**DEPARTMENT OF HEALTH**

**NO. 67** **02 FEBRUARY 2018**

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

## NORMS AND STANDARDS REGULATIONS APPLICABLE TO DIFFERENT CATEGORIES OF HEALTH ESTABLISHMENTS

The Minister of Health has, 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.

## SCHEDULE

## ARRANGEMENT OF REGULATIONS

## CLINICAL SUPPORT SERVICES

10. Medicines and medical supplies
11. Diagnostic services
12. Blood services
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## FACILITIES AND INFRASTRUCTURE

14. Management of buildings and grounds
15. Engineering services
16. Transport management
17. Security services

## GOVERNANCE AND HUMAN RESOURCES

18. Governance
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## DEFINITIONS, PURPOSE AND APPLICATION

### 1. Definitions

**"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;

**"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;

**"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 includes any results of diagnostic investigations performed on the user and is recorded by a health care provider, either personally or under his or her direction;

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

**"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;

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

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

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

**"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; and

**"structure"** means a designated team, committee or forum.

## Scope and application

**2.** These Regulations apply to the health establishment to the extent specified in the measurement tools obtainable from the National Department of Health.

## Purpose of Regulations

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

## USER RIGHTS

### User information

**4** (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 with information relating to—
- (i) the health care services provided by the health establishment;
- (ii) service opening and closing times,
- (iii) visiting hours where relevant; and
- (iv) complaints, compliments and suggestions management system.

*(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

*(c)* display the results of user experience of care surveys conducted within the past twelve months.

### Access to care

**5** (1) The health establishment must ensure that users are attended to in a manner which is consistent with the nature and severity of their health condition,

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

*(a)* implement a system of triage;

*(b)* ensure access to emergency medical transport for users requiring urgent transfer to another health establishment, and that they are accompanied by a health care provider; and

*(c)* adhere to clinical guidelines on stabilizing users presenting in an emergency

before referring them to another health establishment.

(3) The health establishment must maintain a system of referral as established by the responsible authority.

(4) For the purposes of sub-regulation (3), a health establishment must—

*(a)* ensure that users are provided with information relating to their referral to another health establishment; and

*(b)* ensure that a copy of the referral document is kept in the user's health record.

## CLINICAL GOVERNANCE AND CLINICAL CARE

### User health records and management

**6.** (1) The health establishment must ensure that health records of health care users are protected, managed and kept confidential in line with section 14, 15 and 17 of the Act.

(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 the law;

*(b)* ensure confidentiality of health records; and

*(c)* 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).

(3) The health establishment must create and maintain a system of health records of users in accordance with the requirements of section 13 of the Act.

(4) For the purposes of sub-regulation (3), a health establishment must—

*(a)* record the biographical data of the user and the identification and contact information of the user and his or her next of kin; and

*(b)* record information relating to the examination and health care interventions of users.

(5) The health establishment must have a formal process to be followed when obtaining informed consent from the user.

(6) The health establishment must issue a discharge report to users in accordance with section 10 of the Act.

## Clinical management

**7.** (1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

(2) For the purpose of sub-regulation (1) a 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; and
(b) establish and maintain systems, structures and programmes to manage clinical risk.

## Infection prevention and control programmes

**8.** (1) The health establishment must maintain an environment, which minimises the risk of disease outbreaks, the transmission of infection to users, health care personnel and visitors.

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

(a) ensure that there are hand washing facilities in every service area;
(b) provide isolation units or cubicles where users with contagious infections can be accommodated;
(c) ensure there is clean linen to meet the needs of users; and
(d) ensure that health care personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations

## Waste Management

**9.** (1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

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

*(a)* have appropriate waste containers at the point of waste generation;

*(b)* implement procedures for the collection, handling, storage and disposal of waste.

## CLINICAL SUPPORT SERVICES

### Medicines and Medical supplies

**10.** (1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965

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

(a) implement and maintain a stock control system for medicine and medical supplies; and

(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

### Diagnostic services

**11.** (1) Health establishments must ensure that diagnostic services are available and 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 where applicable be accredited by the relevant regulatory body relating to the type of diagnostic service.

### Blood services

**12.** (1) Hospitals and CHCs must ensure that users have access to blood and blood products when required.

(2) For the purpose of sub-regulation (1) the health establishment must ensure that:

(a) blood and blood products are stored, handled and delivered in accordance with a cold chain procedure within the health establishment;

*(b)* the health care personnel involved in the delivery of blood services protect

users and other health care personnel from exposure to hazardous waste; and

*(c)* adverse blood reactions are reported to a committee in the health establishment that monitors adverse incidents.

**Medical equipment**

**13.** (1) Health establishments must ensure that the medical equipment is available and functional in compliance with the law.

(2) For the purpose of sub-regulation (1) the health establishment must ensure that equipment is:

(a) licensed where required from the relevant licensing body; and

(b) in accordance with the essential equipment list in all clinical service areas

## FACILITIES AND INFRASTRUCTURE

**Management of buildings and grounds**

**14.** (1) The health establishment 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 emergency exit and entrance points are provided in all service areas and kept clear at all times; and

(d) 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.

### Engineering services

**15.** (1) The health establishment must ensure that engineering services are in place.

(2) For the purposes of sub-regulation (1) a health establishment must have: 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.

### Transport management

**16.** (1) The health establishment must ensure that vehicles used to transport users and health care personnel are safe and well maintained.

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

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

(b) drivers have valid driver's license and or public transport driving permit.

### Security services

**17.** (1) The health establishment must have systems to protect users, health care personnel and property from security threats and risks.

(2) For the purposes of sub-regulation (1), the health establishment must ensure that security staff are capacitated to deal with security incidents, threats and risks.

## GOVERNANCE AND HUMAN RESOURCES

### Governance

**18.** The health establishment must have a functional governance structure with written Terms of Reference.

**Human resources management**

**19.** (1) The health establishment must ensure that they have systems in place to manage health care personnel in line with relevant legislation, policies and guidelines.

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

*(a)* have and implement a human resource plan that meet the needs of the health establishment;

*(b)* have a performance management and development system in place; and

*(c)* have a system to monitor that health care personnel maintain their professional registration with the relevant councils on an annual basis.

**Occupational health and safety**

**20.** The health establishment must comply with the requirement of the Occupational Health and Safety Act, 1993.

**GENERAL PROVISIONS**

**Adverse events**

**21.** (1) The health establishment must have a system to monitor and report all adverse events.

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

(a) have a register for all adverse events; and

(b) have systems in place to report adverse incidents to a structure in the health establishment or responsible authority that monitors these events.

**Waiting times**

**22.** The health establishment must monitor waiting times against the National Core Standards for Health Establishments in South Africa.

**Short title and commencement**

**23.** These Regulations are called the Norms and Standards Regulations Applicable to Different Categories of Health Establishments, 2017, and will come into operation 12 months after the date of promulgation.

**DR A MOTSOALEDI, MP**
**MINISTER OF HEALTH**
**DATE:** 15/1/2018