordance with applicable medical supplies list.

Diagnostic and Blood Services

35.(1) The health establishment must establish procedures and service level agreements with diagnostic and blood services providers to protect the safety of users when under the care of the service providers.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that there are policies and procedure which specify the roles and responsibilities of each diagnostic service provider to the user as they move between the health establishment and the service providers;
(b) Ensure that users have access to laboratory or point of care diagnostic and radiology services;
(c) Monitor that: -

(i) relevant quality control procedures are carried out and documented by the diagnostic service provider according to the guidelines of the relevant regulatory body;

(ii) investigations and reports are conducted and delivered in accordance with the service level agreement with the service provider;

(d) Ensure that diagnostic services protect users and health care personnel from unnecessary exposure to hazardous material and products;
(e) Ensure that diagnostic service providers have the necessary emergency procedures, call out protocols and equipment to deal with resuscitations and other emergencies in their units;
(f) Ensure that the diagnostic service providers report clinical adverse events to the forum in the Health Establishment that monitors these events; and
(g) Report any contractual breaches in the delivery of outsourced services to the relevant authority.

36.(1) The health establishment must ensure that blood services and blood products are accessible and available to promote optimal clinical outcomes in line with the Human Tissues Act.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that users have access to blood and blood products when needed
(b) Monitor that: -
(i) relevant quality control procedures are carried out and documented by the blood service provider according to the guidelines of the relevant regulatory body;
(ii) blood is handled and delivered in accordance withcold chain procedures and the service level agreement with the blood service provider
(c) Ensure that blood services protect users and health care personnel from unnecessary exposure to hazardous material and products;

(d) Ensure that the adverse blood reactions are reported to the forum in the health establishment that monitors adverse events; and

(e) Report any contractual breaches in the delivery of blood services to the relevant authority.

Therapeutic support services

37.(1) The health establishment must ensure that therapeutic support services promote patient safety and prevent disability.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that users have access to therapeutic support services as required;

(b) Maintain the necessary equipment and consumables to ensure that the service is provided in a safe manner;

(c) Monitor that therapeutic services record the assessments that are conducted and that treatment planned follows guidelines for care;

(d) Maintain and monitor referral procedures, both within the therapeutic disciplines and between health establishments;

(e) Monitor waiting times to access therapeutic support services and, where necessary, implement improvements;

(f) Ensure that users receive assistive devices, and are advised on their use; and

(g) Maintain multidisciplinary forums within therapeutic services that ensure that users are cared for in a multidisciplinary manner within therapeutic support services.

Health Technology

38.(1) The health establishment must ensure that medical equipment is available and functional to provide effective care to users.

(2) For the purposes of sub-regulation (1), the health establishment, must:

(a) Develop medical equipment management plans to meet the needs of the health establishment;

(b) Demonstrate that medical equipment needs will be fulfilled within budget allocations;

(c) Ensure that-

(i) licensed medical equipment is available and functional across all service areas;

(ii) medical equipment has a planned maintenance schedule and it is followed;

(iii) the medical equipment is documented as being functionally compliant with manufacturer operational specifications;

(iv) medical equipment is disposed of in accordance with applicable legislation; and

(c) Monitor the service level agreement for the maintenance of medical equipment and report any contractual breaches in the maintenance of medical equipment to the relevant authority.

39.(1) The health establishment must ensure that medical equipment is safe for users and is used by health care providers in accordance with the manufacturers specifications.

(2) For the purposes of sub-regulation (1), the health establishment, must:

(a) Train health care personnel in the use of medical equipment in their service areas;

(b) Ensure only trained and competent health care providers use specialised medical equipment;

(c) Report adverse events relating to equipment failure or malfunction to the forum reviewing quality and patient safety data;

(d) Ensure that terminal decontamination and safe cleaning occurs according to protocol;

(e) Train health care personnel in the technique for cleaning and disinfection of medical equipment; and

(f) Provide health care personnel with cleaning agents and equipment to clean and disinfect the medical equipment and personal protective equipment.

Mortuary services

40.(1) The health establishment must store, release and transport bodies of the deceased in accordance with the Human Tissue Act, 1983 (Act No. 65 of 1983) to prevent potential risks to the public and health care personnel.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Implement policies and procedures guiding all aspects of preparation, storage, release and transportation of bodies according to the Human Tissue Act;

(b) Provide suitable infrastructure and equipment for the handling, storage (including temporary storage) and transportation of bodies;

(c) Provide staff working with bodies of the deceased with personal protective equipment and clothing;

(d) Train staff working with deceased bodies in the safe storage, handling, transportation and release of bodies; and

(e) Implement a control system, which monitors the movement and release of bodies, including death notifications and related documents.

41.(1) The health establishment must ensure that families of the deceased are treated with respect and dignity to protect their rights.

(2) For the purposes of sub-regulation (1), the health establishment must ensure that its health care personnel:

(a) Demonstrate caring attitudes and treat families of deceased with courtesy and empathy;
(b) Wear clean and standardized protective clothing;
(c) Display their institutional name tags at all times; and
(d) Care for the deceased in a manner that promotes their privacy

Chapter 4

Health promotion and prevention and Public health within health establishments

Population-based planning and service delivery

42.(1) The health establishment must ensure that population-wide burden of disease information is used indetermining the health care needs of the catchment populationand associated package of servicesto promote appropriate care and improved outcomes.

(2) For the purposes of sub-regulation (1), the health establishment must:

a) obtain information on the burden of disease and health service providers in the catchment population; and
b) use the burden of disease information to inform planning and delivery of services to the catchment population.

43.(1) The health establishment must ensure co-ordinated service delivery to its catchment population through collaboration with other health service providers and other sectors impacting on health, to improve the health of users.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Develop, implement and communicate plans with other health service providers regarding coordination of care to the catchment population;

(b) Develop, implement and communicate plans with other sectors and health service providers regarding prevention or control of social determinants of health of their catchment population and users; and

(c) Manage and co-ordinate support received from non-governmental organisations.

(3) For purposes of this regulation-

(a) "other health service providers" include non-governmental organisations, private healthproviders, ambulance services, rehabilitation service and palliative care and community health workers;

(b) "other sectors" include government departments impacting on the social determinants of health such as water, housing, municipal services and environmental health; and

(c) "social determinants of health" refer to the social and economic factors which affect health; such as housing, employment, income, education, food security, family, gender, race, social exclusion, disability and access to health services.

The SDH are the social and economic factors that influence health, and include income, education, social safety networks, employment and working conditions, unemployment and job security, early childhood development, gender, 'race', food insecurity, housing, social exclusion, access to health services, and disability

44.(1) The health establishment must provide outreach services or monitor support received from more specialised outreach services to improve the quality of care provided to the users and the community.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Co-ordinate, monitor and evaluate the efficiency andusefulnessof the outreach services it provides to other health establishments, organisations and users in the catchment area;

(b) Monitor and evaluate the usefulnessof outreach services it receives from other health establishments and public institutions dealing with health matters to its health care personnel.

Health promotion and disease prevention

45.(1) The health establishment must promote health and prevent diseases in users and the catchment population.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Provide a prevention and promotion programme to its users and the catchment population;

(b) Record that users with communicable and non-communicable diseases have received information on relevant lifestyle modifying behaviours;

(c) Collaborate with community health workers, school health providers and other outreach service providers to identify community-specific conditions and run targeted interventions or community campaigns.

Outbreaks, health emergencies and disaster preparedness

46.(1) The health establishment must take all necessary measures to protect users and the public from outbreaks and the impact of health emergencies and disasters.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Establish and maintain a disease surveillance system that identifies, collects, collates and analyses defined notifiable conditions and reports them to the relevant authorities;

(b) Review feedback on disease surveillance received from the relevant authority for inclusion in prevention and control plans;

(c) Implement policies and procedures to respond to disease outbreaks in collaboration with relevant health sector providers and authorities;

(d) Develop and test disaster and outbreak management plans to mitigate against harm in the event of internal and external health related emergencies and outbreaks;

(e) Analysethe health establishment's response in theevent of a disaster or outbreak or test and revise management plans where necessary; and

(f) Have a designated person responsible to oversee, liaise with and communicate information in relation to disaster and outbreak management with the regional intersectoral team.

(3) For the purposes of this regulation "regional intersectoral team" refers to a team of managers from different sectors, includingagriculture, education, water and sanitation, and the environment, whopromote and co-ordinate activities in health.

Environmental controls

47.(1) The health establishment must protect users and the public from environmental hazards in line with the Hazardous Substances Act or the National Environmental Management : Waste Act.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that it is licensed as a hazardous waste producer by the local authority; and

(b) Implement procedures and policies to ensure that knownby-products created by equipment and chemical waste, are managed in accordance with the relevant environmental legislation.

Chapter 5

Leadership and Governance

Oversight, leadership and accountability

48.(1) The health establishment must ensure that its representative board or committee is enabled to make recommendations to improve user safety and the quality and acceptability of services provided by the health establishment.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure that it has a representative board or committee, as the case may be, that meets, at least twice a year;

(b) Provide the representative board or committeewith the necessary information regarding the clinical governance, operational management, financial and quality performance of the health establishment in order for it to assess the health establishment's performance;

(c) Request guidance and implement recommendations from the representative board or committee to improve service delivery.

(3) For the purposes of this regulation a "representative board or committee" means the governing structure of a hospital or clinic, established in terms of section 41 or 42 of the Act, respectively.

49.(1) The health establishment must lead and guide the health care personnel to ensure the delivery of safe and quality health services.

(2) For the purposes of sub-regulation (1), the person in charge and the health establishment's executive management, must:

(a) Maintain up to date policies and procedures for all key operational and clinical functions in the Health Establishment;
(b) Oversee service areas to identify problems and provide guidance and support to the health care personnel;
(c) Demonstrate that the inputs on improvements from all service areas are sought and used by management;
(d) Maintain monitoring systems to ensure that improvements to service delivery are implemented in the service areas; and
(e) Maintain mechanisms to communicate with health care personnel regarding the operations of the health establishment.

Strategic and Risk Management

50.(1) The health establishment's executive management team must be adequately staffed and authorised to oversee the strategic direction and operations of the health establishment, to ensure the delivery of safe and quality health services.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Display an approved organogram of all management posts in a conspicuous manner, which includes their status and reporting lines;
(b) Demonstrate that management's responsibilities are clearly documented;
(c) Ensure that management receive written delegations of authority for the relevant financial year; and
(d) Document that management utilise and function within their assigned delegations.

51.(1) The health establishment must ensure that it plans for resource use and delivers its operations according tothe strategic direction of the health establishment.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Display a vision, mission and values statement, reflecting the strategic direction of the health establishment or that of the relevant authority;
(b) Develop and enforce a code of conduct and ethics in the health establishment;

(c) Develop an operational plan which sets out the manner in which the health establishment will meet its service delivery requirements;
(d) Ensure the operational plan links with the human resources, financial and risk management plans;
(e) Monitor progress towards the achievement of targets contained in the operational plan at agreed intervals, and take actions to address variances;
(f) Ensure that budget allocations and staffing levels allows the operational plan to deliver; and
(g) Identify the main cost and operational drivers of the health establishment and develop strategies and interventions to address them.

52.(1) The health establishment must manage reasonably foreseeable organisational, operational, financial, medico-legal and reputational risks, and take appropriate steps to minimise and mitigate their impact on the quality and safety of health services.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Disseminate and implement a general risk management policy which directs the context and scope of risk and the roles and responsibilities for management of risk;
(b) Establish and maintain appropriate systems to identify and prioritise risks according to their likelihood and impact;
(c) Monitor and manage risks and, where necessary, implement strategies to minimise or eliminate them;
(d) Provide health care personnel with in–service training on risk identification and mitigation strategies; and
(e) Provide required information regarding actual or potential medico-legal cases to the relevant authority, on a proactive basis.

Quality improvement

53.(1) The health establishment must strengthen its systems and processescontinuouslyto improve the acceptability, quality and safety of health services.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Establish and maintain a structure or forum which coordinates, guides and monitors quality improvement activities under the direct leadership of management;

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(b) Ensure thatit has a designated person responsible for quality improvement in the health establishment;
(c) Implement systems for continuous quality improvement across all units and departments;
(d) Develop the capacity for quality improvement in health care personnel through training, mentoring and support;
(e) Collect or obtain information from user and health care personnel surveys, complaints, compliments and self assessments regarding service delivery and gaps in compliance with prescribed norms and standards;
(f) Develop and implement quality improvement plans in response to such information;
(g) Utilise external audit reports, supervisory visits and other inspections to develop and implement quality improvement plans; and
(h) Monitor quality improvement plans against service delivery targets and communicate improvements and compliance to health care personnel.

Chapter 6
Operational Management

Human resources, welfare and employee wellness

54.(1) The health establishment must manage the health care personnel in amanner that ensuresthat they deliver safe and effective care.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Monitor and implement the annual health care personnel plan, whichwas developed with reference to occupancy rates, health care personnel norms, utilisation rates and user profiles;

(b) Implement health care personnel recruitment, selection and retention strategies and procedures in accordance with Labour Relations Act, 1995 (Act No. 66 of 1995) and the executive management's delegations of authority;

(c) Monitor and manage health care personnel absenteeism, turnover and vacancy rates;

(d) Ensure that all registered health care providers-

(i) maintain their registration with the relevant professional council;

(ii) are qualified and experienced to perform their respective clinical roles and remain within their scope of practice as per the relevant professional council; and

(iv) working as independent practitioners in the health establishment are permitted to provide care to users

(e) Make arrangements for health care personnel to receive on-going in-service training and supportive supervision to keep their knowledge,as relevant to their role, up to date;

(f) Provide health care personnel with orientation, training and formal supervision programme on the operational policies and procedures of the health establishment;

(g) Ensure that-

(i) management have the qualifications and experience required for the role;

(ii) management have suitable leadership competencies or undergo training or mentoring to develop these competencies;

(iii) the health care personnel and management have regular performance reviews; and

(iv) health care personnel's roles and responsibilities are clearly documented and aligned with their scope of practice.

55.(1) The health establishment must protect health care personnel from workplace hazards through occupational health and safety systems.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Assign responsibilities under the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) to health care personnel;

(b) Ensure that hazard identification and analysis takes place in every service area to identify workplace hazards;

(c) Implement a health risk surveillance plan for health care personnel who are at high risk of developing occupational illnesses, based on health risk assessments;

(d) Implement a risk management plan to minimize occupationally acquired injuries and diseases, and ensure that controls are monitored based on the severity of the risk; and

(e) Implement and monitor a plan to protect health care personnel from violence and abuse.

56.(1) The health establishment must promote health and psychosocial wellbeingand prevent disease in health care personnel.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Implement a health prevention, promotion and management programme for health personnel and offer counselling to health care personnel on lifestyle modification; and

(b) Conduct annual health care personnel satisfaction surveys and take actions to address gaps, including behaviour and attitude concerns.

Financial management

57.(1) The health establishment must monitor expenditure against the approved and allocated budget and report variances to avoid suspension of services and ensure the delivery of safe and effective care to users.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Monitor-

(i) its monthly expenditure against allocated budget;

(ii) variances in expenditure and report them to the relevant authority or forum that reviews expenditure;

(iv) interruptions of service delivery due to cash flow problems and address and report these to the relevant authority without delay; and

(b) Effect payments to suppliers within 30 days of receipt of invoice.

Supply chain and asset management

58.(1) The health establishment must have the necessary medical and non-medical equipment and supplies, in order to provide safe care that meets the health needs of users.

(2) For the purposes of sub-regulation (1), the health establishment, must:

(a) Establish internal governance structures to oversee supply chain management processes;

(b) Ensure that supply chain management servicesare providedby qualified and experienced employees ;

(c) Develop specifications for assets and equipment needs as identified in the operational plan;

(d) Ensure that supply chain management processes are implemented with transparency and segregation of duties;

(e) Demonstrate that the purchasing decisions made are aligned with the needs identified in the operational plan;

(f) Ensure that medical and non-medical supplies are available for health personnel to use and that emergency items can be procured urgently when needed;

(g) Monitor stock outs and lead times to procurement of medical and non medical supplies; and

(h) Monitor the service level agreements for the supply of non-medical equipment and supplies and report any contractual breaches to the relevant authority.

59.(1) The health establishment must ensure that assets and non medical equipment are functional, and are managed and controlled to maximise use and reduce losses in order to provide safe and effective care.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Maintain an asset register or inventory register;

(b) Monitor assets, report and address variances in assets;

(c) Implement a maintenance programme to ensure the functionality of assets and non medical equipment;

(d) Monitor the service level agreement for the maintenance of non-medical equipment and supplies and report any contractual breaches to the relevant authority; and

(e) Dispose of assets in accordance with its asset disposal policy.

Transport management

60.(1) The health establishment must ensure that vehicles used to transport users and health care personnel or goods are safe and available when needed.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Ensure there is access to safe, regular transport for-
(i) users who are required to access non emergency referral services in other health establishments;

(ii) health care personnel for outreach services or transportation of goods;

(b) Ensure thatall -

(i) vehicles, owned or used, are licensed and maintained;

(ii) employed or contracted drivers have valid licenses; and

(c) Monitor transport usage to prevent misuse of vehicles.

Information management

61.(1) The health establishment must have accurate information to inform managerial and clinical decision-making on the safety, reliability and efficiency of care provided.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Record information related to managerial, clinical and administrative information electronically or manually;

(b) Analyse, use and report managerial, clinical and administrative information for the whole health establishment and, where possible, at service unit level; and

(c) Implement contingency plans for information technology system failures to ensure continuity of services.

Health records management

62.(1) The health establishment must ensure that health records are available when needed to protect users and the health establishment against the risks of delayed, unsafe or inappropriate care.

(2) For the purposes of sub-regulation (1), the health establishment, must:

(a) Implement a record storage and retrieval system;

(b) Appoint a trained and competent member of staff to oversee the information management department;

(c) Train all managers in the use of and interpretation of information for the monitoring, evaluation and planning of services;

(d) Protect the confidentiality and security of health records with appropriate security control measures in the records area in line with the Protection of Personal Information Act, 2013 (Act No. 4 of 2013);

(e) Maintain an archival system for the stipulated duration of time according to the National Archives and Records Service of South Africa Act, 1996 (Act No. 43 of 1996; and

(f) Ensure the protection of health records from theft, fire or water damage.

Chapter 7

Facilities and Infrastructure

Definitions applicable to this Chapter

63. In this Chapter-

"building engineering controls" refer to building controls used to prevent the spread and reduce the concentration of droplet nuclei in the air and include ventilation, particulate air filtration and ultraviolet germicidal irradiation;

"building engineering services" includes ventilation and air-conditioning, medical gas installations, electrical installations, including generators, electronic installations and water supply, sewerage and drainage services;

"fit for service" means planned, organised, furnished and equipped to meet all staff and patient safety needs;

"linen" includes bed sheets, pillow cases, towels, theatre and patient gowns, theatre drapes, dish cloths, kitchen overalls, staff uniforms and overalls, mattresses and mattress covers, blankets, and pillows;

"national building regulations" means the national building regulations issued in terms of the National Building Regulations and Buildings Standards Act, 1997 (Act No. 103 of 1997);

"waste" means any substance, whether or not that substance can be reduced, re-used, recycled and recovered that is surplus, unwanted, rejected, discarded, abandoned or disposed of, which the generator has no further use of for the purposes of production, that must be treated or disposed of.

Buildings and grounds

64.(1) The health establishment must ensure that the buildings on the premises and the grounds meet all applicable legislative and regulatory requirements, to protect the safety of users and health care personnel.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Obtain all the required compliance certificates in terms of the National Building Regulations or guidelines; and

(b) Cost and implement plans to ensure that the buildings and grounds meet the national building regulations and guidelines.

65.(1) The health establishment must properly maintain its buildings and grounds to protect the safety of users and health care personnel and ensure access.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Inspect and maintain the buildings and grounds in accordance with the maintenance schedule;

(b) Ensure that-

(i) the buildings and grounds are accessible to the users;

(ii) emergency access points are kept clear; and

(c) Provide mechanisms for userswith disabilities or special needs to access all service areas.

66.(1) The health establishment must ensure that its infrastructure-

(a) is fit for service,

(b) is compliant with occupational health and safety laws and environmental norms and standards, and

(c) meets the needs of the users and health care personnel to provide safe care.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Plan the layout of the buildings and grounds or adapt it to suit the needs of the users;

(b) Inspect its facilities in accordance with the health establishment inspection schedule and, where necessary, implement corrective actions;

(c) Provide-

(i) sheltered waiting areas for users which are dimensioned according to the specifications in the guidelines adjacent to or in close proximity to the consulting or service areas;

(ii) user in-patient areas which are furnished in accordance with minimum specifications in the guidelines; and

(ii) rest areas for health care personnel which are furnished in accordance with minimum specifications in the guidelines.

67.(1) The health establishment must maintainbuilding engineering controls to reduce the risk of airborne transmission of infection to users and health care personnel.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Provide-

(i) isolation units or cubicles where users with hazardous infections can be accommodated;

(ii) ventilation systems in theatres which reduce the risk of airborne infection transmissions and are serviced according to the manufacturers specifications; and

(b) Ensure that there is natural or mechanical ventilation in areas where infection control risk assessments have identified the need for these interventions.

Building engineering services

68.(1) The health establishment must ensure that building engineering services are maintained and functional to protect the safety of users and health care personnel and provide premises that are fit for service.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Document the location and layout of all the main building engineering services;

(b) Ensure that-

(i) routine and emergency electrical power, water supplies and sewage disposal allows for uninterrupted services to be provided;

(ii) routine and emergency medical gas and vacuum systems are in accordance with the level of services provided and allow for uninterrupted services;

(iii) ventilation is provided in theatres, user accommodation and waiting areas according to the specifications in the guidelines;

(iv) it complies with water quality laws and environmental health norms and standards for the disposal of water; and

(v) machinery and equipment are functional, tested, maintained and decommissioned according to applicable regulations.

69.(1) The health establishment must have effective communication systems to enable urgent medical care or support to be provided to users.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Maintaina functional communication system that allows-

(i) users to contact the health establishment to seek medical assistance when needed;

(ii) health personnel to seek assistance, when needed;

(b) Maintain a functional and recognisable alert system which ensures that-

(i) health care personnel can communicate their need for assistance urgently;

(ii) users can communicate their need for assistance urgently; and

(c) Where appropriate, have a public alert system that can communicate any emergency instructions to users.

(3) For the purposes of this regulation "recognisable" means the health care personnel or users are able to identify the alert signal warning sound.

Safe and Secure Environment

70.(1) The health establishment must protect the users, health care personnel, equipment and property from security risks.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Implement-

(i) security systems throughout the health establishment and buildings and grounds at all times;

(ii) specific security access control measures and processes to protect vulnerable and high risk users;

(b) Provide internal and external lighting in all areas;

(c) Report and address all security incidents;

(d) Promote safety and security awareness amongst health care personnel and users;

(e) Train and provide security staff with the equipment to deal with security incidents and threats ;and

(f) Monitor the service level agreement for security services and report any contractual breaches to the relevant authority.

Hygiene and cleanliness

71.(1) The health establishment must ensure that public areas, buildings and grounds are kept clean to maximise the user's safety and comfort.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Perform cleaning in public areas according to a routine schedule, using cleaning agents and equipment;

(b) Ensure that cleaning personnel are trained to perform public area cleaning;

(c) Monitor the service level agreement for cleaning services and report any contractual breaches to the relevant authority;

(d) Implement pest control measures in internal and external areas; and

(e) Monitor the implementation of the anti-smoking policy within the facility.

Waste Management

72.(1) The health establishment must ensure that waste is handled, stored and disposed of in a safe manner to reduce potential health risks and to protect the environment.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Implement an effective waste management procedure within the health establishment and buildings and grounds;

(b) Appoint trained health care personnel to oversee and enforce compliance with relevant waste management procedures and in line with the National Environmental Management: Waste Act ;

(c) Segregate and transport waste within the facility according to the waste management guidelines;

(d) Securely store and remove waste from the facility according to waste management guidelines and in line with the National Environmental Management: Waste Act;

(e) Ensure the availability and suitability of waste containers appropriate to the type of waste generate to health care personnel and users in all relevant areas; and

(f) Provide suitable and accessible containers to dispose of waste.

Linen Services

73.(1) The health establishment must provide sufficient, clean and visually acceptable linen and mattresses to protect users and health care personnel from the risk of infections and injuries.

(2) For the purposes of sub-regulation (1), the health establishment, must:

(a) Ensure that linen and mattresses are available to meet the needs of service provision and of users;

(b) Handle clean, dirty, soiled, and infectious linen and mattresses according to applicable guidelines;

(c) Provide health care personnel handling linen with protective equipment and training to prevent microbial transmission and chemical injuries;

(d) Provide functional equipment to meet the needs of the linen services; and

(e) Monitor the service level agreement for linen services and report any contractual breaches to the relevant authority.

(3) For the purposes of this regulation "visually acceptable" means free from soiling, stains, holes or damage.

Food services

74.(1) The health establishment must provide food services that promote the user's nutritional, cultural and religious needs.

(2) For the purposes of sub-regulation (1), the health establishment, mustmonitorthat users are provided with food and beverages that caters for their nutritional, cultural and religious needs.

75.(1) The health establishment must protect users and health care personnel from unsafe food.

(2) For the purposes of sub-regulation (1), the health establishment must:

(a) Implement protocols and procedures which guide all aspects of food procurement, storage, preparation and serving;

(b) Monitor that food hygiene procedures are implemented in accordance with applicable legislation;

(c) Provide functional equipment for food preparation;

(d) Ensure that the equipment for food preparation is used in accordance with the manufacturers' specifications; and

(e) Ensure that the cultural beliefs and spiritual preferences of service users are recognised.

Dr A Motsoaledi, MP

Minister of Health

Date: 27/1/2015

SCHEDULE 1
APPLICABILITY MATRIX

Definitions and Interpretation

1. In this Schedule-

"acute hospital" means a facility that provides medical, surgical, or psychiatric care and treatment for users who are acutely sick or the injured and excludes long term care.

"clinic" means a primary health care facility based point of care that is closest to the community being served providing only outpatient services; and

"community health centre" means a primary health care facility based point of care that is closest to the community being served providing outpatient and limited inpatient services.

(2) For the purposes of this Schedule "hospital" refers only to public and private acute hospitals, psychiatric and Tuberculosis hospitals.

Regulation No.	Applicability	Alternative requirements for other health establishments
11(2)(a) and (c) 11(2)(a) to (d)	Hospitals and community health centres Hospitals only	
13(2)(b)	Hospitals only	
18(2)(e)(iii)	Hospitals only	
20(2)(c)	Hospitals only	Clinics must participate in collaborative fora and programmes at district, sub-district or regional level
23(2)(c) 23(2)(f) 23(3)(b) 23(3)(e)	Hospitals only Hospitals and community health centres Hospitals and community health centres Hospitals only	

24(2)(b) 24(2)(c)	Hospitals only	Clinics and community health centres must participate in collaborative forum at district, sub-district or regional level Clinics and community health centres must have access to a part-time health care provider to oversee and provide supportive supervision
27(2)(b)	Hospitals only	Clinics and community health centres must delegate an individual to perform the functions, who must be trained
31(2)(a)	Hospitals, Community Health Centres and Private Clinics only	Public clinics do not require a license and must have a pharmacist designated for supervising medicine management from the district.
36(2)	Hospitals only	
37(2)(b) and (c)	Hospitals only	
53(2)(b)	Hospitals only	Clinics and community health centres must have access to the function from a regional or district appointed person
58(2)(a) to (e)	Hospitals only	
62(2)(b)	Hospitals only	Clinics and community health centres must have access to the function at a regional or district or sub-district management level
72(2)(b)	Hospitals only	Clinics and community health centres must designate a person to oversee the function

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.

This gazette is also available free online at **www.gpwonline.co.za**

SCHEDULE

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COMPLAINTS HANDLING, INVESTIGATION AND THE OMBUD

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	

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from Government Printing Works

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