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Contents

DEPARTMENT OF HEALTH

NO. 10 **04 JANUARY 2017**

NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)

NORMS AND STANDARDS REGULATIONS APPLICABLE TO DIFFERENT CATEGORIES OF HEALTH ESTABLISHMENTS

The Minister of Health intends, under section 90(1A) of the National Health Act, 2003 (Act No. 61 of 2003), and after consultation with the Office, to make the Regulations in the Schedule.

Interested persons are invited to submit any substantiated comments in writing on the proposed amendments to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Public Entities Governance), within three months from date of publication of this notice.

SCHEDULE

ARRANGEMENT OF REGULATIONS

CHAPTER 2

USER RIGHTS

CHAPTER 3

CLINICAL GOVERNANCE AND CLINICAL CARE

CHAPTER 4

CLINICAL SUPPORT SERVICES

CHAPTER 5

HEALTH PROMOTION AND DISEASE PREVENTION

CHAPTER 6

LEADERSHIP AND GOVERNANCE

CHAPTER 7

OPERATIONAL MANAGEMENT

CHAPTER 8

FACILITIES AND INFRASTRUCTURE

CHAPTER 9
GENERAL PROVISIONS

47. Short title and commencement

CHAPTER 1
DEFINITIONS, PURPOSE AND APPLICATION

Definitions

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

"abuse" means–
(a) sexual abuse; or
(b) physical abuse; or
(c) emotional, verbal and psychological abuse; or
(d) harassment;

"adverse incident" means an unanticipated, undesirable or potentially serious incident occurring as a result of health care services provided to a user, and which resulted in harm to a user, which was not due to the users underlying health condition;

"analyse" means to examine methodically by separating into parts and studying their interrelations;

"building regulations" means the building regulations issued in terms of any of the following legislation or regulations–
(a) National Building Regulations and Buildings Standards Act, 1977 (Act No. 103 of 1977); or
(b) Regulation Governing Private Hospitals and Unattached Operating Theatre Units, published in Government Gazette, Notice No. R. 158 of 1 February 1980; or
(c) Regulation Governing Private Health Establishments, Western Cape, published in Provincial *Gazette Extraordinary* 5728, Provincial Notice No. 187 of 22 June 2001;

"clinic" means any health establishment that provides mainly outpatient services to the community;

"clinical risk" means the likelihood that an adverse incident will cause injury or harm to users;

"clinical service area" means an area within a health establishment where users receive treatment and care;

"Community Health Centre (CHC)" means any health establishment that provides mainly outpatient services and short stay to the community;

"hazard" means any source of potential damage, harm, adverse health effects on users or health care personnel, or any threat to their safety;

"hazardous waste" means waste that contains organic or inorganic elements or compounds that may, owing to their inherent physical, chemical or toxicological characteristics have a detrimental impact on users or health care personnel's health or the environment;

"health care service" means all services providing any or all of preventive, promotive, curative or rehabilitative services;

"health record" means any record made by a health care provider, at the time of or shortly after seeing the user, upon examination or treatment, that contains information about the health of the user, and is recorded by a health care provider, either personally or under his or her direction and includes any results of diagnostic investigations performed on the user;

"high-risk" means exposure to a situation that threatens the health or life of a user;

"in-patient" means users who are admitted to the health establishment's clinical service areas in order to receive health care;

"management" means the executive management and all heads of departments, including clinical and non-clinical service areas of a health establishment;

"national department" means the national department responsible for health;

"outreach service" means all health care services rendered by a health establishment outside its institutional premises through the deployment of its resources;

"personal protective equipment" means items specifically used to protect healthcare personnel, users and relatives from exposure to blood, body fluids, secretion and excretion or from droplet or airborne organisms and includes, gloves, aprons, gowns, caps, masks and protective eye wear;

"policy" means an authoritative document that prescribes or direct the course of action by the health establishment;

"quality" means the degree to which health care services increase the likelihood of desired outcomes;

"relevant authority" means the national department of health, a provincial department of health, municipal authority, or executive management of a private health care establishment, private hospital or private hospital group;

"responsible authority" means a sub-district, district or management of a private health care establishment that provides supervisory support to the health establishment;

"safe" means free from any hazard or harm;

"standard operating procedure" means a document containing step by step instructions on how to perform a technical procedure or activity;

"structure" means a team, committee, forum or a designated individual;

"supportive supervision" means any directions provided by a supervising health care provider that conveys information on the theoretical knowledge and clinical techniques needed by a supervised health care provider to enhance their professional practice and safeguard the quality of care within the health establishment;

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

"user safety" means the practice of identifying, reporting, analyzing and preventing errors that lead to adverse events; and

"waiting time" means the time spent by a user waiting for services during the operating hours of the health establishment.

Scope and application

2. These Regulations apply to all health establishments to the extent indicated in these Regulations.

Purpose of Regulations

3. The purpose of these Regulations is to promote and protect the health and safety of users and health care personnel.

CHAPTER 2
USER RIGHTS

Dignity of users

4. (1) All health establishments must provide services in a manner that is respectful of users' rights, facilitates informed choice, minimises harm, and acknowledges cultural and individual values and beliefs. (2) For the purposes of sub-regulation (1), a health establishment must ensure that ─ *(a)* it has organisational policies and practices about user rights that are consistent with sections 10, and 27(1)*(a)* and (3) of the Constitution and Chapter 2 of the Act; *(b)* information on patient rights is provided and explained to users and carers; *(c)* health care personnel demonstrate knowledge and understanding of user rights and incorporate them as part of their everyday practice. *(d)* users can ascertain the identity of all the health care providers involved in the provision of services to a user; and *(e)* the physical, visual, auditory and personal privacy of users is respected at all times.	

Information for users

5. (1) Health establishments must ensure that users are provided with adequate information about the health care services available at the health establishment and information about accessing those services.	
(2) For the purposes of sub-regulation (1), a health establishment must—	
(a) provide users and the general public with information relating to—	All health establishments
(i) the health care services of the health establishment;	
(ii) service opening and closing times,	
(iii) visiting hours; and	
(iv) the compliance status of the health establishment in terms of the Procedural Regulation;	
(b) provide users with information on any fees that are payable for health care services, insofar it being practical to do so before the commencement of the provision of health care services; and	Hospitals, private clinics
(c) display the most recent results of user experience of care surveys.	All health establishments
(3) The information contemplated in sub-regulation (1) must be provided in two or more of the official languages of South Africa, including the language that is spoken by the majority of the population in the region in which the health establishment is located.	

Signage

6. All health establishments must ensure that there is clear signage and other means to provide directions to guide the user to the different areas within the health establishment that are appropriate to the type and size of establishment.	

Systems of referral

7. (1) All health establishments must maintain a system of referral as established by the relevant authority. (2) For the purposes of sub-regulation (1), a health establishment must— *(a)* ensure that users are provided with information relating to their referral to another health establishment, including— (i) the reasons for referral; (ii) the name and contact details of the health establishment to which they are referred; and (iii) the specific department or health care provider they are referred to (if appropriate); *(b)* ensure that a copy of the referral document is kept in the user's health record; and *(c)* monitor the operation of their referral system; and *(d)* where they are the receiving health establishment, ensure that the relevant information relating to further care of the user is transmitted back to the referring health establishment. (3) For the purposes of sub-regulation (2), **"referral"** means to re-assign the responsibility for delivering health care services to a particular user from one health establishment to another	

Access to Emergency care

8. (1) All health establishments must ensure that users are attended to in an emergency in manner which is consistent with the nature and severity of the user's condition. (2) For the purposes of sub-regulation (1), a health establishment must— *(a)* measure and adhere to waiting times for emergency services in line with the recommended timeframes in the South African Triage Scale;	

(b) implement a system of triage using appropriately trained health care providers; *(c)* ensure access to emergency medical transport for users requiring urgent transfer to another health establishment; *(d)* have and adhere to clinical guidelines on stabilizing users presenting in an emergency before referring them to another health establishment; *(e)* ensure that all critically ill users requiring continuous care are accompanied by a health care provider when they are referred to another health establishment; and *(f)* have a system of handover of users between the emergency medical services and the health establishment. (3) For the purposes of sub-regulation(2)— *(a)* **"critically ill"** means a user who has an actual or potentially life-threatening health problem; *(b)* **"South African Triage Scale"** means a tool used by health establishments to determine the clinical urgency of users presenting in an emergency situation in order to provide care to those in most need first; *(c)* **"triage"** means to sort users using an evidence-based triage scale in order to determine the clinical urgency of users presenting to the emergency services in order to provide care to those in most need first.	

Waiting times

9. (1) All health establishments must take appropriate measures to reduce the delays experienced by users in accessing and receiving health care services. (2) For the purposes of sub-regulation (1), the health establishment must— *(a)* monitor waiting times against norms set by the relevant authority or targets set by the health establishment, as the case may be; and *(b)* take reasonable steps to reduce waiting times where necessary.	

Waiting periods

10. (1) All health establishments must ensure that users requiring elective procedures receive these services within a waiting period set by the relevant authority. (2) For the purposes of sub-regulation (1), the health establishment must— *(a)* monitor waiting periods for elective procedures against norms set by the relevant authority, or targets set by the health establishment, as the case may be; and *(b)* institute measures to reduce the waiting period for elective procedures. (3) For the purposes of sub-regulation (2)*(a)*,**"elective procedure"** means a planned non-emergency medical procedure.	

Patient experience of care surveys

11. (1) All health establishments must establish systems and processes, in accordance with norms set by a relevant authority, to monitor and improve the users' experience of health care services. (2) For the purposes of sub-regulation (1), a health establishment must— *(a)* ensure that users are informed of and provided with mechanisms to give feedback or suggestions; *(b)* obtain, at least annually, feedback from users by way of user experience of care surveys; and *(c)* use information from a survey to make improvements to the health care services.	

Complaints, compliments and suggestion

12. (1) All health establishments must ensure that users complaints, compliments and suggestions are recognised, reported and analysed, and that this information is used to improve quality. (2) For the purposes of sub-regulation (1), a health establishment must— *(a)* have an easily accessed, responsive, and fair process for receiving complaints, compliments and suggestions from users, which is documented; *(b)* ensure that users have information about making a complaint, compliment or suggestions and ensure that information about this process is available to users; *(c)* have a system for monitoring, assessing and responding to complaints, compliments and suggestions;	

(d) maintain an up-to-date complaints register that includes all complaints, dates, and actions taken in response; and *(e)* comply with norms set by a relevant authority in relation to receiving, recording and responding to complaints.	

CHAPTER 3
CLINICAL GOVERNANCE AND CLINICAL CARE

User health records

13. (1) All health establishments must create and maintain accurate and updated health records of the health care services provided to users. (2) For the purposes of sub-regulation (1), a health establishment must— *(a)* record the necessary biographical data of the user and the identification and contact information of the user and his or her next of kin; *(b)* ensure that— (i) all user contacts with the health establishment are recorded including, where relevant to the type of establishment, dated clinic visits, in-patient stays or dated emergency unit attendances; (ii) where relevant to the type of establishment, user admissions are ICD10 coded to enable billing according to the relevant tariff; and (iii) health records are protected in accordance with the requirements of section 17 of the Act; *(c)* record the history, clinical assessment and diagnosis in the user's health record when he or she presents himself or herself at the health establishment; *(d)* ensure that health records contain — (i) details of the user's care plan, diagnostic investigations, treatment prescribed, implementation, and accounts of the user's responses to treatment; and (ii) a record of the signature, name and qualification of any healthcare provider who attends to or examines the user; *(e)* ensure that informed consent has been obtained by the health care provider for specified procedures and filed in the user's health record;	

(f) where applicable, have a record of any instruction related to resuscitation and end-of-life care for a user in the health records; *(g)* correctly label each page of the user's health records; and *(h)* issue a discharge report to users in accordance with section 10 of the Act.	

Clinical management of national priority health conditions

14. (1) All health establishments must establish and maintain clinical management systems and procedures that give effect to a national policy and guidelines on the treatment of national priority health conditions. (2) For the purposes of sub-regulation (1), the health establishment must ─ *(a)* ensure that clinical policies and guidelines for priority health conditions issued by the national department are available and communicated to health care personnel; *(b)* provide in-service training on the policies and guidelines related to priority health conditions to health care personnel; *(c)* undertake, at least monthly, clinical audits in accordance with the national policy and guidelines on priority health conditions; *(d)* track users who default on their treatment plan on the priority health conditions and give them the opportunity to complete their treatment; and *(e)* monitor and improve the clinical outcomes associated with the national priority health conditions within the health establishment. (3) For the purposes of sub-regulation (2) ─ *(a)* **"clinical audit"** means the systematic process designed to evaluate relevant aspects of the care of users to determine whether they have received treatment according to national policy and guidelines;	

(b) **"clinical outcome"** means the health state of the user resulting from the administration of health care services; and *(c)* **"priority health condition"** means conditions designated by the Minister in writing on the basis of current evidence and forecasts on issues that matter to public health, and has the potential for safe and cost-effective treatment.	

Clinical leadership and clinical risk

15. (1) All health establishments must establish and maintain systems, structures and programmes that are appropriate to the health establishment and the services it provides, to mitigate clinical risk and promote clinical leadership for the purpose of safeguarding the quality and safety of the health care services provided by the establishment. (2) For the purposes of sub-regulation (1), a health establishment must- *(a)* have a functional clinical leadership structure responsible for overseeing quality of care and user safety for the establishment; *(b)* have assigned responsibility for co-ordination of quality improvement in the health establishment to a member of the clinical leadership structure; *(c)* ensure the clinical leadership structure establishes and maintains a quality improvement programme that ─ (i) analyses, monitors and acts upon 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, administering and use of medicines as part of a pharmaceutical and therapeutics programme;	

(d) implement and monitor the execution of quality improvement plans developed in response to quality and user safety data;

(e) display and communicate the results of the implementation of the quality improvement plans to health care personnel;

(f) implement a supportive supervision programme for health care providers on the clinical policy and procedures to improve user safety in the clinical service areas; and

(g) provide training and institute a formal supervision programme for health care personnel on quality improvement.

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

(a) **"antimicrobial stewardship programme"** means a programme implemented by a health establishment to reduce the risks associated with increasing microbial resistance and to extend the effectiveness of antimicrobial treatments;

(b) **"functional clinical leadership structure"** means a structure with terms of reference approved by the person or organisation responsible for the supervision and control of a health establishment;

(c) **"pharmaceutical and therapeutics programme"** means a programme implemented by the health establishment to oversee medicine management systems and promote effective use of medicines; and.

(d) **"quality improvement"** means the combined and continuous efforts by health care providers, personnel and health establishments to make the changes that will lead to improved user outcomes and experience, performance and better health provider development.

Clinical risk management

16. (1) All health establishments must maintain a system for identifying, minimising and mitigating reasonably foreseeable clinical risks to the health and safety of users and healthcare personnel that is appropriate for the health establishment. (2) For the purposes of sub-regulation (1), a health establishment must— *(a)* have systems and processes for identifying and analysing the clinical risks to users and healthcare personnel in every clinical service area at the establishment graded according to their severity; *(b)* implement a risk management programme that addresses each identified clinical risk; and *(c)* provide appropriate training on clinical risk identification, user and healthcare personnel safety, and clinical risk mitigation strategies.	

User safety incidents

17. (1) All health establishments must have a user safety programme to safeguard users against the risks associated with unsafe and inappropriate care. (2) For the purposes of sub-regulation (1), a health establishment or responsible authority must— *(a)* have a functional user safety structure responsible for overseeing the user safety programme for the establishment; *(b)* have a guideline or standard operating procedure that outlines its approach to identifying, categorising and monitoring user safety incidents; *(c)* maintain a surveillance system to collect, categorise and analyse user safety incidents; *(d)* report user safety incidents to the relevant authority;	

(e) investigate user safety incidents to determine the root causes, identify trends and take corrective action in line with the severity of the events; and *(f)* have to ensure that users are informed if they have been affected by a safety incident, and keep users informed of the progress and outcome of any investigation. (3) For the purposes of sub-regulation (2), *(a)* **"surveillance system"** means the on-going systemic collection, consolidation, analysis and timely dissemination of health data to relevant authority for the purposes of planning, implementation and evaluation of health care services; *(b)* **"User safety incident"** means an event or circumstance that could have resulted, or did result in harm to a user as a result of the health care services provided, and not due to the underlying health condition. An incident can be a near miss, no harm incident or harmful incident (adverse event); and *(c)* **"User safety structure"** means a structure with terms of reference approved by the person or organisation responsible for the supervision and control of a health establishment that meets regularly to discuss matters pertaining to user safety incidents.	

Clinical processes

18. (1) Health establishments must implement and maintain clinical processes for the identification, assessment and treatment of users that are appropriate for the type of establishment and the scope of services it provides. (2) For the purposes of sub-regulation (1), a health establishment must have guidelines for ─ *(a)* the handover of users between shifts;	Hospital and CHC only

(b) clinical assessments; and	All health establishments
(c) protection of– (i) high risk maternity users and their newborns, infants and children; and (ii) mental health care users and other vulnerable users from abuse, neglect or injury;	All health establishments
(3) For the purposes of sub-regulation (2), the health establishment must – (*a*) ensure training of health care personnel on the guidelines; and (*b*) monitor implementation of the guidelines.	All health establishments
(4) For the purposes of sub-regulation (2)– *(a)* **"handover"** means the transfer of the responsibility for treatment from one health care provider to another by informing them of the clinical investigations ordered, treatment plan, management of care, and any clinical deterioration or evolving problems experienced by the user; *(b)* **"mental health care user"** has the meaning assigned to it in section 1 of the Mental Health Care Act, 2002 (Act No. 17 of 2002); *(c)* **"neglect"** means acts of omission or commission which cause harm to a user or place the user at risk of harm; and *(d)* **"vulnerable users"** means users with physical and intellectual disabilities, persons with a mental illness, the elderly, minors, people with reduced mobility, the frail, terminally ill, migrants and refugees.	

Users undergoing high risk procedures

19. (1) Health establishments must implement and maintain processes to protect users undergoing high risk procedures that are appropriate to the type of establishment and the scope of service it offers.	
(2) For the purpose of sub regulation (1), a health establishment must have systems in place to–	All health establishments
(a) guide the safe administration of medication and safe injection practices;	
(b) ensure safety checks are done before, during and after surgery;	Hospital and CHC only
(c) guide the safe execution of invasive procedures;	All health establishments
(d) ensure users requiring resuscitation receive an immediate response by health care providers trained in resuscitation; and	All health establishments
(e) ensure blood and blood products are ordered, handled and administered in accordance with the Act.	Hospital and CHC
(3) For the purposes of sub-regulation (2) ─	
(a) **"invasive procedure"** means a medical procedure in which a part of the body is entered by puncture or incision, such as repairing of cuts, insertion of tubes or drains.	
(b) **"safe injection practices"** means the administration of injections without causing harm to the user; and	
(c) **"surgery"** means a procedure where the health care provider makes at least one incision through the skin or mucous membranes and the incision is closed before the user leaves the operating room.	

Infection prevention and control programmes

20. (1) All health establishments must maintain a managed environment, which minimises the risk of infection to users, health personnel, and visitors.

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

(a) have an Infection Prevention and Control Programme;

(b) have a designated Infection Prevention and Control structure with clear roles and responsibilities to implement the Infection Prevention and Control Programme;

(c) maintain a formal surveillance and reporting system to identify and track health care associated infections;

(d) maintain a formal surveillance and reporting system to identify and track antimicrobial resistance;

(e) train healthcare personnel and users on infection prevention and control practices;

(*f*) have systems in place to -

(i) minimise the risk of transmission of health care associated infections;

(ii) prevent and reduce the transmission of airborne infections;

(iii) decontaminate medical devices; and

(*g*) have systems in place to keep the environment clean by -

(i) ensuring that cleaning personnel are trained to clean all areas;

(ii) implementing pest control measures in all areas; and

(iii) monitoring the performance of the cleaning services and take corrective measures where applicable.

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

(a) **"decontamination"** means a process that removes or destroys microorganisms to render the object safe for use and includes cleaning, disinfection and sterilisation;

(b) "**health care associated infection"** means an infection that occurs in a user during the provision of health care services in a health establishment that was not present or incubating at the time of admission; and *(c)* **"Infection Prevention and Control structure"** means a team, committee, forum or a designated individual with terms of reference approved by the person or organisation responsible for the supervision and control of a health establishment, that meets regularly to discuss infection prevention and control matters.	

Health care risk waste

21. (1) All health establishments must ensure that health care risk waste is handled, stored, and disposed of safely in accordance with relevant legislation. (2) For the purposes of sub-regulation (1), a health establishment or responsible authority must as appropriate to the type and scale of the establishment ─ *(a)* have and implement annual plans for dealing with risks based on a risk assessment conducted to identify hazardous waste at the establishment; *(b)* have appropriate waste containers at the point of waste generation; *(c)* implement procedures for the collection, handling, storage and disposal of health care risk waste; *(d)* implement procedures for recording of waste removed for destruction; *(e)* manage and safely dispose of sharps; and *(f)* measure and evaluate the performance of the health care risk waste removal services and take corrective action when─ (i) health care personnel fail to adhere to the procedures for the collection, handling, separation, storage and disposal of health care risk waste; or	

(ii) external service providers breach their contractual obligations.

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

(a) **"health care risk waste"** means medical waste such as infectious waste, sharps, anatomical waste, pathological waste, hazardous clinic waste, genotoxic and cytotoxic, pharmaceutical waste, and radioactive waste, whether infectious or not, that poses a risk to the health and safety of users and heath care personnel;

(b) **"sharps"** means medical needles and other sharp medical instruments such as scalpels, blades, lancets, broken glass and vials; and

(c) **"relevant legislation"** means but is not limited to ─

(i) the Hazardous Substances Act, 1973 (Act No. 15 of 1973) and its Regulations;

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

(iii) the National Environmental Management Act,1998 (Act No. 107 of 1998);

(iv) the Healthcare Risk Waste Management Regulations, published in Government *Gazette* 35405, Notice No. 452 of 1 June 2012;

(v) the National Norms and Standards Relating to Environmental Health, published in Government *Gazette* 36849, Notice No. 943 of 20 September 2013;

(vi) the Occupational Health and Safety Act, 1993 (Act No. 83 of 1993); and

(vii) provincial legislation dealing with health care risk waste.

CHAPTER 4
CLINICAL SUPPORT SERVICES

Definitions applicable to this Chapter

22. In this Chapter—

"administer" means the giving of a prescribed dose of medication to a 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 medicine list" means the list of medicines issued by the Minister from time to time, that satisfy the health care needs of the population and must always be available in the right dosage and quantity within a health establishment;

"formulary" means a list of medicines that are accepted for use within a health establishment;

"Good Pharmacy Practice" means the rules of good pharmacy practice made from time to time by the South African Pharmacy Council in terms of section 35A*(b)*(ii) of the Pharmacy Act;

"medical equipment" means any instrument, apparatus or machine, intended for use in the clinical diagnosis, treatment, monitoring and direct care of users that needs to be calibrated, maintained, repaired and decommissioned;

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

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

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

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

"South African Pharmacy Council" means a juristic person established in terms of section 2 of the Pharmacy Act;

"therapeutic support services" means the prevention, treatment, rehabilitation and cure of medical conditions or injuries through the use of therapeutic services or methods such as occupational therapy, physiotherapy, dietetics, podiatry and optometry.

Medicines and medical supplies

23. (1) All health establishments must oversee the provision of pharmaceutical services in accordance with the Pharmacy Act, 1974 (Act No. of 1974). (2) For the purposes of sub-regulation (1), a health establishment or responsible authority must ─ *(a)* designate and maintain a functional structure with clearly defined roles and responsibilities to oversee pharmaceutical services; *(b)* have a license issued according with the Pharmacy Act; *(c)* have a system to ensure that the ordering, storage and preparation of medicines follows good pharmacy practice; *(d)* ensure that users have access to their prescribed medicines; *(e)* ensure that safety protocols in relation to the prescribing, dispensing and the administering of medicines are in place to protect users from medication errors. (3) For the purposes of sub-regulation (2), **"medication errors"** means errors that may lead to the inappropriate use of medication or harm to the user at any point from when the medication is prescribed to when it is taken.	

Medical supplies

24. (1) All health establishments must ensure that they have sufficient medical supplies for the delivery of services. (2) For the purposes of sub-regulation (1), a health establishment or responsible authority must ─ *(a)* designate and maintain a functional structure with clearly defined roles and responsibilities to oversee the management of medical supplies; *(b)* monitor that the ordering, supply and delivery of medical supplies is in accordance with the contractual obligations of the suppliers; *(c)* implement and maintain stock control and inventory procedures for medical supplies; *(d)* provide access to medical supplies during the health establishment's operating hours and emergency supplies after hours; and *(e)* ensure that all medical supplies required for the care of users are in stock. (3) For the purposes of sub-regulation (2), **"medical supplies"** means products other than medicines that are used for therapeutic purposes such as gloves, gauze, cotton, administration sets, needles, catheters, oxygen masks.	

Diagnostic services

25. (1) Health establishments must ensure that diagnostic services offered at the establishment are safe for users and for health care personnel involved in delivering these services. (2) For the purposes of sub-regulation (1), a health establishment must ─ *(a)* provide access to diagnostic services during the operating hours of the health establishment;	All health establishments

(b)	where applicable be accredited by the relevant regulatory body relating to the type of diagnostic service;	Hospital and CHC only
(c)	have measures in place to protect users and health care personnel from exposure to hazardous materials when using diagnostic services;	Hospital and CHC only
(d)	ensure that diagnostic service areas have emergency procedures, call-out protocols and equipment to deal with resuscitations and other emergencies;	Hospital and CHC only
(e)	have systems in place to report adverse incidents to a structure in the health establishment or responsible authority that monitors these events; and	All health establishments
(f)	have systems for measuring and evaluating the performance of the diagnostic services, are appropriate to the type and scale of the services offered by the establishment, and taking corrective action as appropriate when ─ (i) health care personnel fail to adhere to diagnostic services procedures; or (ii) external service providers breach their contractual obligations.	All health establishments

Blood services

26. (1) Hospitals and CHCs must ensure that blood services and blood products are available and administered in accordance with the Act. (2) For the purposes of sub-regulation (1), a hospital or CHC clinic must ensure that ─ *(a)* blood and blood products are made available to users when required;	

(b) blood and blood products are ordered in accordance with the health establishment's policies and procedures; *(c)* blood and blood products are stored, handled and delivered in accordance with a cold chain procedure within the health establishment; *(d)* the health care personnel involved in the delivery of blood services protect users and other health care personnel from exposure to hazardous waste; and *(e)* adverse blood reactions are reported to a committee in the health establishment that monitors adverse incidents. (3) For the purposes of sub-regulation (2) ─ *(a)* **"adverse blood reaction"** means any adverse incident that occurs as a result of the transfusion of blood or blood products; *(b)* **"blood products"** means any component of blood which is intended for use in transfusion, and includes red blood cells, platelets and plasma; *(c)* **"blood services"** means the activities associated with recruiting donors, collecting blood and blood products, testing, processing, storing and distributing blood and blood products; and *(d)* **"cold chain procedure"** means the continued refrigeration of blood and blood products from the point of their origin, through to their transportation, unloading, distribution and storage at the location where they will be used.	

Rehabilitation and support services

27. (1) All health establishments must ensure that its users have access to appropriate rehabilitation and social support services as are applicable to the type of establishment and the type and scale of services it offers. (2) For the purposes of sub-regulation (1), a health establishment must ensure users─ *(a)* are rehabilitated according to relevant clinical protocols;	

(b) receive required assistive devices; and *(c)* are being referred when necessary. (3) For the purposes of sub-regulation (2*)*, **"assistive device"** means assistive, adaptive and rehabilitative devices for users with temporary or permanent disabilities which enable these users to perform actions and tasks.	

Medical equipment management

28. (1) Health establishments must ensure that the establishment's medical equipment is available and functional.	All health establishments
(2) For the purposes of sub-regulation (1), a health establishment or responsible authority must—	
(a) ensure that medical equipment is —	
(i) procured in accordance with relevant legislative requirements;	Hospital and CHC only
(ii) licensed where required from the relevant licensing body;	All health establishments
(iii) available in accordance with the essential equipment list in all clinical service areas;	All health establishments
(iv) functional; and	All health establishments
(v) maintained and repaired according to a planned maintenance schedule, developed in accordance with the manufacturer's specifications;	All health establishments
(b) measure and evaluate the performance of equipment suppliers against their contractual obligations and take corrective action where breaches occur;	All health establishments

(c)	ensure that medical equipment is safe for users and used in accordance with the manufacturer's specifications; and	All health establishments
(d)	train health care personnel in the use, calibration and testing of medical equipment as appropriate to their clinical service areas.	All health establishments

Mortuary services

29. (1) Health establishments must store, release and transport bodies of the deceased in accordance with regulations made under section 68(1)*(b)* of the Act.		
(2) For the purposes of sub-regulation (1), the health establishment and the responsible authority must ─		
(a)	implement policies and procedures guiding all aspects of safe preparation, storage, infection control, release and transportation of bodies;	Hospital and CHC only
(b)	have access to an area for the handling, storage, including temporary storage, and viewing of bodies;	All health establishments
(c)	have protocols in place to allow the viewing of bodies of the deceased by the family and other authorities;	All health establishments
(d)	provide health care personnel working with bodies of the deceased with personal protective equipment;	Hospital and CHC only
(e)	train health care personnel working with bodies of the deceased in the safe storage, handling, transportation and release of bodies; and	Hospital and CHC only

(f) implement a control system, which monitors the movement and release of bodies, including death notifications and the issuance of related documents. (3) For the purposes of sub-regulation (2),**"access"** means the availability of an ─ *(a)* onsite facility for long term or temporary storage of bodies of the deceased; or *(b)* off-site facility with an external service provider responsible for the handling, storage and transportation of bodies.	Hospital only

CHAPTER 5
HEALTH PROMOTION AND DISEASE PREVENTION

Health promotion and disease prevention

30. (1) The health establishment must implement systems to promote health and prevent disease. (2) For the purposes of sub-regulation (1), the public health establishment must ─ *(a)* collaborate with community health workers, school health providers and other service providers and sectors in dealing with community-specific health conditions and run targeted interventions; and *(b)* ensure that users with communicable and non-communicable diseases receive information on relevant lifestyle behaviour modification. (3) For the purposes of sub-regulation (2)*(a)* **"other service providers and sectors"** means non-governmental organisations, private health establishments, rehabilitative services, palliative care, community care workers, and district clinical specialist teams, or any other organ of state involved in the delivery of social services.	All health establishments

Outbreaks, health emergencies and disaster preparedness

31. (1) All health establishments must implement appropriate measures to protect users, healthcare personnel and the public from disease outbreaks and to help minimise the negative impact of health emergencies and disasters. (2) For the purposes of sub-regulation (1), a health establishment or responsible authority must — *(a)* comply with regulations made under section 90(1)*(k)* of the Act; *(b)* have a disaster and disease outbreak response plan;	

(c) try their disaster and outbreak management plans in line with an intersectoral plan and revise it in response to the outcome of the trial as appropriate; and *(d)* assign a health care provider to oversee, liaise with and communicate information in relation to disaster and outbreak management with relevant organs of the state. (3) For the purposes of this regulation – *(a)* **"health emergencies and disasters"** means any unforeseeable events that requires urgent response in order to protect the public from harm and minimise loss of life; *(b)* **"intersectoral plan"** means a plan that sets out the processes and procedures to manage and respond to disasters and outbreaks as prepared and adopted by different organs of state, including departments responsible for agriculture, education, water and sanitation, and environmental affairs; and *(c)* **"outbreak"** means an occurrence of a particular disease in excess of what would normally be expected in a defined community, geographical area or is the result of seasonal variation.	

Environmental controls

32. (1) All health establishments must have appropriate systems and procedures for protecting users, health personnel and the public from environmental hazards in accordance with applicable environmental legislation. (2) For the purposes of sub-regulation (1) **"applicable environmental legislation"** includes– *(a)* the Air Pollution Prevention Act, 1965 (Act No. 45 of 1965), as amended; *(b)* the Environment Conservation Act, 1989 (Act No. 73 of 1989); *(c)* the National Environmental Management: Air Quality Act, 2004 (Act No. 39 of 2004);	I

(d) the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008); and *(e)* the National Environmental Management Act, 1998 (Act No. 107 of 1998).	

CHAPTER 6
LEADERSHIP AND GOVERNANCE

Oversight, leadership and accountability

33. (1) All health establishments must have a functional oversight leadership structure to manage the regulated obligations of the establishment. (2) For the purposes of sub-regulation (1), a health establishment must ─ *(a)* have a functional leadership structure with clearly defined roles and responsibilities whom is tasked by the person or organisation responsible for the operation of the establishment, with ensuring that the establishment complies with regulatory obligations; *(b)* have systems in place to provide its leadership structure with information regarding the clinical governance, operational management, and financial and quality performance of the health establishment; and *(c)* have systems in place whereby the management of the health establishment is held accountable for the operation of the health establishment and its compliance with regulatory obligations. (3) For the purposes of sub-regulation (2)─ *(a)* **"oversight leadership structure**" means the governing structure of a health establishment; and *(b)* **"functional"** means that the oversight leadership structure as appointed, meets according to the frequency stipulated in its terms of reference.	

CHAPTER 7
OPERATIONAL MANAGEMENT

Human resources management

34. (1) All health establishments must manage their health care personnel in a manner that ensures that they deliver safe and effective care.

(2) For the purposes of sub-regulation (1), the health establishment must, as appropriate to the type and size of the establishment–

(a) have a human resource development plan;

(b) in consultation with the relevant authority, ensure that the number and skills mix of health care personnel meet the needs of the health establishment;

(c) ensure that all healthcare providers –

(i) maintain their registration with the relevant statutory health professional councils where applicable;

(ii) regularly update their knowledge and skills to perform their respective roles;

(iii) work within their scope of practice; and

(iv) have authorisation to provide care to users while working as independent health care providers in the health establishment;

(d) arrange for health care providers to receive continuous in-service training to improve their knowledge relating to their roles and responsibilities;

(e) ensure that all healthcare personnel receive supportive supervision to improve their performance; and

(f) ensure that –

(i) healthcare personnel and management have regular performance reviews; and

(ii) healthcare personnel's roles and responsibilities are clearly documented and aligned with their scope of practice.

(3) For the purposes of sub-regulation (2), **"scope of practice"** means the range of procedures, actions, and processes which a health care provider is permitted to perform by their relevant statutory health professional council and any practice that may be prescribed from time to time by that council.	

Occupational health and safety

35. All health establishments must protect health care personnel from workplace hazards by establishing and implementing occupational health and safety systems accordance with the requirements of the Occupational Health and Safety Act, 1993.	

Transport management

36. (1) All health establishments or responsible authority must ensure that vehicles used to transport users and health care personnel in non-emergency situations are safe and are available when required. (2) For the purposes of sub-regulation (1), a health establishment or responsible authority must ─ *(a)* ensure that there is access to safe and regular transport for─ (i) users who are required to access non-emergency referral services in other health establishments; and (ii) health care personnel involved in outreach services; and *(b)* ensure that ─ (i) vehicles, owned or used, are licensed and maintained; (ii) employed or contracted drivers have a valid driver's license or public transport driving permit as may be required to perform their functions; and (iii) vehicles are not misused.	

Information management

37. (1) All health establishments must establish systems to produce accurate and timely information to inform managerial and clinical decision-making on the safety, reliability and efficiency of the health care services provided by the establishment. (2) For the purposes of sub-regulation (1), a health establishment or responsible authority must ─ *(a)* designate the responsibility for the overall management of information to an information manager; *(b)* ensure that health care personnel are trained to collect and record information in line with the health establishment's information management policy and plan; *(c)* make available equipment, networks and systems to allow the recording of information; *(d)* ensure that all information reported in terms of sections 79(1)*(d)* and 79(2)*(b)* of the Act is checked for accuracy and verified by designated healthcare personnel; *(e)* analyse, use and report on managerial, clinical and administrative information for the health establishment and, where possible, at service unit level; and *(f)* implement contingency plans to address and recover from the impact of any failure in equipment, networks and information technology systems.	

Health record management

38. (1) All health establishments must ensure that health records are available and can be retrieved when needed. (2) For the purposes of sub-regulation (1), the health establishment, must ─ *(a)* have a health record filing, archiving, disposing, storage and retrieval system which complies with applicable legislation;	

	(b) designate trained health care personnel to oversee the health records department, and set out their roles and responsibilities; *(c)* train all administrative and records health care personnel in the storage, retrieval, archiving, disposing and confidentiality of health records; *(d)* protect the confidentiality of health records; and *(e)* secure health records with appropriate security control measures in the records storage area and in the clinical service area in accordance with the Protection of Personal Information Act, 2013 (Act No. 4 of 2013).	

CHAPTER 8
FACILITIES AND INFRASTRUCTURE

Definitions applicable to this Chapter

39. In this Chapter—

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

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

"linen" means items such as bed sheets, pillow cases, towels, theatre and user gowns, theatre drapes, dish cloths, kitchen overalls, staff uniforms and overalls, mattresses, curtains and mattress covers, blankets, duvets and pillows.

Management of buildings and grounds

40. (1) All health establishments and their grounds must meet the requirements of the building regulations. (2) For the purposes of sub-regulation (1), a health establishment must as appropriate for the type of buildings and grounds of the establishment— *(a)* have all the required compliance certificates in terms of the building regulations; *(b)* have a maintenance plan for buildings and the ground; *(c)* ensure buildings and grounds are physically accessible to users; *(d)* ensure emergency access points are provided in all service areas and kept clear at all times; *(e)* provide sheltered waiting areas for users that are adjacent to or in close proximity to the clinical service areas; *(f)* furnish in-patient areas and rest areas for health care personnel in accordance with relevant guidelines;	

(g) ensure there are clean and properly functioning toilets for users and healthcare personnel; and *(h)* ensure there are hand-washing facilities for users and healthcare personnel. (3) For the purposes of sub-regulation (1), the health establishment must as appropriate to the type of establishment and the scope and scale of services offered ─ *(a)* provide isolation units or cubicles where users with contagious infections can be accommodated; and *(b)* have ventilation systems that maintain the inflow of fresh air, temperature, humidity and purity of the air within specified limits set for different service areas such as theatres, kitchen and isolation units. (4) For the purposes of sub-regulation (3), **"contagious infection"** means an infection capable of being transmitted from one person to another by direct or indirect contact.	

Building engineering services

41. (1) All health establishments must ensure that building engineering services are functional and enable safe and uninterrupted delivery of health care services as appropriate for the type of establishment and type and scale of services offered by the establishment. (2) For the purposes of sub-regulation (1), a health establishment must have ─ *(a)* 24-hour electrical power, medical gas, lighting and water supply; *(b)* systems for safe disposal of sewerage; and *(c)* machinery and equipment for electrical, medical gas and water supply that are maintained and decommissioned according to the building regulations.	

Communication system

42. (1) Health establishments must have a functioning communication system that is appropriate for the type of establishment and the type and scale of services it offers.	
(2) For the purposes of sub-regulation (1), a health establishment must—	All health establishments
(a) have a functional communication system that allows—	
(i) users to contact the health establishment;	
(ii) health care personnel to perform their duties; and	
(b) have a call system to ensure that users can communicate their need for assistance.	Hospital and CHC only
(3) For the purposes of sub-regulation (2)—	
(a) **"functional communication system"** means a communication system that is able to receive incoming and handle outgoing or internal calls and is manned during the operating hours of the health establishment; and	
(b) **"communication system"** includes a telephone, radio, cell phone and switchboard.	

Security services

43. (1) All health establishments must have systems to protect users, health care personnel and property from security threats and risks.	
(2) For the purposes of sub-regulation (1), a health establishment or responsible authority must ,as appropriate to the type of establishment—	
(a) have approved standard operating procedures that identify security threats and risks, assess their severity and likelihood, and outlines the mitigation strategies and action that must be taken in response to these risks;	
(b) have personnel responsible for ensuring adherence to the security procedure by the health establishment;	

(c) promote security awareness amongst health care personnel and users; *(d)* ensure that security staff are trained and given appropriate equipment to deal with security incidents and threats; and *(e)* measure the performance of the security services and take corrective action when ─ (i) health care personnel fail to adhere to security procedures; or (ii) external service providers breach their contractual obligations. (3) For the purposes of sub-regulation (2), **"security threats and risks"** means any criminal activity or threat of a potential criminal activity on the property, health care personnel or users in the health establishment including theft, assault, abuse and injury.	

General waste management

44. (1) All health establishments must have system and processes that are appropriate for the kind of establishment and for the scope and scale of services offered, for ensure that general waste is handled, stored and disposed of in a safe manner in accordance with the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008). (2) For the purposes of sub-regulation (1), subject to regulation 21, the health establishment must ─ *(a)* implement a general waste management plan; *(b)* designate trained health care personnel to oversee the management of general waste in accordance with the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), and the service level agreement;	

(c) ensure that health care personnel dealing with general waste are protected from acquiring infections through –

(i) the use of personal protective equipment; and

(ii) prophylactic immunisations;

(d) segregate and transport general waste within the clinical and support service areas in accordance with National Norms and Standards Relating to Environmental Health, published in Government *Gazette* 36849, Notice No. 943 of 20 September 2013;

(e) store, remove and dispose of general waste from the health establishment in accordance with waste management procedure;

(f) make available general waste containers; and

(g) measure the performance of general waste management services and take corrective action when ─

(i) health care personnel fail to adhere to waste management procedures; or

(ii) external service providers breach their contractual obligations.

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

(a) **"general waste"** means waste that does not pose an immediate hazard or threat to health or to the environment, and includes —

- domestic waste;
- building and demolition waste;
- business waste;
- inert waste; and

(b) **"support service area"** means an area within a health establishment other than where users receive treatment and care.

Linen services

45. (1) All health establishments must provide clean linen as required for the type of establishment and scope and scale of services it offers. (2) For the purposes of sub-regulation (1), a health establishment or responsible authority, must ─ *(a)* have or have access to laundry services; *(b)* ensure there is linen to meet the needs of users and service delivery; *(c)* have systems to ensure that laundry services are in accordance with the linen management procedures relevant to the type of health establishment; and *(d)* monitor the performance of the linen services and take corrective action when ─ (i) health care personnel fail to adhere to linen management procedures; or (ii) external service providers breach their contractual obligations.	

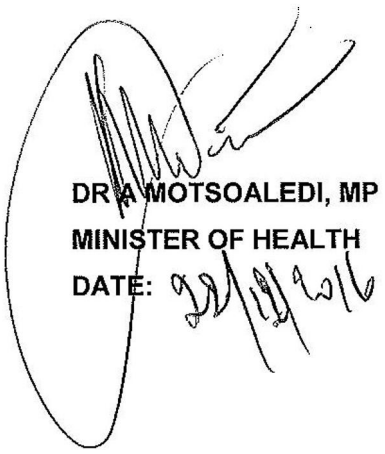
Food services

46. (1) Hospitals and CHCs must provide safe food that conforms to the user's nutritional, cultural and religious needs. (2) For the purposes of sub-regulation (1), a health establishment must as appropriate to the scope and scale of services it offers - *(a)* ensure that users and health care personnel are provided with food and beverages that caters for their nutritional, cultural and religious needs; and *(b)* monitor the performance of food services and take corrective action when─ (i) health care personnel fail to adhere to food management procedures; or (ii) external service providers breach their contractual obligations, as the case may be.	

CHAPTER 9
GENERAL PROVISIONS

Short title and commencement

47. These Regulations are called the Norms and Standards Regulations Applicable to Different Categories of Health Establishments, and come into operation on the date of publication in the Government *Gazette*.



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