
CHAPTER 1

DEFINITIONS, PURPOSE AND RESPONSIBILITY FOR HEALTH

1. *DEFINITIONS*

In *this Act*, unless the context indicates otherwise -

“*academic health service complex*” will comprise several health establishments and a consortium of educational institutions all working together to educate and train a wide range of health professionals and conduct research;

“*authorised institution*” means an institution as contemplated in section 64;

“*basic health service*” means those services as *prescribed* by the *Minister*, after consultation with the *National Health Authority*;

“*blastomere*” means any of the cells which originate from a fertilized ovum;

“*capital expenditure*” means-

- (a) an expenditure made for or on behalf of a *health establishment* that, under generally accepted accounting principles, is not ordinarily chargeable as an expense of operation or maintenance and includes the cost of any surveys, designs, plans, working drawings and specifications essential to the acquisition, improvement, replacement, expansion or modification of any *health establishment* but excludes the cost of any feasibility study; and
- (b) a lease, donation or other arrangement that would be a *capital expenditure* if the money or any other property of value had changed hands;

“*certificate of need*” means the certificate referred to in section 47, which entitles the holder thereof to operate a *health establishment* on fulfilment of any term and condition set out in the certificate;

“clinical trials” is an investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy;

“communicable disease” means a disease resulting from an infection due to pathogenic agents or toxins generated by it, following the direct or indirect transmission of the agent from the source to the host;

“construction” means the erection, building, alteration, reconstruction, improvement, extension or modification undertaken for any purpose on behalf of a **health establishment** and includes the lease or purchase of equipment, excavation and so forth ;

“cotermious” means sharing similar boundaries;

“Director-General” means the head of the **national department** of health;

“disability” means a long term or recurring physical or mental impairment which substantially limits a **person’s** ability to perform an activity in the manner or within the range considered normal for a human being;

“discharge report” means a report specifying -

- (a) **user** registration information;
- (b) **health establishment** information;
- (c) date and time of admission at and discharge from **health establishment**;
- (d) **health care provider** information;
- (e) presenting complaint;
- (f) diagnosis;
- (g) investigations undertaken;
- (h) treatment provided; and
- (i) ongoing treatment management plan, or if appropriate, certification that no further treatment is required in respect of the presenting complaint;

“District Health Authority” means a body that has been established in accordance with the provisions of section 43;

“donation” in this Act means the *donation* of an *organ* in accordance with the procedures contemplated in Chapter 8 and includes the giving of consent in accordance with that Chapter to the post-mortem examination of such a body and **“donate”** and **“donor”** have corresponding meaning;

“emergency treatment” means treatment which is needed to treat a life-threatening but reversible deterioration in a person’s health status and it continues to be **emergency treatment** until the condition of the person has stabilised or has been reversed to a particular extent;

“gamete” means either of the two generative cells essential for human reproduction;

“health care provider” means a *person* providing health services;

“health district” means a district whose boundaries have been demarcated in accordance with the procedure contemplated in sections 41 and 42;

“health establishment” means the whole or part of a public or private institution, facility, agency, building or place whether organised for profit or not that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, preventative or other health services;

“health officer” means “health officer” as defined in the Health Act, 1977 (Act no. 63 of 1977);

“health research” includes any action contributing to knowledge of -

- (a) biological, clinical or psychological social processes in human beings;
- (b) improved methods for the provision of health services;
- (c) human pathology;
- (d) the causes of disease; and
- (e) the effects of the environment on the human body;

“health surveillance” shall include morbidity and mortality surveillance of disease surveillance, health systems surveillance, epidemiological surveillance, and socio-demographic surveillance;

“human cloning” means the creation of identical organisms from living or dead individuals by manipulation of genetic material, including:

- (a) removal of nuclear material from an *oocyte* or a female *gamete*, embryo or embryo cells and replace it with nuclear material from a *zygote* or somatic cell at any stage from foetal or adult development; or
- (b) embryo splitting or *blastomere* separation;

“Inspectorate of Health Establishment” means the inspectorate established in terms of section 38(1) and correspondingly **“Inspectorate”** bears the same meaning;

“Minister” means the member of cabinet responsible for health;

“municipality” means a *municipality* as defined in the Municipal Systems Act, 2000 (Act 32 of 2000);

“national department” means the *national department* responsible for health;

“National Health Authority” means the body established in terms of section 28;

“National Health Management Committee” means the committee established in terms of section 30(1);

“norm” means a statistical normative rate of provision or measurable target outcome over a specified period of time;

“oocyte” means a developing human egg cell;

“organ” means any part of the human body adapted by its structure to perform particular vital functions, including the eye and its accessories but excluding any skin and appendages, flesh, bone, bone marrow, body fluid, blood or *gamete*;

“palliative care” means the active total care of persons whose disease is not responsive to curative treatment;

“prescribe” means prescribe by regulation;

“private health establishment” means a *health establishment* that does not constitute or is not owned or controlled by an organ or quasi-organ of the State;

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

"Provincial Health Authority" means a body established in terms of section 35;

"public health establishment" means a *health establishment* that constitutes or is owned or controlled by an organ or quasi-organ of the State;

"rehabilitation" means a goal-orientated and time-limited process aimed at enabling impaired persons to reach an optimum mental, physical and/or social functional level;

"relevant Member of the Executive Council" means the member of the Executive Council responsible for health in a province;

"the Constitution" means the Constitution of the Republic of South Africa, 1996 (Act 108 of 1996);

"tissue" means any human *tissue* including any flesh, bone, gland, organ, or body fluid, including any implanted medical or other assistive device, but excluding any bone marrow, blood or *gamete*;

"use" in relation to *tissue*, includes to preserve or dissect;

"user" means the *person* receiving treatment or using a health service; and in certain circumstances may include, where the person concerned is -

- (a) below the age contemplated in section 39(4) of the Child Care Act, 1983 (Act No.74 of 1983), that person's parent or guardian or a person authorised by law or court order to act on that person's behalf;
- (b) incapable of taking decisions, the person's next of kin or a person authorised by law or court order to act on that person's behalf;
- (c) where the person is deceased, an executor of that person's deceased estate;

"zygote" means the product of the union of a male and a female *gamete* outside the human body.

2. **APPLICATION AND INTERPRETATION**

In an instance where a conflict arises between the provisions of this Act and those of any other health legislation, with the exception of legislation that expressly amends this Act, the provisions of this Act will apply.

3. **PURPOSE OF THIS ACT**

The purpose of *this Act* is -

- (a) to establish a national health system which -
 - (i) encompasses public, private and non-governmental providers of health services; and
 - (ii) provides the population of the Republic with the best possible health services that available resources can afford;
- (b) to set out the rights and duties of both *health care providers* and *users*; and
- (c) to provide for related matters.

4. **RESPONSIBILITY FOR HEALTH**

- (1) The *Minister* is responsible within the limits of available resources to -
 - (a) protect, promote, improve and maintain the health of the population;
 - (b) promote the inclusion of health services in the socio-economic development plan of the country;
 - (c) determine the policies and measures necessary to protect, promote, improve and maintain the health and well-being of the population;
 - (d) ensure the rendering of *basic health services* to the population of the Republic;
 - (e) prioritise the health services that the state can provide taking into consideration health needs and resources available.

- (2) (a) The *national* and each *provincial department* and *municipalities* must establish health services, and each *municipality*, all *public health establishments* and *health care providers* must render health services within the limits of available resources.
- (b) The *national department, provincial departments, municipalities, public health establishments* and *health care providers* must act in accordance with *this Act* when exercising or performing any power, duty or function relating to health.

5. ***PERSONS ELIGIBLE FOR FREE HEALTH SERVICES IN PUBLIC HEALTH ESTABLISHMENTS***

The Minister may, subject to any conditions as may be *prescribed*, determine that certain persons are eligible for free health services at *public health establishments*.

CHAPTER 2

RIGHTS AND DUTIES OF USERS AND HEALTH CARE PROVIDERS

6. ***RIGHT OF USERS TO INFORMATION ON HEALTH SERVICES***

The *national* and *provincial departments, district health authorities* and municipalities must ensure that adequate and comprehensive information is disseminated on the health services for which they are responsible.

7. ***EMERGENCY TREATMENT***

Subject to any limitations which the *Minister* or the *relevant members of the Executive Council* may *prescribe*, a *public* or *private health establishment* shall not deny a person requiring *emergency treatment* such treatment if the establishment is open and able to provide the necessary treatment.

8. ***PARTICIPATION IN DECISIONS***

Every *user* has a right to participate in any decision affecting his or her personal health and treatment, unless it is not reasonably practicable for the *user* to participate.

9. ***FULL KNOWLEDGE***

- (1) Every *health care provider* must inform a *user* in an appropriate manner of -
 - (a) the *user's* health status;
 - (b) the range of diagnostic procedures and treatment options generally available to the *user* ; and
 - (c) the benefits, risks, costs and consequences generally associated with each option.
- (2) *Health care providers* must provide a *discharge report* to any person who has received treatment in that establishment and has requested the *discharge report*.

10. ***REQUIREMENT FOR CONSENT***

Subject to any other law, no person or *health establishment* may provide a *user* with treatment of any nature, whether for examination, hospitalisation, specimen-taking, surgery, medicinal treatment or other intervention, unless -

- (a) the *user* has been adequately informed as required in section 9(1) and has consented to the treatment;
- (b) a law or court order has authorised the treatment;
- (c) the treatment is necessary for the protection of public health; or
- (d) any delay in treating a *user* might result in his or her death or irreversible damage to his or her health and the *user* has not impliedly or by conduct refused that treatment.

11. ADMISSION TO A HEALTH ESTABLISHMENT WITHOUT CONSENT

- (1) A *health establishment* must notify the head of the *provincial department* in the province in which that establishment is situated within 48 hours of the time that a *user* is admitted for treatment to that establishment without his or her consent.
- (2) The provisions of subsection 1 do not apply if the *user* consents to the treatment in that establishment within 24 hours of admission.
- (3) If a 48 hour period contemplated in subsection (1) expires on a Saturday, Sunday or public holiday, the *health establishment* may notify the head of the *provincial department* at any time before noon of the next day that is not a Saturday, Sunday or public holiday.

12. TREATMENT FOR EXPERIMENTAL OR RESEARCH PURPOSES

- (1) A *health establishment* must inform the *user* being treated in that establishment in the appropriate manner if any treatment procedures applied to that *user* are, at the time of treatment, intended to be part of an experimental or research project.
- (2) No *health establishment* may apply any treatment procedure on a *user* being treated at that establishment for a purpose contemplated in subsection (1) unless the following persons have each given prior written authorisation for the *use* of the procedure -
 - (a) the *user* ;
 - (b) the *health care provider* primarily responsible for the *user's* treatment; and
 - (c) the head of the *health establishment* and the ethics committee concerned, or any other *person* or body to whom that authority has been delegated.

13. OBLIGATIONS TO KEEP A RECORD

- (1) The person or body in charge of a *public* or *private health establishment* must maintain a permanent health record of every *user* of health services at that establishment in the *prescribed* manner.

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- (2) Any person required to maintain health records must do so in compliance with the provisions of the National Archives of South Africa Act, 1996 (Act no. 43 of 1996), and the Promotion of Access to Information Act, 2000 (Act no. 2 of 2000).

14. CONFIDENTIALITY

- (1) Every *user* is entitled to confidentiality of all information concerning the *user*, including information relating to her or his health status, treatment, or stay in a *public* or *private health establishment*.
- (2) No person or *health establishment* may disclose any information which a person is entitled to have kept confidential in terms of subsection (1), unless -
- (a) the *user* consents in writing to that disclosure; or
 - (b) *this Act*, a court order, or any other law, requires that disclosure.

15. HEALTH USER'S RIGHT OF ACCESS TO RECORDS

A person referred to in the Promotion of Access to Information Act (Act No.2 of 2000), as the Information Officer must allow access to the health records of a user in accordance with the provisions of that Act.

16. USER'S ACCESS

- (1) A person who holds parental authority over a *user* who is a minor is entitled to have access to the health records of that *user* unless -
- (a) the head of the *health establishment* concerned determines that that disclosure of the content of that record to the holder of parental authority could be prejudicial to the *user*;
 - (b) the *user*, after being consulted by the head of the *health establishment*, refuses to allow the contents of her/his health records to be disclosed to the holder of parental authority; or

- (c) the access would be in contravention of the rights of the user contained in the Choice on Termination of Pregnancy Act, 1996 (Act no 92 of 1996).
- (2) The head of a *health establishment*, after consulting the *health care provider* primarily responsible or another *health care provider* designated by the head of the *health establishment* concerned, may temporarily deny a *user* access to information contained in the *user's* health record if disclosure of that information would be likely to be seriously prejudicial to the *user*.

17. ADMINISTRATIVE STAFF ACCESS TO HEALTH RECORDS

Administrative staff at any *public* or *private health establishment* may have access to the health records of a *user* for any legitimate purpose within the ordinary course of their duties.

18. HEALTH CARE PROVIDER ACCESS TO HEALTH RECORDS

A *health care provider* may examine a *user's* health records for purposes of treatment, study, teaching or research, with the authorisation of the *user*, head of the establishment concerned and the ethics committee.

19. PROTECTION OF HEALTH RECORDS

- (1) The Information Officer of a *public* or *private health establishment* in which a *user's* details or files are recorded, must set up control measures to prevent unauthorised access to those records and to the storage facility in which, or system by which, those records are kept.
- (2) Any person who knowingly -
 - (a) fails to perform a duty imposed on them in terms of subsection (1);
 - (b) falsifies any record by adding, deleting, or changing any information contained in that record;
 - (c) creates, changes or destroys a record without the authority to do so;
 - (d) fails to create or change a record when properly required to do so;

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- (e) provides false information with the intent that it be included in a record;
 - (f) without authority, copies or attempts to copy, any part of a record, by any means;
 - (g) without authority, connects the personal identification elements of a *user's* record with any element of that record that concerns the *user's* condition, treatment or history;
 - (h) gains or attempts to gain, unauthorised access to a record or record-keeping system, by any means, including intercepting information being transmitted from one person, or one part of a record-keeping system, to another;
 - (i) without authority, connects any part of a computer or other electronic system on which records are kept to -
 - (i) any other computer or other electronic system;
 - (ii) any terminal or other installation connected to or forming part of any other computer or other electronic system; or
 - (iii) attempts or actually does modify or impair the operation of -
 - (aa) any part of the operating system of a computer or other electronic system on which a *user's* records are kept; or
 - (bb) any part of the programme used to record, store, retrieve or display information on a computer or other electronic system on which a *user's* records are kept,

commits an offence.

20. **LAYING OF COMPLAINTS**

- (1) Any person or *user* is entitled to lay a complaint about the manner in which he or she is treated at a *health establishment* and to have the complaint investigated.
- (2) In laying a complaint, the person or *user* referred to in subsection (1) must follow the complaints procedure established in terms of section 21.

21. COMPLAINTS PROCEDURES

The *relevant Member of the Executive Council*, with the concurrence of the *Provincial Health Authority*, must -

- (a) *prescribe* procedures to be followed by *users* for laying complaints regarding the provision of health services; and
- (b) establish mechanisms to inform the *users* of the procedures.

22. DUTIES OF USERS

Users have the following obligations -

- (a) to adhere to the rules and regulations that exist in the relevant *health services* and *establishments* contemplated in the provisions of this Act ;
- (b) to provide the *health care provider* with accurate and all relevant information pertaining to the *user's* health status and to generally co-operate with *health care providers* when using health services;
- (c) to treat *health care providers* with dignity and respect;
- (d) to assist in maintaining *health establishments* in habitable conditions;
- (e) to sign a discharge certificate if they refuse to accept recommended treatment;
- (f) to refrain from the use of tobacco products, *non-prescribed* alcohol products, and all such other products or substances which are hazardous, whilst on the premises of the *health establishments*; and
- (g) prohibited from carrying firearms and/or any weapons in contravention of any law onto the premises of a *health establishment*.

23. RIGHT TO A SAFE WORKING ENVIRONMENT

Subject to any other law, every *health establishment* must implement measures to minimise -

- (a) damage or injury to the person or property of *health care providers* working at that establishment; and
- (b) disease transmission.

24. NON-DISCRIMINATION ON GROUNDS OF HEALTH

- (1) No *health care provider* may be unfairly discriminated against on account of his or her health status.
- (2) Notwithstanding subsection (1), but subject to any other law, the head of the *health establishment* concerned may impose any such condition as may be deemed necessary on the services that may be rendered by a *health care provider* on the basis of the health status of the *health care provider*, and in accordance with any guidelines determined by the *Minister*.

CHAPTER 3

NATIONAL HEALTH – STRUCTURES AND FUNCTIONS

25. FUNCTIONS OF THE NATIONAL DEPARTMENT OF HEALTH

The functions of the *national department* are listed in Schedule 1.

26. PERFORMANCE OF NATIONAL FUNCTIONS BY THE PROVINCES

- (1) The *Minister* may delegate to a *relevant member of an Executive Council* the performance of any function listed in Schedule 1 Part B if -
 - (a) the *relevant Member of the Executive Council* has made a request to perform the function;
 - (b) the *Minister* is satisfied that the *provincial department* is able to perform the function; and

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- (c) funding and other necessary resources are available for the performance of that function.
 - (2) The **Minister** may withdraw a delegation made in terms of subsection (1) if reasonable grounds exist that the **provincial department** is unable to continue to perform that function properly.
 - (3) The **Minister** may impose any such conditions as he or she deems necessary upon any delegation referred to in terms of subsection (1), and may at any time vary or withdraw such conditions.

27. **ASSUMPTION OF PROVINCIAL FUNCTIONS BY THE NATIONAL DEPARTMENT OF HEALTH**

- (1) If the **Minister** has reasonable grounds to believe that a **provincial department** is not performing any of the functions listed in Schedule 2, the **Minister** must request the **relevant Member of the Executive Council** to furnish written representations on the matter.
- (2) After due consideration of the written representations referred to in sub-section (1) above, the **Minister** may, pursuant to the provisions of section 100 of **the Constitution**, issue directions to remedy the situation, which may include a direction that any function listed in Schedule 2 be performed within that province by the **national department**.

28. **ESTABLISHMENT AND COMPOSITION OF THE NATIONAL HEALTH AUTHORITY**

- (1) A **National Health Authority** is hereby established.
- (2) The **National Health Authority** consists of -
 - (a) the **Minister**,
 - (b) the **relevant Members of the Executive Councils**;
 - (c) 3 **persons** representing organised local government appointed by the national organisation contemplated in section 163(a) of **the Constitution**; and

- (d) the **Director-General**, the Deputy **Directors-General** of the **national department**, the heads of **provincial departments**, and the head of the South African Military Health Service shall serve in an *ex officio* capacity.

29. DUTIES AND POWERS OF THE NATIONAL HEALTH AUTHORITY

- (1) The **National Health Authority** must function in an advisory capacity to the **Minister**.
- (2) The **National Health Authority** must at the request of the **Minister** or may of its own accord advise the **Minister** on -
- (a) policy concerning any matter that will protect, promote, improve and maintain the health of the population, including -
- (i) responsibilities for health by individuals, the public sector, non-governmental sector and the private sector;
 - (ii) targets, priorities, norms and standards relating to the equitable provision and financing of health services;
 - (iii) efficient co-ordination of health service;
 - (iv) human resources planning, production, management and development;
 - (v) development, procurement, and use of health service technology;
 - (vi) equitable financial mechanisms for the funding of health service;
 - (vii) the designing and implementation of programmes to provide for effective referral of patients, or to enable integration of **public** and **private health establishments**;
 - (viii) financial and other assistance received from foreign governments and inter-governmental or non-governmental organisations including the conditions applicable to receiving such assistance and the mechanisms to ensure compliance with these conditions;
 - (ix) epidemiological surveillance and monitoring of national and provincial trends with regard to major diseases and risk factors for disease; and

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- (x) obtaining, processing and use of statistical returns.
 - (b) proposed legislation pertaining to health matters prior to such legislation being introduced in Parliament or a provincial legislature;
 - (c) any request by a provincial health department to perform functions listed in Part B of Schedule 1;
 - (d) norms and standards for the establishment of health establishments;
 - (e) guidelines for the management of *health districts*;
 - (f) the implementation of health policy;
 - (g) an integrated national strategy for *health research*; and
 - (h) the performance of any other function as may be determined by the *Minister*.
- (3) In performing its functions, the *National Health Authority* must -
- (a) strive to reach its decisions by consensus; and
 - (b) where decisions cannot be reached by consensus the decision of the majority of the members of the *National Health Authority* is deemed to be the decision of the *National Health Authority*.
- (4) For the purposes of performing its functions, the *National Health Authority* may in its discretion consult or receive representations from any person, body or authority.
- (5) The *National Health Authority* may create a committee(s) to advise it on any matter.
- (6) The *National Health Authority* must be presided over by the *Minister* or his or her nominee, and shall determine its own procedure for conducting its business.

30. ESTABLISHMENT AND COMPOSITION OF THE NATIONAL HEALTH MANAGEMENT COMMITTEE

- (1) A *National Health Management Committee* is hereby established.
- (2) The *National Health Management Committee* must consist of -

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- (a) the *Director-General* and the deputy *Directors-General* of the *national department*;
 - (b) the head of each *provincial department*;
 - (c) the head of the South African Military Health Service; and
 - (d) representatives of the management of *health districts*.
- (3) The number of *persons* contemplated in subsection (2)(d) will be determined by the *National Health Authority* in consultation with the national organisation contemplated in section 163(a) of *the Constitution*.

31. DUTIES AND POWERS OF THE NATIONAL HEALTH MANAGEMENT COMMITTEE

- (1) The *National Health Management Committee* must -
 - (a) of its own accord, or at the request of the *National Health Authority*, investigate and consider any matter relating to health, and report on its findings to the *National Health Authority*;
 - (b) if requested to do so, make recommendations to the *National Health Authority* with regard to any matter relating to health;
 - (c) co-ordinate policy implementation; and
 - (d) in general perform the acts that are considered by the *National Health Management Committee* to be necessary or expedient to ensure that the objects of *this Act* are achieved.
- (2) The *National Health Management Committee* may establish one or more sub-committees to inquire into, and to report to the Committee regarding any matter falling within the scope of the Committee's functions.
- (3) The *National Health Management Committee* must determine the composition of a sub-committee and designate a member to be the chairperson of the sub-committee.
- (4) The *National Health Management Committee* may at any time dissolve or reconstitute a sub-committee established under subsection (2).

32. **PREPARATION OF NATIONAL HEALTH PLANS**

- (1) The **Director-General** must prepare strategic medium term and annual health plans for the exercise of the powers and the performance of the duties of the **national department** which must form the basis of –
 - (a) the annual budget as required by the **national department** responsible for finance and state expenditure; and
 - (b) any other governmental planning exercise as may be required by any other law.
- (2) The **Director-General** must annually compile a summary of the health plans of the **national department** and **provincial departments** and submit these to the **National Health Authority** for recommendation.
- (3) The national health plans must comply with any policy adopted in terms of sections 4 and 29.
- (4) The **National Health Authority** may determine the time frames, guidelines and the format for the preparation of national and provincial health plans.

CHAPTER 4

PROVINCIAL HEALTH – STRUCTURES AND FUNCTIONS

33. **FUNCTIONS OF A PROVINCIAL DEPARTMENT OF HEALTH**

The functions of a **provincial department** are listed in Schedule 2.

34. **PROVINCIAL HEALTH SERVICES**

Every **provincial department** must act in accordance with policy determined by the **National Health Authority** in terms of section 29 when establishing and operating its health services.

35. ESTABLISHMENT OF PROVINCIAL HEALTH AUTHORITY

A *Provincial Health Authority* is established in respect of each Province.

36. COMPOSITION OF PROVINCIAL HEALTH AUTHORITY

- (1) The *Provincial Health Authority* consists of -
 - (a) the *relevant Member of the Executive Council*;
 - (b) the Councillor responsible for health in the Metropolitan Council where such municipalities exist;
 - (c) the Councillor responsible for health in each of the District Councils in the province;
 - (d) a representative of the provincial local government association responsible for health;
 - (e) the head of a *provincial department* in an *ex officio* capacity;
 - (f) the representatives of the management of health districts in an *ex officio* capacity; and
 - (g) any other person whom the *relevant Member of the Executive Council* considers appropriate, in an *ex officio* capacity.
- (2) A person contemplated in subsection (1)(c) must be appointed by in accordance with the provisions of section 163(a) of *the Constitution*.
- (3) The number of persons contemplated in subsection (1)(e) will be determined by the *Provincial Health Authority* in consultation with the national organisation contemplated in section 163(a) of *the Constitution*.

37. DUTIES AND PROCEDURES OF PROVINCIAL HEALTH AUTHORITY

The *Provincial Health Authority* is established in respect of each Province.

- (1) The *Provincial Health Authority* must function in an advisory capacity to the *relevant Member of the Executive Council*.
- (2) The *Provincial Health Authority* must at the request of the *relevant Member of the Executive Council* or may of its own accord advise the *relevant Member of the Executive Council* on -
 - (a) policy concerning any matter that will promote the health of the population within the province;
 - (b) legislation related to health policy before it is introduced in the relevant provincial legislation;
 - (c) any request by a *District Health Authority* to perform functions listed in Part B of Schedule 2; and
 - (d) the performance of any other function as may be determined by the *relevant Member of the Executive Council*.
- (3) The *Provincial Health Authority* may consult with or receive representations from any person, body or authority.
- (4) The *relevant Member of the Executive Council*, or any other *person* nominated by the former, must preside over the *Provincial Health Authority*.
- (5) The *Provincial Health Authority* may determine its own procedures for conducting business.

38. ESTABLISHMENT OF INSPECTORATE FOR HEALTH ESTABLISHMENTS

- (1) In each province, the *relevant Member of the Executive Council* must establish an *Inspectorate for Health Establishments*, whose function is to monitor and evaluate compliance by *health establishments* with the relevant requirements as may be set out in *this Act*.
- (2) The *Inspectorate for Health establishments* must submit a monthly (or quarterly) report on its activities to the *relevant Member of the Executive Council* who in turn must submit an annual report to the *Minister*.

39. PREPARATION OF PROVINCIAL HEALTH PLANS

- (1) The head of the *provincial department* must, within a reasonable period after the commencement of *this Act, with the concurrence* of the *Provincial Health Authority*, prepare strategic medium term and annual plans for the exercise of the powers of, the performance of the duties of, and the provision of health services in the province by the *provincial department*.
- (2) Provincial health plans must conform to any policy and guidelines issued in terms of section 29.
- (3) The *Provincial Health Authority* may determine time frames and guidelines for the preparation of district health plans including their format.
- (4) The head of the *provincial department* must submit the plans referred to in subsection (1) to the *Director-General* within the stipulated time frames and in accordance with the guidelines determined by the *National Health Authority* as contemplated in section 32.

CHAPTER 5

THE DISTRICT HEALTH SYSTEM

40. ESTABLISHMENT OF THE DISTRICT HEALTH SYSTEM

In addition to this chapter, provincial health legislation must provide for the establishment of a district health system in a province.

41. DEMARCATION OF HEALTH DISTRICTS

- (1) The entire area of the Republic of South Africa must be demarcated into *health districts*.
- (2) The boundaries of all *health districts* must be *coterminous* with municipal boundaries.
- (3) Notwithstanding the provisions of subsection (2), a *health district* may be situated in more than one municipality.

42. VARIATION OF HEALTH DISTRICT BOUNDARIES

- (1) The *relevant Member of the Executive Council* may, in consultation with the Minister, vary the boundaries of any *health district* and may create new *health districts* or abolish existing *health districts*.
- (2) The variation of the boundaries and the creation or abolition of *health districts* referred to in subsection (1) must –
 - (a) be made after consultation with –
 - (i) the *District Health Authority* and the municipality affected by the proposed variation, creation or abolition; and
 - (ii) the Executive Council of the province concerned; and
 - (b) be published in the *Gazette*.

43. DISTRICT HEALTH AUTHORITY

- (1) Provincial health legislation must provide for the establishment of *District Health Authorities* in the provinces by the *relevant members of the Executive Council*, in consultation with the members of the Executive Council responsible for Provincial and Local government.
- (2) The *District Health Authorities* referred to in subsection (1) –
 - (a) may be-
 - (i) a municipality;
 - (ii) a provincial department; or
 - (iii) a body constituted in terms of provincial health legislation; and
 - (b) shall plan for and ensure the delivery of health services in a particular health district.
- (3) Provincial health legislation referred to in subsection (1) shall also provide for the management of *District Health Authorities*.

44. MUNICIPAL HEALTH SERVICES

- (1) The following constitutes municipal health services and must be rendered by the municipalities:
 - (a) environmental health services;
 - (b) promotive and preventive health services; and
 - (c) other municipal health services, in addition to those referred to in subparagraphs (a) and (b), that are rendered by other municipalities at the time of coming into operation of this Act.
- (2) Municipal health services referred to in subparagraph (1)(c) may only be rendered by municipalities if-
 - (i) the affected municipality;
 - (ii) the *relevant member of the Executive Council*; and
 - (iii) the member of the Executive Council responsible for Provincial and Local Government,agree to the rendering of such services.
- (3) In addition to municipal health services referred to in subsection (1) and other health services referred to in subsection (2), a province may request a municipality to perform further services and such request must be –
 - (i) supported by members of the members of the Executive Council responsible for health and provincial and local government matters as well the municipality concerned;
 - (ii) accompanied by the necessary funding arrangements for the performance of such further health services.

45. **HEALTH SERVICES**

- (1) Health services that are rendered by municipalities at the time of coming into operation of this Act shall be deemed to have been assigned to municipalities in terms of section 156(4) of the Constitution.
- (2) Nothing in subsection (1) must be construed as prohibiting a province from requesting a municipality to render health services after the coming into operation of this Act and such request must be by way of an assignment in terms of section 156(4) of the Constitution.
- (3) The services referred to in subsections (1) and (2) must be deemed to have been so assigned if the municipality concerned, *the relevant member of the Executive Council*, and a member of the Executive Council responsible for Provincial and Local Government, agree to such assignment.

46. **PREPARATION OF DISTRICT HEALTH PLANS**

Provincial health legislation must provide for the preparation of district health plans by *District Health Authorities* and the submission of such plans to the *relevant Member of the Executive Council*.

CHAPTER 6

HEALTH ESTABLISHMENTS

47. **CLASSIFICATION OF HEALTH ESTABLISHMENTS**

The *Minister* may by regulation –

- (a) classify all *health establishments* into such categories as is considered appropriate; and
- (b) determine, amongst other things, the establishment of hospital boards in the case of hospitals, and in the case of such classified *public health establishments*, their management system.

48. APPLICATION FOR CERTIFICATE OF NEED

Any *person* desiring to-

- (a) establish, modify or acquire a *health establishment*;
- (b) increase the number of beds or acquire *prescribed* specialised equipment;
- (c) provide *prescribed* specialised services; or
- (d) continue operating a *health establishment* existing at the time of commencement of this Act,

must apply in the *prescribed* manner to the *Director-General* for a *certificate of need*.

49. REVIEW OF APPLICATION FOR CERTIFICATE OF NEED

A person aggrieved by the decision of the *Director-General* may, within seven days of being notified of such decision, in writing request the *Minister* to review such decision.

50. DURATION OF CERTIFICATE OF NEED

The duration of the validity of a *certificate of need* shall be prescribed but shall not exceed 10 years.

51. REGULATIONS RELATING TO CERTIFICATES OF NEED

The *Minister* may, after consultation with the *National Health Authority*, make regulations relating to -

- (a) requirements for the renewal of a certificate of need;
- (b) requirements for a certificate of need of *health establishments* existing at the time of commencement of this Act;
- (c) requirements for the type, size, management, staffing and equipment in *health establishments*;

- (d) requirements relating to building standards, maintenance of physical facilities, and operational issues;
- (e) reporting requirements of *health establishments*; and
- (f) any other matter related to the issuance of a certificate of need, inspection and administration of *health establishments*.

52. ENFORCEMENT, REMEDIES AND SANCTIONS

- (1) The *Inspectorate of Health Establishments* shall inspect every *health establishment* at least once annually to ensure compliance with *this Act*, but may conduct announced or unannounced inspections of a *health establishment* at any time.
- (2) The *Inspectorate of Health Establishments* may order the total or partial closure of a *health establishment* if a *certificate of need* was not issued in respect of that *health establishment* prior to any activities contemplated in section 48 being undertaken.
- (3) The *Inspectorate of Health Establishments* must issue a written notice of non-compliance to the head of a *health establishment* if the *Inspectorate of Health Establishments* determines that –
 - (a) the *health establishment* does not comply with –
 - (i) any provision of *this Act*;
 - (ii) any condition imposed in a *certificate of need*;
 - (iii) building regulations; or
 - (iv) the provisions of any other law; or
 - (b) a *health care provider* who is employed by, or refers *users* to, the *health establishment* has a financial interest in the ownership or control of that *health establishment*.
- (4) An order issued in terms of subsection (2) for the total or partial closure of a *health establishment* must be issued in writing to the head of a *health establishment*.

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- (5) It is an offence for any *person* to act in accordance of section 48(a), (b) or (c) without a *certificate of need*.
- (6) If a person is convicted of an offence in terms of subsection (5), that person will be liable on conviction to a fine not exceeding R100, 000, 00 or a period of imprisonment not exceeding five years, or both fine and imprisonment.

53. *PROVISION OF HEALTH SERVICES AT HOSPITALS*

- (1) The *Minister*, in the case of prescribed hospitals or the *relevant Member of the Executive Council* in respect of all other hospitals within the jurisdiction of the relevant province, may:
- (a) determine the range of health services to be provided at any particular hospital;
 - (b) *prescribe* the procedure and criteria for admission to and referral from a hospital or group of hospitals;
 - (c) subject to subsection (2) *prescribe* schedules of fees, including penalties for not following the procedures contemplated in paragraph (b) for:
 - (i) different categories of *users*;
 - (ii) for various forms of treatment; and
 - (iii) for various categories of hospitals; and
 - (d) determine the proportion of revenue generated by a particular hospital that may be retained by that hospital, and how those funds may be used.
- (2) When determining a schedule of fees the fee for a particular service may not be varied in respect of *users* who are not ordinarily resident in a province.
- (3) Notwithstanding the provisions of subsection (2), a province whose residents make *use* of another province's services must compensate that province for services rendered.
- (4) The *Minister*, after consultation with the *National Health Authority*, must appoint a hospital board for each central hospital or for a group of central hospitals.

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- (5) The functions of the hospital boards shall be as prescribed.
 - (6) The *relevant member of the Executive Council*, after consultation with the *Provincial Health Authority*, must appoint hospital boards in respect of each hospital or group of hospitals in that province, excluding central hospitals.
 - (7) The boards contemplated in subsections (4) and (5) must be composed of –
 - (a) one representative from the national department in the case of central hospitals;
 - (b) one representative from the provincial department in the case of central and other hospitals;
 - (c) one representative from any other department in respect of central hospitals;
 - (d) persons with expertise in areas such as accounting, financial management, human resources management, information management and legal matters;
 - (e) representatives of the communities served by the hospital, including special interest groups representing users; and
 - (f) representatives of staff and management.
 - (8) Members of a hospital board will be appointed for a period of three years at a time, and the *Minister*, in the case of central hospitals, or the *relevant member of the Executive Council*, in the case of other hospitals, may replace them on good cause shown.

54. CLINIC AND COMMUNITY HEALTH CENTRE COMMITTEES

- (1) Provincial legislation shall provide for the establishment of a clinic committee or committees, or community health centre committee or committees for clinics and community health centres as the case may be, in the province.
- (2) The composition of committees referred to in subsection (1) shall include, but not be limited to –
 - (i) local government councillors;
 - (ii) members of the community served by the health facility;

- (iii) persons with expertise in legal and financial matters;
 - (iv) the head of the clinic or health centre; and
 - (v) any other person designated by the *relevant member of the Executive Council*.
- (3) The functions of the committees shall be prescribed.

55. THE PROVISION OF HEALTH SERVICES AT NON-HEALTH ESTABLISHMENTS AND AT PUBLIC HEALTH ESTABLISHMENTS OTHER THAN HOSPITALS

- (1) The *Minister* may *prescribe* –
- (a) minimum standards and requirements for the rendering of health services in locations other than *health establishments*, including schools and other public places; and
 - (b) penalties for failure to comply with such standards or requirements.
- (2) Provincial health legislation must provide for health services to be provided at *health establishments* other than hospitals in the province concerned.

56. THE INTER-RELATIONSHIP BETWEEN PUBLIC HEALTH ESTABLISHMENTS

- (1) Subject to *this Act*, a *user* shall be entitled to attend any *public health establishment* for purposes of receiving health services on such terms as may be determined by the *Minister* or the *relevant Member of the Executive Council*.
- (2) If a *public health establishment* is not capable of providing the necessary treatment or care, such a *user* must be referred by the *public health establishment* concerned to an appropriate *public health establishment* in such manner and on such terms as may be determined by the *Minister* or the *relevant Member of the Executive Council*.
- (3) If a *user* chooses to make use of a *health establishment* other than a health post, clinic or community health centre without an appropriate referral letter, the *user* shall be required to pay a by-pass fee, except in emergencies.

57. RELATIONSHIP BETWEEN PUBLIC AND PRIVATE HEALTH ESTABLISHMENTS

- (1) The *Minister* must *prescribe* mechanisms to enable a co-ordinated relationship between private and *public health establishments* in the delivery of health services.
- (2) The *national department* and *provincial departments*, districts and *municipalities* may enter into contractual or other arrangements with private practitioners, *private health establishments* and non-governmental organisations in order to achieve the objectives of this Act.
- (3) An arrangement contemplated in subsection (2) may permit the use of *public health establishments* by the private health sector in accordance with the provisions of the Public Finance Management Act, 1999 (Act 1 of 1999), and Municipal Finance Management legislation, as the case may be.

58. OBLIGATIONS OF PRIVATE HEALTH ESTABLISHMENTS

- (1) Every *private health establishment* must appoint an administrative officer for purposes of liaison with district health authorities, *provincial* and *national departments*.
- (2) Every *private health establishment* must ensure that it has adequate insurance cover to indemnify a *user* for damages that he or she might suffer as a consequence of the wrongful or unlawful, or both wrongful and unlawful, acts of its staff and/or employees.

59. EVALUATING THE SERVICES OF HEALTH ESTABLISHMENTS

- (1) All *health establishments* must comply with the quality requirements as prescribed by the *Minister* in consultation with the National Health Authority.
- (2) The quality requirements contemplated in subsection (1) may relate, but need not be limited to staffing, equipment, hygiene, safety or cost-effectiveness of services.
- (3) The *Inspectorate for Health Establishments* must monitor and enforce compliance with such quality requirements.