GOVERNMENT NOTICES

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.

(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.

(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;

(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