

The National Health Act 61 of 2003

A Guide

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* Chapter or section not yet proclaimed

Introduction

The National Health Act 61 of 2003 (NHA) is arguably the most important Act passed by Parliament to give effect to the right of everyone to have access to health care services. This right is guaranteed by section 27 of the Constitution of the Republic of South Africa, 1996 (“the Constitution”), which places express obligations on the state to progressively realise socio-economic rights, including access to health care.

This booklet aims to make the NHA accessible and easily understandable, so that individuals, communities and organisations are better able to enforce their health rights. While many critical provisions of the NHA have yet to be implemented, the Act in its current form does provide significant opportunities for the enforcement of rights.

To understand the utility and significance of the NHA it is important to understand the historical background to the Act. The NHA is the culmination of key health system policies dating from 1994. It reflects elements of the ANC Health Plan of 1994 as well as the 1997 White Paper on Health Systems Transformation. Some of these elements include: the decentralisation of health care services through the district health system, the need for improving quality and standards of health care in both the public and private sectors, the need for human resources planning and development, and increasing access to health care services for everyone. However as described below, a number of these health reforms remain to be properly implemented.

While the NHA sets the foundation of the health care system, it works in combination with other pieces of legislation which relate to other areas of the health care system such as the development, registration, regulation and access to medicines. Most of these are

described briefly in Appendix “B”, including:

- The Choice of Termination of Pregnancy Act 92 of 1996
- The Health Professions Act 56 of 1974
- The Medicines and Related Substances Act 101 of 1965
- The Medical Schemes Act 131 of 1998
- The Nursing Act 33 of 2005
- The Traditional Health Practitioners Act 22 of 2007

As always when dealing with matters of health, rights and law in South Africa, it is necessary to return to section 27 of the Constitution, which provides as follows:

Health care, food, water, and social security

- (1) Everyone has the right to have access to -
 - (a) health care services, including reproductive health care;
 - (b) sufficient food and water; and
 - (c) social security, including, if they are unable to support themselves and their dependents, appropriate social assistance
- (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights; and
- (3) No one may be refused emergency medical treatment.

The NHA is meant to be one of the legislative measures that will facilitate the progressive realisation of the right to health. Section 27 and other provisions of the Constitution set the parameters for health care planning and delivery. It is from the Constitution that the NHA gets its authority and essential content, and it is from the

Constitution that it gets its limitations, not the other way around. The NHA and other health legislation only provide detail – they cannot in any way alter the constitutional promise of the right to have access to health care services.

The NHA provides the foundational structure of the national, provincial, and district health care system. It is designed to create the framework for delivering health care services for the entire country, including the opportunity for the national Department of Health (DoH) to form relationships between public and private hospitals and to regulate the minimum standard of care to which all people living in South Africa are entitled. It also creates the system to train, retain, and further build human resources for the delivery of health care. In particular, it sets the requirements for the DoH with regard to reporting and providing for the adequate provision and distribution of health professionals.

At the time of publication some 36 provisions of the NHA have not been promulgated (brought into force). Of those that have been promulgated, many have not yet been implemented and await Regulations. As a result, it is difficult to take full advantage of the NHA until the remaining provisions are brought into effect and more sets of regulations are finalised. The sections that the President has yet to proclaim, or in respect of which regulations have yet to be finalized, are marked throughout the text. This being said, below is a highlight of several ways in which the NHA can already be used:

Getting Access to Health Care

Free Health Care Services

Section 4 of the NHA gives – in general terms – the ways in which people are able to gain access to health care services. While the Minister of Health (“the Minister”) is supposed to provide more detail about who is eligible for certain free health care services, there are several categories of persons mentioned in the Act who are already able to demand some services in the public health care sector. These include:

- Pregnant and lactating women who are not members of medical schemes;
- Children below the age of six who are not members of medical schemes;
- In respect of primary health care services, all persons who are not members of medical schemes; and
- For all pregnant women, termination of pregnancy services in accordance with the provisions of the Choice of Termination of Pregnancy Act 92 of 1996.

If you fall within the listed categories, you are already entitled to demand these free services at public health care facilities.

Emergency Treatment

Section 5 of the NHA, in line with section 27(3) of the Constitution, says that no one may be refused emergency medical treatment by any health care provider, health worker, or health establishment. This includes both public and private health facilities. If you or someone else needs emergency medical treatment, you can go to

any hospital and they must treat you if they are able. However, as no further regulations have been made regarding the definition and provision of emergency services, some private hospitals insist on payment for any treatment provided to you, even if it is an emergency. Likewise, individual health facilities are able to provide their own interpretation of what counts as emergency medical treatment.

Consent to Medical Treatment

Section 6 of the NHA gives you the right – before you are given any medical treatment – to be told of what treatment options are available to you, the benefits and risks of each treatment, and the cost of each treatment. Sections 7 and 8 also say that you have the right to participate in making any decisions regarding what treatment you want and that you must consent before any treatment is given to you, unless it is an emergency and you aren't able to consent. For example, if you are unconscious.

Section 9 recognises that there are times when people can be forcibly admitted to a health establishment whether they consent or not. In those cases, the hospital or other health establishment must inform the relevant provincial department of health that the person has been admitted without his or her consent. The provincial department is then supposed to monitor the person's treatment to ensure that his or her rights are respected.

It is important to note that a person can only be forced to be admitted to a health establishment or to receive treatment in exceptional circumstances, such as when that person is a danger to him or herself, or to the public generally. For example, if a person is very depressed and threatens to commit suicide, his or her family may try to have that person admitted at a health facility without his or her consent because the person is not able to make

good decisions for his or her own health. Likewise, if a person has a disease that could pose a public health risk, such as Ebola, that person may have to be treated without his or her consent in order to protect the public health. In these rare circumstances, it is the provincial department of health's responsibility to ensure that the infringement of the person's right to refuse medical treatment is justified and as least restrictive as possible.

In addition, a person may be forced to undergo medical testing without consent if he or she is accused of committing a sexual assault. The Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007 (Sexual Offences Act) allows a sexual assault survivor, an interested person,¹ or an investigating officer to seek a court order compelling the alleged offender to take an HIV test and disclose the results to the survivor, the interested person, the investigating officer, or the prosecutor. The procedures for compulsory testing in these circumstances are in the Sexual Offences Act and its regulations, not in the NHA.

Laying of Complaints

Section 18 of the NHA gives you the right to complain about how you have been treated by a health facility. The procedures to follow in laying a formal complaint must clearly be displayed in all health facilities and must be given to you if you ask for them. You must follow these procedures in order for your complaint to be investigated. Private health care facilities must allow you to complain to the head of the facility.

¹The Act defines "Interested Person" as any person who has a material interest in the well-being of the victim, including a spouse, same sex or heterosexual permanent life partner, parent, guardian, family member, care giver, curator, counselor, medical practitioner, health service provider, social worker or teacher of the victim.

Getting Involved in the Health Care System

Provincial Health Councils

Sections 26 and 27 create provincial health councils. These councils mirror the National Health Council, which is made up of all the provincial MECs for health and is meant to advise the Minister of Health. The provincial councils are responsible for advising the provincial department on health policy and include members of municipalities and local and provincial government. They can also consider presentations provided by members of the community. The contact information for each of the nine provincial health councils is included in Annexure “C” of this booklet.

Provincial Consultative Bodies

Section 28 of the NHA requires that each province have a consultative body which promotes and facilitates the sharing of information on provincial health issues. These bodies mirror the National Consultative Health Forum that is established at the national level in terms of section 24. The provincial consultative body must include relevant stakeholders, such as community health organisations, and must meet at least every 12 months. To the extent that the information is available, contact information for each provincial consultative body is included in Appendix C of this booklet.

District Health Councils

Section 31 requires the relevant member of the executive council for health (“the MEC for Health”) in each province to create a District Health Council for each health district. As is the case with provincial health councils, there isn’t an official role for members of

the community to play. Nevertheless, these bodies are important for members of civil society to consider since they help set district and provincial policy. Until each province passes its own legislation, it won't be known how each district health council will function. To our knowledge, no district health councils have been established. However, contact information for all district health offices is included in Appendix "C" of this booklet.

Hospital Boards

Section 41 requires the Minister to appoint hospital boards for each central hospital or group of central hospitals. These boards must include representatives of the communities served by the hospitals. Unfortunately, the President had not yet proclaimed section 41 when this booklet went to print, which means the hospital boards have not been appointed in terms of this Act as of yet, even though hospital boards exist. When section 41 is proclaimed, these boards will provide community members with the opportunity to provide input into the governing of the major hospitals that serve them.

Clinic and Community Health Centre Committees

At the time this booklet went to print, section 42 had also not yet been proclaimed by the President. However, these committees should be created soon after the section is proclaimed. These committees must include members of the community. What the responsibilities these committees will have is not yet known, as the NHA leaves it to the provinces to determine the committees' responsibilities. Ideally, through strong community participation in the drafting of the provincial health bills and on these committees

thereafter, the committees will provide opportunities for communities to aid in the governance of their own clinics and health centres.

Health Planning and Budgeting

One of the critical issues continuing to face health policy is the lack of proper needs based planning and budgeting. The problem is multi-layered and includes the fiscal planning design as determined by the Constitution, the budgeting process at the national level and the insufficient interface between the various levels of government. The problem manifests itself in various ways, such as an insufficient supply of medicines, the failure of provinces to spend according national health priorities and a failure to plan for, train and retain sufficient health care workers in the public health care system. The NHA attempts to address this issue in several ways.

District Health Plans

Section 33 requires each district or metropolitan health manager to create annual district health plans. These health plans must be developed according to guidelines published by the DoH. Knowing the contents of these plans is important, and provides the ability to monitor what those responsible for health at the district level are trying to accomplish (or failing to accomplish) for the district and to hold them accountable.

If individuals, communities and organisations are more aware of the plans and budgets for the district, they can take action to ensure a proper needs assessment is done so that the health care system is able to get the money it needs to function according to its own plans and the needs of the community.

Human Resources

Chapter 7 of the NHA, in particular section 48 and 52, require the Minister to make plans for human resources training, retention and distribution throughout the country. Similarly, sections 25(3) and 33 require provincial and district level human resources plans. The most recent national plans were published in 2006 and are available on the department of health's website (see footnote 62). Provincial and district level human resources plans must be made available when requested from the provincial department of health or your local district health manager. Contact information for district health offices and provincial departments of health are in Appendix "C" of this booklet.

The 2006 *A National Human Resources for Health Planning Framework* published by the DoH, provides a set of 11 core guiding principles which are meant to guide human resources planning and implementation. Amongst the core principles are that:

- South Africans must enjoy a reliable supply of skilled and competent health professionals for self-sufficiency; and
- Planning and development of human resources linked to the needs and demands of the health system must be strengthened

These plans are essential because, without a proper plan for the training and retention of health care workers, the delivery of the promises made in the NHA, the provincial health plans, the district health plans, and ultimately in the Constitution, are undermined because there aren't enough people to provide health care services. As with any governmental plan, knowing the contents and objectives of the plan allows individuals, communities and organisations to review them and ensure the plans are adequately

supported by the budget. If a district human resources plan calls for the employment of more nurses, doctors, and support staff, there must be a corresponding additional budget allocation for human resources in the district, or the plan has no chance of succeeding.

Conclusion

Unfortunately there is much that needs to be implemented in the NHA before all its protections and benefits will be available to people. Provinces need to fulfill their obligations under the NHA by passing provincial health legislation and creating the provincial bodies, such as the provincial consultative bodies, required by the NHA. The DoH needs to finish implementing the oversight bodies, such as the Inspectorate for Health Establishments (section 77) and the Office of Standards Compliance (section 78), and draft and finalise several essential sets of regulations such as those on human resources, essential health services, and primary health care services, and move to have the remaining provisions of the NHA proclaimed by the President.

It is hoped that by putting the text of the NHA into the hands of people in communities and organizations, they can start to mobilise to demand full implementation of their rights under the NHA and under the Constitution.

Adila Hassim
Mark Heywood
Brian Honermann

NATIONAL HEALTH ACT

*61 OF 2003*²

(English text signed by the President)

ACT

To provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services; and to provide for matters connected therewith.

Preamble

RECOGNISING-

- the socio-economic injustices, imbalances and inequities of health services of the past;
- the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights;
- the need to improve the quality of life of all citizens and to free the potential of each person;

BEARING IN MIND THAT-

- the State must, in compliance with section 7(2) of the Constitution, respect, protect, promote and fulfil the rights enshrined

²President Mbeki signed the NHA into law on 18 July 2004, declaring that all sections of the Act proclaimed that day would go into effect on 2 May 2005. The remaining sections of the Act were meant to be proclaimed later, once regulations to give them effect had been drafted and finalized. Unfortunately, as of 9 September, 2008, only one additional section had been proclaimed. This means that 36 of the 94 sections of the Act are still not in force. These sections are identified throughout this text.

in the Bill of Rights, which is a cornerstone of democracy in South Africa;

- in terms of section 27(2) of the Constitution the State must take reasonable legislative and other measures within its available resources to achieve the progressive realisation of the right of the people of South Africa to have access to health care services, including reproductive health care;
- section 27(3) of the Constitution provides that no one may be refused emergency medical treatment;
- in terms of section 28(1)(c) of the Constitution every child has the right to basic health care services;
- in terms of section 24(a) of the Constitution everyone has the right to an environment that is not harmful to their health or well-being;

AND IN ORDER TO-

- unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa;
- provide for a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services;
- establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourages participation;
- promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other

relevant sectors within the context of national, provincial and district health plans,

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:-

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4 Eligibility for free health services in public health establishments

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- 62 Donation of human bodies and tissue of deceased persons
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SCHEDULE

1 Definitions

In this Act, unless the context indicates otherwise-

- ‘authorised institution’** means any institution designated as an authorised institution in terms of section 54;
- ‘blood product’** means any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells;
- ‘central hospital’** means a public hospital designated by the Minister to provide health services to users from more than one province;
- ‘certificate of need’** means a certificate contemplated in section 36;
- ‘communicable disease’** means a disease resulting from an infection due to pathogenic agents or toxins generated by the infection, following the direct or indirect transmission of the agents from the source to the host;
- ‘Constitution’** means the Constitution of the Republic of South Africa, 1996 (Act 108 of 1996);
- ‘death’** means brain death;
- ‘Director-General’** means the head of the national department;
- ‘district health council’** means a council established in terms of section 31;
- ‘essential health services’** means those health services prescribed by the Minister to be essential health services after consultation with the National Health Council;³

³As of 9 September, 2008, the Minister had not yet published regulations defining “essential health services”. For more information on the significance of a definition for

‘embryo’ means a human offspring in the first eight weeks from conception;

‘Forum of Statutory Health Professional Councils’ means the Forum established by section 50;

‘gamete’ means either of the two generative cells essential for human reproduction;

‘gonad’ means a human testis or human ovary;

‘health agency’ means any person other than a health establishment-

- (a) whose business involves the supply of health care personnel to users or health establishments;
- (b) who employs health care personnel for the purpose of providing health services; or
- (c) who procures health care personnel or health services for the benefit of a user,

and includes a temporary employment service as defined in the Basic Conditions of Employment Act, 1997 (Act 75 of 1997), involving health workers or health care providers;⁴

‘health care personnel’ means health care providers and health workers;

‘health care provider’ means a person providing health services in terms of any law, including in terms of the-

- (a) Allied Health Professions Act, 1982 (Act 63 of 1982);

“essential health services”, see note 21 below.

⁴According to section 1 of the Basic Conditions of Employment Act 75 of 1997, a “temporary employment service” means any person who, for reward, procures for, or provides to, a client, [people]-

- (a) who render services to, or perform work for, the client; and
- (b) who are remunerated by the temporary employment service.

- (b) Health Professions Act, 1974 (Act 56 of 1974);
- (c) Nursing Act, 1978 (Act 50 of 1978);⁵
- (d) Pharmacy Act, 1974 (Act 53 of 1974); and
- (e) Dental Technicians Act, 1979 (Act 19 of 1979);

‘health district’ means a district contemplated in section 29;

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

‘health nuisance’ means a situation, or state of affairs, that endangers life or health or adversely affects the well-being of a person or community;

‘health officer’ means any person appointed as a health officer under section 80 or designated as such in terms of that section;

‘health research’ includes any research which contributes to knowledge of-

- (a) the biological, clinical, psychological or social processes in human beings;
- (b) improved methods for the provision of health services;
- (c) human pathology;
- (d) the causes of disease;
- (e) the effects of the environment on the human body;
- (f) the development or new application of pharmaceuticals, medicines and related substances; and
- (g) the development of new applications of health technology;

⁵The Nursing Act of 1978 has been repealed and replaced by the Nursing Act 33 of 2005.

‘health research ethics committee’ means any committee registered in terms of section 73;

‘health services’ means-

- (a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution;⁶
- (b) basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution;⁷
- (c) medical treatment contemplated in section 35(2)(e) of the Constitution;⁸ and
- (d) municipal health services;

‘health technology’ means machinery or equipment that is used in

⁶Section 27 of the Constitution provides as follows:

Health Care, food, water and social security

- (1) Everyone has the right to have access to -
 - (a) health care services, including reproductive health care;
 - (b) sufficient food and water;
 - (c) and social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
- (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights
- (3) No one may be refused emergency medical treatment.

⁷According to section 28(1)(c) of the Constitution, every child has the right to basic nutrition, shelter, basic health care services and social services.

⁸According to section 35(2) of the Constitution, everyone who is detained by the state, such as an inmate in a correctional centre, must be held in a way that respects his or her dignity and provides him or her with legal representation, adequate nutrition and medical treatment at state expense. In *Minister of Health of the Province of the Western Cape v Goliath and Others* (13741/07) [2008] ZAWCHC 41 (28 July, 2008) (*Goliath*) the High Court in the Western Cape accepted, without deciding, that persons detained in terms of the NHA are also entitled to the protections contained in section 35(2) of the Constitution. For more on the *Goliath* case, see footnote 24.

the provision of health services, but does not include medicine as defined in section 1 of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965);⁹

‘health worker’ means any person who is involved in the provision of health services to a user, but does not include a health care provider;

‘hospital’ means a health establishment which is classified as a hospital by the Minister in terms of section 35;

‘Inspectorate for Health Establishments’ means any inspectorate established in terms of section 77;

‘military health establishment’ means a health establishment which is, in terms of the Constitution and the Defence Act, 2002 (Act 42 of 2002), the responsibility of and under the direct or indirect authority and control of the President, as Commander in Chief, and the Minister of Defence, and includes-

- (a) the Institutes for Aviation and Maritime Medicine;
- (b) the Military Psychological Institute;
- (c) military laboratory services; and
- (d) military training and educational centres;

‘Minister’ means the Cabinet member responsible for health;

‘municipal council’ means a municipal council contemplated in section 157(1) of the Constitution;¹⁰

⁹According to section 1 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) a “medicine” means any substance that is claimed to be able to diagnose, treat, mitigate, modify or prevent a disease. A medicine, however, is not a machine. For example, even though a device such as a pace maker does help prevent heart attacks, it would not be considered a medicine while a tablet which reduces the risk of heart disease would be a medicine. A pace maker would be a “health technology”, according to the definition above.

¹⁰According to the Constitution, a municipal council is the elected body that is given both administrative and legislative powers in respect of a particular municipality.

‘municipal health services’, for the purposes of this Act, includes-

- (a) water quality monitoring;
- (b) food control;
- (c) waste management;
- (d) health surveillance of premises;
- (e) surveillance and prevention of communicable diseases, excluding immunisations;
- (f) vector control;
- (g) environmental pollution control;
- (h) disposal of the dead; and
- (i) chemical safety,

but excludes port health, malaria control and control of hazardous substances;

‘municipality’ means a municipality as defined in section 1 of the Local Government: Municipal Systems Act, 2000 (Act 32 of 2000);¹¹

‘national department’ means the national Department of Health;

‘National Health Council’ means the Council established by section 22(1);

‘national health policy’ means all policies relating to issues of national health as approved by the Minister;

‘National Health Research Committee’ means the Committee established in terms of section 69(1);

Section 157(1) of the Constitution sets out the requirements for the composition and election of the municipal councils.

¹¹ According to section 1 of the Local Government: Municipal Systems Act, the definition of “municipality” depends on how the word is used. It either refers to the municipal government (i.e., the municipal council itself) or to the physical geographic area of a municipality. Throughout the text, the NHA ordinarily uses the word “municipality” on its own to refer to a municipal government. When it intends to refer to a geographic area, it uses the term “metropolitan or district municipality”.

‘National Health Research Ethics Council’ means the Council established by section 72(1);

‘national health system’ means the system within the Republic, whether within the public or private sector, in which the individual components are concerned with the financing, provision or delivery of health services;

‘non-communicable disease’ means a disease or health condition that cannot be contracted from another person, an animal or directly from the environment;

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

‘Office of Standards Compliance’ means the Office established in terms of section 78(1);

‘oocyte’ means a developing human egg cell;

‘organ’ means any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh, bone, bone marrow, body fluid, blood or a gamete;

‘organ of state’ means an organ of state as defined in section 239 of the Constitution;¹²

‘pollution’ means pollution as defined in section 1 of the National Environmental Management Act, 1998 (Act 107 of 1998);¹³

¹²According to section 239 of the Constitution, an organ of state includes all governmental departments at the national, provincial, or local level. This includes, for example, the DoH, provincial departments of health and local government health departments. Statutory institutions, such as the National Health Council or the Forum for Statutory Health Professionals, are also considered to be organs of state. Administrators of public facilities, such as public hospitals, are also organs of state.

¹³Section 1 of the National Environmental Management Act defines pollution as anything, including things like noises and smells, which changes the environment in some way that has a negative effect on human health, the ecosystem in the area, or on the ability for people to use the land.

- ‘premises’** means any building, structure or tent together with the land on which it is situated and the adjoining land used in connection with it and includes any land without any building, structure or tent and any vehicle, conveyance or ship;
- ‘prescribed’** means prescribed by regulation made under section 90;
- ‘primary health care services’** means such health services as may be prescribed by the Minister to be primary health care services;¹⁴
- ‘private health establishment’** means a health establishment that is not owned or controlled by an organ of state;
- ‘provincial department’** means any provincial department responsible for health;
- ‘Provincial Health Council’** means a Council established by section 26(1);
- ‘public health establishment’** means a health establishment that is owned or controlled by an organ of state;¹⁵

¹⁴While the Minister has not prescribed regulations regarding primary health care service, there are a number of policies that have been implemented, including: ‘Primary Health Care Package for South Africa: A set of norms and standards’, March 2000 (available at: <http://www.doh.gov.za/docs/policy/norms/full-norms.pdf>); ‘Standard Treatment Guidelines and Essential Drugs List for Primary Health Care’, revised in 2003 (available at: <http://www.doh.gov.za/docs/facts-f.html>); and ‘A User’s Guide to primary Health Care Services’ (available at: <http://www.doh.gov.za/docs/factsheets/guidelines/yourclinic/index.html>). See footnote 21 for more on the significance of a definition for “primary health care services”.

¹⁵All public health establishments are bound by the provisions of section 195 of the Constitution. Because of its importance, section 195 is reproduced here in full:

Basic values and principles governing public administration

- (1) Public administration must be governed by the democratic values and principles enshrined in the Constitution, including the following principles:
 - (a) A high standard of professional ethics must be promoted and maintained.

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

‘relevant member of the Executive Council’ means the member of the Executive Council of a province responsible for health;

-
- (b) Efficient, economic and effective use of resources must be promoted.
 - (c) Public administration must be development-oriented.
 - (d) Services must be provided impartially, fairly, equitably and without bias.
 - (e) People’s needs must be responded to, and the public must be encouraged to participate in policy-making.
 - (f) Public administration must be accountable.
 - (g) Transparency must be fostered by providing the public with timely, accessible and accurate information.
 - (h) Good human-resource management and career-development practices, to maximise human potential, must be cultivated.
 - (i) Public administration must be broadly representative of the South African people, with employment and personnel management practices based on ability, objectivity, fairness, and the need to redress the imbalances of the past to achieve broad representation.
- (2) The above principles apply to -
 - (a) administration in every sphere of government;
 - (b) organs of state;
 - (c) and public enterprises.
 - (3) National legislation must ensure the promotion of the values and principles listed in subsection (1). The appointment in public administration of a number of persons on policy considerations is not precluded, but national legislation must regulate these appointments in the public service.
 - (4) Legislation regulating public administration may differentiate between different sectors, administrations or institutions.
 - (5) The nature and functions of different sectors, administrations or institutions of public administration are relevant factors to be taken into account in legislation regulating public administration.

‘statutory health professional council’ means-

- (a) the Health Professions Council of South Africa established by section 2 of the Health Professions Act, 1974 (Act 56 of 1974);¹⁶
- (b) the South African Nursing Council established by section 2 of the Nursing Act, 1978 (Act 50 of 1978);¹⁷
- (c) the South African Pharmacy Council established by section 2 of the Pharmacy Act, 1974 (Act 53 of 1974);
- (d) the Allied Health Professions Council of South Africa established by section 2 of the Allied Health Professions Act, 1982 (Act 63 of 1982);
- (e) the South African Dental Technicians Council contemplated in section 2 of the Dental Technicians Act, 1979 (Act 19 of 1979); and
- (f) such other statutory health professional council as the Minister may prescribe;

‘this Act’ includes any regulation made thereunder;

‘tissue’ means human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete;

‘use’, in relation to tissue, includes preserve or dissect;

‘user’ means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a

¹⁶Section 12 of the Health Professions Amendment Act 29 of 2007 will have a significant impact on the composition of the Health Professions Council of South Africa (HPCSA). This is because it amended section 15 of the main Act so as to remove the power of registered practitioners to elect their own professional boards. Instead, the Minister is given the power to appoint professional boards on the basis of nominations received. In turn, these nominated boards designate representatives to sit on the HPCSA.

¹⁷See note 5 above.

health service, and if the person receiving treatment or using a health service is-

- (a) below the age contemplated in section 39(4) of the Child Care Act, 1983 (Act 74 of 1983),¹⁸ 'user' includes the person's parent or guardian or another person authorised by law to act on the first mentioned person's behalf; or
- (b) incapable of taking decisions, 'user' includes the person's spouse or partner or, in the absence of such spouse or partner, the person's parent, grandparent, adult child or brother or sister, or another person authorised by law to act on the firstmentioned person's behalf;

'zygote' means the product of the union of a male and a female gamete.

¹⁸The Child Care Act was repealed by the Children's Act 38 of 2005. Section 129 of the new Children's Act sets the rules for when a child is able to consent to medical treatment. For normal medical procedures, a child can consent if he or she is over 12 years and has the ability to understand the benefits, risks, and consequences of the treatment. Consent for surgical treatment is the same, except the child must also be assisted in making a decision by a parent or guardian. Consent for the termination of pregnancy is different. Section 5 of the Choice of Termination of Pregnancy Act 92 of 1996 says that a minor must be counselled about the importance of speaking to a parent, guardian, family member or friend before terminating a pregnancy. Importantly, however, she can not be denied a termination if – after counselling – she chooses not to talk to anyone else.

Chapter 1

OBJECTS OF ACT, RESPONSIBILITY FOR HEALTH AND ELIGIBILITY FOR FREE HEALTH SERVICES

2 Objects of Act

The objects of this Act are to regulate national health and to provide uniformity in respect of health services across the nation by-

- (a) establishing a national health system which-
 - (i) encompasses public and private providers of health services; and
 - (ii) provides in an equitable manner the population of the Republic with the best possible health services that available resources can afford;
- (b) setting out the rights and duties of health care providers, health workers, health establishments and users; and
- (c) protecting, respecting, promoting and fulfilling the rights of-
 - (i) the people of South Africa to the progressive realisation of the constitutional right of access to health care services, including reproductive health care;
 - (ii) the people of South Africa to an environment that is not harmful to their health or well-being;
 - (iii) children to basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution;¹⁹ and
 - (iv) vulnerable groups such as women, children, older persons and persons with disabilities.

¹⁹According to section 28(1)(c) of the Constitution, every child has the right to basic nutrition, shelter, basic health care services and social services.

3 Responsibility for health

- (1) The Minister must, within the limits of available resources-
 - (a) endeavour to protect, promote, improve and maintain the health of the population;²⁰
 - (b) promote the inclusion of health services in the socio-economic development plan of the Republic;
 - (c) determine the policies and measures necessary to protect, promote, improve and maintain the health and well-being of the population;
 - (d) ensure the provision of such essential health services, which must at least include primary health care services, to the population of the Republic as may be prescribed after consultation with the National Health Council; and²¹
 - (e) equitably prioritise the health services that the State can provide.
- (2) The national department, every provincial department and every municipality must establish such health services as are required in terms of this Act, and all health establishments

²⁰In *Treatment Action Campaign and Another v Rath and Others* (12156/05) [20080 ZAWCHC 34 (13 June 2008), the High Court in the Western Cape held that the Minister of Health's obligation to protect, promote, improve and maintain the health of the population created obligations on the Minister to implement national health policy, including policies established in other legislation such as the Medicines and Related Substances Act (Medicines Act). For more information, see Appendix "B" relating to the Medicines Act.

²¹Even though section 3 requires the Minister of Health to ensure that essential health services – which must include but are not limited to primary health care services – are provided, it leaves it to the Minister to determine the content of both "essential health services" and "primary health care services". As of 9 September, 2008, the Minister had not yet published a definition for either. This means that section 3 is difficult to enforce. The Minister's failure to act defeats the very purpose of the provisions of this section.

and health care providers in the public sector must equitably provide health services within the limits of available resources.

4 Eligibility for free health services in public health establishments

- (1) The Minister, after consultation with the Minister of Finance, may prescribe conditions subject to which categories of persons are eligible for such free health services at public health establishments as may be prescribed.²²
- (2) In prescribing any condition contemplated in subsection (1), the Minister must have regard to-
 - (a) the range of free health services currently available;
 - (b) the categories of persons already receiving free health services;
 - (c) the impact of any such condition on access to health services; and
 - (d) the needs of vulnerable groups such as women, children, older persons and persons with disabilities.
- (3) Subject to any condition prescribed by the Minister, the State and clinics and community health centres funded by the State must provide-

²²As of 9 September, 2008, the Minister had not yet published any conditions regarding eligibility for free health services. This means that the categories of persons and the range of services mentioned in subsection (3) are currently not subject to any conditions. In other words, for example, all women are entitled to access free termination of pregnancy services in the public sector in accordance with the Choice of Termination of Pregnancy Act. The Minister could further extend the range of free services available, in consultation with the Minister of Finance. These may be subject to conditions as determined by the Ministers.

- (a) pregnant and lactating women and children below the age of six years, who are not members or beneficiaries of medical aid schemes, with free health services;
- (b) all persons, except members of medical aid schemes and their dependants and persons receiving compensation for compensable occupational diseases, with free primary health care services; and
- (c) women, subject to the Choice on Termination of Pregnancy Act, 1996 (Act 92 of 1996), free termination of pregnancy services.

Chapter 2

RIGHTS AND DUTIES OF USERS AND HEALTH CARE PERSONNEL

5 Emergency treatment

A health care provider, health worker or health establishment may not refuse a person emergency medical treatment.²³

²³The Constitutional Court in *Soobramoney v Minister of Health (Kwazulu-Natal)*, 1998 (1) SA 765 (CC) (*Soobramoney*) helped define what emergency medical treatment means in terms of section 27(3) of the Constitution. In *Soobramoney*, the applicant was suffering from renal failure which required on-going dialysis treatment in order to keep him alive. Mr Soobramoney claimed that because the treatment was life-saving, it should be considered “emergency medical treatment” which cannot be refused. The Court, however, said that “emergency medical treatment” refers to treatment that is necessary because of a “sudden catastrophe which calls for immediate medical attention”. A person suffering from a treatable but incurable condition, such as renal failure, does not fall within the protection of section 27(3) of the Constitution, but is instead protected by the obligations imposed on the state by section 27(2), which requires the state to take all reasonable measures to ensure access to health care services is progressively realised. The Constitutional Court’s ruling allowed Mr Soobramoney to be refused any further dialysis treatment in the public health care sector. Mr Soobramoney died from his condition a week after the Constitutional Court’s judgment.

6 User to have full knowledge

- (1) Every health care provider must inform a user of-
 - (a) the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;
 - (b) the range of diagnostic procedures and treatment options generally available to the user;
 - (c) the benefits, risks, costs and consequences generally associated with each option; and
 - (d) the user's right to refuse health services and explain the implications, risks, obligations of such refusal.
- (2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

7 Consent of user

- (1) Subject to section 8, a health service may not be provided to a user without the user's informed consent, unless-
 - (a) the user is unable to give informed consent and such consent is given by a person-
 - (i) mandated by the user in writing to grant consent on his or her behalf; or
 - (ii) authorised to give such consent in terms of any law or court order;
 - (b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the con-

sent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed;

- (c) the provision of a health service without informed consent is authorised in terms of any law or a court order;²⁴
- (d) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or
- (e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service.

²⁴The draft Regulations Regarding Communicable Diseases propose certain requirements which must be met before the state can apply for a court order to compel a person to be forcibly isolated and treated without their consent as:

- The disease or health risk must be one that has previously been determined to be hazardous to the public health (such as Ebola or drug-resistant TB)
- The state must first attempt other measures besides forced isolation and treatment to prevent the spread of the disease
- There must be a determination that forced isolation or treatment is the most justifiable course of action to prevent the spread of the disease
- It must be highly likely that, without intervention, the disease will be spread to others.

Only after these conditions are met may the state or a health care worker apply to the High Court to have someone forcibly isolated.

A recent case, *Minister of Health of the Province of the Western Cape v Goliath and Others* (13741/07) [2008] ZAWCHC 41 (28 July, 2008), was brought to compel four patients who had extensively drug-resistant tuberculosis (XDR-TB) to be forcibly isolated at Brooklyn Chest Hospital until they were no longer infectious to the community. The court order held that the patients could be isolated against their will, using international precedent regarding isolation of patients with TB around the world and the provisions of section 7 allowing for treatment without consent of the patient. Unfortunately, the court did not consider the requirements in section 9 of the NHA. In addition, it must be noted that this case is largely limited to the specific facts presented to the court.

- (2) A health care provider must take all reasonable steps to obtain the user's informed consent.²⁵
- (3) For the purposes of this section 'informed consent' means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6.

8 Participation in decisions

- (1) A user has the right to participate in any decision affecting his or her personal health and treatment.
- (2) (a) If the informed consent required by section 7 is given by a person other than the user, such person must, if possible, consult the user before giving the required consent.
(b) A user who is capable of understanding must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7.
- (3) If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she must be informed as contemplated in section 6 after the provision of the health service in question unless the disclosure of such information would be contrary to the user's best interest.

²⁵For a patient in a hospital or clinic to give informed consent, he or she must know about and understand what health service is going to be given to him or her. He or she must also know about and understand the risks of that service. This well-recognised principle of our law was first set out in *Stoffberg v Elliott* 1923 CPD 12 and was confirmed by the Supreme Court of Appeal in *Louwrens v Oldwage* 2006 (2) SA 161 (SCA). However, even though a patient must know about and understand the risks before giving consent, his or her doctor does not have to warn him or her of every possible risk (such as the risk of minor harm that is unlikely to occur).

9 Health service without consent

- (1) Subject to any applicable law, where a user is admitted to a health establishment without his or her consent, the health establishment must notify the head of the provincial department in the province in which that health establishment is situated within 48 hours after the user was admitted of the user's admission and must submit such other information as may be prescribed.
- (2) If the 48-hour-period contemplated in subsection (1) expires on a Saturday, Sunday or public holiday, the health establishment must notify the head of the provincial department of the user's admission and must submit the other information contemplated in subsection (1) at any time before noon of the next day that is not a Saturday, Sunday or public holiday.
- (3) Subsection (1) does not apply if the user consents to the provision of any health service in that health establishment within 24 hours of admission.

10 Discharge reports

- (1) A health care provider must provide a user with a discharge report at the time of the discharge of the user from a health establishment containing such information as may be prescribed.
- (2) In prescribing the information contemplated in subsection (1), the Minister must have regard to-
 - (a) the nature of the health service rendered;
 - (b) the prognosis for the user; and
 - (c) the need for follow-up treatment.
- (3) A discharge report provided to a user may be verbal in the

case of an outpatient, but must be in writing in the case of an inpatient.

11 Health services for experimental or research purposes²⁶

- (1) Before a health establishment provides a health service for experimental or research purposes to any user and subject to subsection (2), the health establishment must inform the user in the prescribed manner that the health service is for experimental or research purposes or part of an experimental or research project.
- (2) A health establishment may not provide any health service to a user for a purpose contemplated in subsection (1) unless the user, the health care provider primarily responsible for the user's treatment, the head of the health establishment in question and the relevant health research ethics committee, or any other person to whom that authority has been delegated, has given prior written authorisation for the provision of the health service in question.

12 Duty to disseminate information

The national department and every provincial department, district health council and municipality must ensure that appropriate, adequate and comprehensive information is disseminated on the health services for which they are responsible, which must include-

- (a) the types and availability of health services;
- (b) the organisation of health services;

²⁶ As of 9 September, 2008, section 11 had not yet been proclaimed by the President.

- (c) operating schedules and timetables of visits;
- (d) procedures for access to the health services;
- (e) other aspects of health services which may be of use to the public;
- (f) procedures for laying complaints; and
- (g) the rights and duties of users and health care providers.

13 Obligation to keep record

Subject to National Archives of South Africa Act, 1996 (Act 43 of 1996), and the Promotion of Access to Information Act, 2000 (Act 2 of 2000), the person in charge of a health establishment must ensure that a health record containing such information as may be prescribed is created and maintained at that health establishment for every user of health services.

14 Confidentiality²⁷

- (1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.
- (2) Subject to section 15, no person may disclose any information contemplated in subsection (1) unless-
 - (a) the user consents to that disclosure in writing;
 - (b) a court order or any law requires that disclosure; or
 - (c) non-disclosure of the information represents a serious threat to public health.

15 Access to health records

- (1) A health worker or any health care provider that has access to the health records of a user may disclose such personal information to any other person, health care provider or health establishment as is necessary for any legitimate purpose within

²⁷In *Tshabalala-Msimang and Another v Makhanya and Others* (18656/07) [2007] ZAGPHC 161 (30 August 2007), the Minister of Health sued the editor, two journalists, and the publisher of the Sunday Times for allegedly violating her right to privacy under the Constitution and infringing the NHA's protections against obtaining or disclosing the contents of a person's medical records without his or her consent. The High Court said that details of a public figure's private medical records may be published if publication is in the public interest. However, possession of the medical records by the media may still be a crime under section 17 of the NHA. While the court allowed the continued publication of articles regarding the Minister, it also ordered that the records be returned to the health establishment. In most circumstances, a non-public figure's medical records are not a matter of public interest and the media would not be allowed to publish them, even if a reporter was able to get access to them. Additionally, health care workers are not ordinarily allowed to discuss a person's health status with anyone other than the patient. In this way, for example, the NHA attempts to protect people against being stigmatized when they go to a clinic to get treatment for a disease such as HIV/AIDS.

the ordinary course and scope of his or her duties where such access or disclosure is in the interests of the user.

- (2) For the purpose of this section, 'personal information' means personal information as defined in section 1 of the Promotion of Access to Information Act, 2000 (Act 2 of 2000).²⁸

²⁸ According to section 1 of the Promotion of Access to Information Act - 'personal information' means information about an identifiable individual, including, but not limited to-

- (a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the individual;
- (b) information relating to the education or the medical, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved;
- (c) any identifying number, symbol or other particular assigned to the individual;
- (d) the address, fingerprints or blood type of the individual;
- (e) the personal opinions, views or preferences of the individual, except where they are about another individual or about a proposal for a grant, an award or a prize to be made to another individual;
- (f) correspondence sent by the individual that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;
- (g) the views or opinions of another individual about the individual;
- (h) the views or opinions of another individual about a proposal for a grant, an award or a prize to be made to the individual, but excluding the name of the other individual where it appears with the views or opinions of the other individual; and
- (i) the name of the individual where it appears with other personal information relating to the individual or where the disclosure of the name itself would reveal information about the individual,

but excludes information about an individual who has been dead for more than 20 years;

16 Access to health records by health care provider

- (1) A health care provider may examine a user's health records for the purposes of-
 - (a) treatment with the authorisation of the user; and
 - (b) study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee.
- (2) If the study, teaching or research contemplated in subsection (1)(b) reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the authorisations contemplated in that subsection.

17 Protection of health records

- (1) The person in charge of a health establishment in possession of a user's health records must set up control measures to prevent unauthorised access to those records and to the storage facility in which, or system by which, records are kept.
- (2) Any person who-²⁹
 - (a) fails to perform a duty imposed on them in terms of subsection (1);
 - (b) falsifies any record by adding to or deleting or changing any information contained in that record;
 - (c) creates, changes or destroys a record without authority to do so;
 - (d) fails to create or change a record when properly required to do so;

²⁹See footnote 27.

- (e) provides false information with the intent that it be included in a record;
- (f) without authority, copies any part of a record;
- (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 unauthorised access to a record or record-keeping system, 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; or
 - (ii) any terminal or other installation connected to or forming part of any other computer or other electronic system; or
- (j) without authority, modifies or impairs the operation of-
 - (i) any part of the operating system of a computer or other electronic system on which a user's records are kept; or
 - (ii) 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 and is liable on conviction to a fine or to imprisonment for a period not exceeding one year or to both a fine and such imprisonment.

18 Laying of complaints

- (1) Any person may lay a complaint about the manner in which he or she was treated at a health establishment and have the

- complaint investigated.
- (2) The relevant member of the Executive Council and every municipal council must establish a procedure for the laying of complaints within those areas of the national health system for which they are responsible.
 - (3) The procedures for laying complaints must-
 - (a) be displayed by all health establishments in a manner that is visible for any person entering the establishment and the procedure must be communicated to users on a regular basis;
 - (b) in the case of a private health establishment, allow for the laying of complaints with the head of the relevant establishment;
 - (c) include provisions for the acceptance and acknowledgment of every complaint directed to a health establishment, whether or not it falls within the jurisdiction or authority of that establishment; and
 - (d) allow for the referral of any complaint that is not within the jurisdiction or authority of the health establishment to the appropriate body or authority.
 - (4) In laying a complaint, the person contemplated in subsection (1) must follow the procedure established by the relevant member of the Executive Council or the relevant municipal council, as the case may be.

19 Duties of users

A user must-

- (a) adhere to the rules of the health establishment when receiving treatment or using health services at the health establishment;

- (b) subject to section 14 provide the health care provider with accurate information pertaining to his or her health status and co-operate with health care providers when using health services;
- (c) treat health care providers and health workers with dignity and respect; and
- (d) sign a discharge certificate or release of liability if he or she refuses to accept recommended treatment.

20 Rights of health care personnel

- (1) Health care personnel may not be unfairly discriminated against on account of their health status.
- (2) Despite subsection (1) but subject to any applicable law, the head of the health establishment concerned may in accordance with any guidelines determined by the Minister impose conditions on the service that may be rendered by a health care provider or health worker on the basis of his or her health status.
- (3) Subject to any applicable law, every health establishment must implement measures to minimise-
 - (a) injury or damage to the person and property of health care personnel working at that establishment; and
 - (b) disease transmission.
- (4) A health care provider may refuse to treat a user who is physically or verbally abusive or who sexually harasses him or her.

Chapter 3

NATIONAL HEALTH

21 General functions of national department

- (1) The Director-General must-
 - (a) ensure the implementation of national health policy in so far as it relates to the national department; and
 - (b) issue guidelines for the implementation of national health policy.
- (2) The Director-General must, in accordance with national health policy-
 - (a) liaise with national health departments in other countries and with international agencies;
 - (b) issue, and promote adherence to, norms and standards on health matters, including-
 - (i) nutritional intervention;
 - (ii) environmental conditions that constitute a health hazard;
 - (iii) the use, donation and procurement of human tissue, blood, blood products and gametes;
 - (iv) sterilisation and termination of pregnancy;
 - (v) the provision of health services, including social, physical and mental health care;
 - (vi) health services for convicted persons and persons awaiting trial;
 - (vii) genetic services; and
 - (viii) any other matter that affects the health status of people in more than one province;

- (c) promote adherence to norms and standards for the training of human resources for health;
 - (d) identify national health goals and priorities and monitor the progress of their implementation;
 - (e) co-ordinate health and medical services during national disasters;
 - (f) participate in intersectoral and interdepartmental collaboration;
 - (g) promote health and healthy lifestyles;
 - (h) promote community participation in the planning, provision and evaluation of health services;
 - (i) conduct and facilitate health systems research in the planning, evaluation and management of health services;
 - (j) facilitate the provision of indoor and outdoor environmental pollution control services;
 - (k) facilitate and promote the provision of health services for the management, prevention and control of communicable and non-communicable diseases; and
 - (l) co-ordinate health services rendered by the national department with the health services rendered by provinces and provide such additional health services as may be necessary to establish a comprehensive national health system.
- (3) (a) The Director-General must prepare strategic, medium term health and human resources plans annually for the exercise of the powers and the performance of the duties of the national department.³⁰
- (b) The national health plans referred to in paragraph (a) must form the basis of-

³⁰The Annual National Health Plan 2007/2008 is available at: <http://www.doh.gov.za/docs/reports/annual/2007-08/index.html>

- (i) the annual budget as required by the national department responsible for finance and state expenditure; and
 - (ii) any other governmental planning exercise as may be required by any other law.
- (4) The national health plans must comply with national health policy.
- (5) The Director-General must integrate the health plans of the national department and provincial departments annually and submit the integrated health plans to the National Health Council.³¹

22 Establishment and composition of National Health Council

- (1) A council to be known as the National Health Council is hereby established.
- (2) The National Health Council consists of-
 - (a) the Minister, or his or her nominee, who acts as chairperson;
 - (b) the Deputy Minister of Health, if there is one;
 - (c) the relevant members of the Executive Councils;
 - (d) one municipal councillor, representing organised local government and appointed by the national organisation contemplated in section 163 (a) of the Constitution;
 - (e) the Director-General and the Deputy Directors-General of the national department;
 - (f) the head of each provincial department;

³¹The integration of national and provincial health plans is discussed in the Annual National Health Plan mentioned in note 30 above.

- (g) one person employed and appointed by the national organisation contemplated in section 163(a) of the Constitution;³² and
- (h) the head of the South African Military Health Service.

23 Functions of National Health Council

- (1) The National Health Council must 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 and the public and private sector;
 - (ii) targets, priorities, norms and standards relating to the equitable provision and financing of health services;
 - (iii) efficient co-ordination of health services;
 - (iv) human resources planning, production, management and development;
 - (v) development, procurement and use of health technology;
 - (vi) equitable financial mechanisms for the funding of health services;
 - (vii) the design and implementation of programmes to provide for effective referral of users between health establishments or health care providers, or to enable integration of public and private health establishments;

³²Section 163 of the Constitution requires that legislation be enacted by Parliament to “provide for the recognition of national and provincial organizations representing municipalities.” The national organisation referred to in section 163(a) is the South African Local Government Association (SALGA), established in accordance with the provisions of the Organised Local Government Act 52 of 1997.

- (viii) financial and other assistance received from foreign governments and intergovernmental or nongovernmental organisations, 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
 - (x) obtaining, processing and use of statistical returns;
- (b) proposed legislation pertaining to health matters prior to such legislation being introduced into Parliament or a provincial legislature;
 - (c) norms and standards for the establishment of health establishments;
 - (d) guidelines for the management of health districts;
 - (e) the implementation of national health policy;
 - (f) the national and provincial integrated health plans contemplated in section 21(5);
 - (g) an integrated national strategy for health research; and
 - (h) the performance of any other function determined by the Minister.
- (2) The National Health Council may determine the time frames, guidelines and the format for the preparation of national and provincial health plans.
 - (3) The National Health Council must strive to reach its decisions by consensus but where a decision cannot be reached by consensus, the decision of the majority of the members of the National Health Council is the decision of the National Health Council.
 - (4) The National Health Council may consult with or receive repre-

sentations from any person, organisation, institution or authority.

- (5) The National Health Council may create one or more committees to advise it on any matter.
- (6) The National Health Council determines the procedures for its meetings.
- (7) A quorum for the National Health Council is at least half of the members plus one.
- (8) The Minister or his or her nominee contemplated in section 22(2)(a) must convene the first meeting of the National Health Council within 60 days of the commencement of this Act.

24 National Consultative Health Forum

- (1) The Minister must establish a body to be known as the National Consultative Health Forum.
- (2) The National Consultative Health Forum must promote and facilitate interaction, communication and the sharing of information on national health issues between representatives of the national department, national organisations identified by the Minister and provincial consultative bodies contemplated in section 28.
- (3)
 - (a) Subject to paragraphs (b) and (c), the Minister must determine the composition and the place, date and time of any meeting of the National Consultative Health Forum.
 - (b) The National Consultative Health Forum must include relevant stakeholders.
 - (c) The National Consultative Health Forum must meet at least once every 12 months.

Chapter 4

PROVINCIAL HEALTH

25 Provincial health services, and general functions of provincial departments

- (1) The relevant member of the Executive Council must ensure the implementation of national health policy, norms and standards in his or her province.
- (2) The head of a provincial department must, in accordance with national health policy and the relevant provincial health policy in respect of or within the relevant province-
 - (a) provide specialised hospital services;
 - (b) plan and manage the provincial health information system;
 - (c) participate in interprovincial and intersectoral co-ordination and collaboration;
 - (d) co-ordinate the funding and financial management of district health councils;
 - (e) provide technical and logistical support to district health councils;
 - (f) plan, co-ordinate and monitor health services and must evaluate the rendering of health services;
 - (g) co-ordinate health and medical services during provincial disasters;
 - (h) conduct or facilitate research on health and health services;
 - (i) plan, manage and develop human resources for the rendering of health services;
 - (j) plan the development of public and private hospitals, other health establishments and health agencies;
 - (k) control and manage the cost and financing of public health

- establishments and public health agencies;
- (l) facilitate and promote the provision of port health services, comprehensive primary health services and community hospital services;
 - (m) provide and co-ordinate emergency medical services and forensic pathology, forensic clinical medicines and related services, including the provision of medico-legal mortuaries and medico-legal services;
 - (n) control the quality of all health services and facilities;
 - (o) provide health services contemplated by specific provincial health service programmes;
 - (p) provide and maintain equipment, vehicles and health care facilities in the public sector;
 - (q) consult with communities regarding health matters;
 - (r) provide occupational health services;
 - (s) promote health and healthy lifestyles;
 - (t) promote community participation in the planning, provision and evaluation of health services;
 - (u) provide environmental pollution control services;
 - (v) ensure health systems research; and
 - (w) provide services for the management, prevention and control of communicable and non-communicable diseases.
- (3) The head of a provincial department must-
- (a) prepare strategic, medium term health and human resources plans annually 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; and
 - (b) submit such plans to the Director-General within the time frames and in accordance with the guidelines determined by the National Health Council.

- (4) Provincial health plans must conform with national health policy.

26 Establishment and composition of Provincial Health Council

- (1) A council to be known as the Provincial Health Council is hereby established in each province.
- (2) Every Provincial Health Council consists of-
 - (a) the relevant member of the Executive Council, or his or her nominee, who acts as chairperson;
 - (b) one Councillor from each of the metropolitan municipalities in the province if there are such municipalities in the province in question;
 - (c) one Councillor from each of the district municipalities in the province;
 - (d) the head of the provincial department;
 - (e) not more than three representatives involved in the management of local government; and
 - (f) such number of other persons as the relevant member of the Executive Council may consider appropriate.
- (3) The persons contemplated in subsection (2)(e) must be appointed by the national and relevant provincial organisation contemplated in section 163(a) of the Constitution.³³

27 Functions of Provincial Health Council

- (1) A Provincial Health Council must advise the relevant member of the Executive Council on-

³³For more on section 163 of the Constitution see note 32 above.

- (a) policy concerning any matter that will protect, promote, improve and maintain the health of the population within the province, including-
 - (i) responsibilities for health within the province by individuals and the public and private sector;
 - (ii) targets, priorities, norms and standards within the province relating to the equitable provision and financing of health services;
 - (iii) efficient co-ordination of health services within the province and between neighbouring provinces;
 - (iv) human resources planning, production, management and development;
 - (v) development, procurement and use of health technology within the province;
 - (vi) equitable financial mechanisms for the funding of health services within the province;
 - (vii) the design and implementation of programmes within the province to provide for effective referral of users between health establishments or health care providers or to enable integration of public and private health establishments;
 - (viii) financial and other assistance received by the province from foreign governments and intergovernmental or nongovernmental organisations, the conditions applicable to receiving such assistance and the mechanisms to ensure compliance with these conditions;
 - (ix) epidemiological surveillance and monitoring of provincial trends with regard to major diseases and risk factors for disease; and
 - (x) obtaining, processing and use of statistical returns;

- (b) proposed legislation relating to health matters before it is introduced in the relevant provincial legislature;
 - (c) norms and standards for the establishment of health establishments;
 - (d) guidelines for the management of health districts;
 - (e) the implementation of national and provincial health policy; and
 - (f) the performance of any other function determined by the relevant member of the Executive Council.
- (2) A Provincial Health Council may determine the time frames, guidelines and the format for the preparation of district health plans within its jurisdiction.
 - (3) A Provincial Health Council may consult with or receive representations from any person, organisation, institution or authority.
 - (4) A Provincial Health Council determines the procedures for its meetings.
 - (5) The Provincial Health Council may create one or more committees to advise it on any matter.
 - (6) A quorum of a Provincial Health Council is at least half of the members plus one.
 - (7) The relevant member of the Executive Council or his or her nominee contemplated in section 26(2)(a) must convene the first meeting of the Provincial Health Council within 90 days of commencement of this Act.

28 Provincial consultative bodies

- (1) The relevant member of the Executive Council must establish a consultative body for his or her province.

- (2) A provincial consultative body must promote and facilitate interaction, communication and the sharing of information on provincial health issues between representatives of the provincial department and provincial and municipal organisations identified by the relevant member of the Executive Council.
- (3) (a) Subject to paragraphs (b) and (c) the relevant member of the Executive Council must determine the composition and the place, date and time of any meeting of the provincial consultative body in his or her province.
 - (b) A provincial consultative body must include relevant stakeholders.
 - (c) A provincial consultative body must meet at least once every 12 months.

Chapter 5

DISTRICT HEALTH SYSTEM

29 Establishment of district health system

- (1) A district health system is hereby established.
- (2) The system consists of various health districts, and the boundaries of health districts coincide with district and metropolitan municipal boundaries.

30 Division of health districts into subdistricts

- (1) (a) The relevant member of the Executive Council may, with the concurrence of the member of the Executive Council responsible for local government in the province in question and subject to subsection (2), divide any health district

- in the province into subdistricts and may determine and change the boundaries of such subdistricts.
- (b) Where a health district falls within more than one province, the members of the Executive Council of all the relevant provinces must agree to any division, determination or change contemplated in paragraph (a).
 - (c) Details of any division, determination or change must be published in the Gazette.
- (2) The members contemplated in subsection (1) must have due regard to the principles laid down in sections 27³⁴ and 195³⁵ of the Constitution and the criteria laid down in section 25 of the Local Government: Municipal Demarcation Act, 1998 (Act 27 of 1998),³⁶ particularly in so far as they relate to-
- (a) equity;
 - (b) access to services;
 - (c) quality;
 - (d) overcoming fragmentation;
 - (e) comprehensive services;
 - (f) effectiveness;
 - (g) efficiency;
 - (h) local accountability;
 - (i) community participation;
 - (j) developmental and intersectoral approach; and

³⁴Section 27 of the Constitution covers the right to have access to health care, food, water, and social security. The text of section 27 set out in note 6 above.

³⁵Section 195 of the Constitution sets out the basic principles governing public administration. The entire text of section 195 is set out in note 15 above.

³⁶Section 25 of the Local Government: Municipal Demarcation Act, 1998 (Act 27 of 1998) sets out a list of factors that must be considered when determining a municipal boundary. The factors include things such as how different boundaries will effect the economy, delivery of services (such as health care), people's employment, and whether the boundary will help to integrate the area, rather than divide it.

- (k) sustainability.

31 Establishment of district health councils

- (1) The relevant member of the Executive Council, after consultation with the member of the Executive Council responsible for local government in the province in question and the municipal council of the relevant metropolitan or district municipality, must establish a district health council for every health district in his or her province.
- (2) (a) A district health council consists of-
 - (i) a member of the metropolitan or district municipal council situated in the health district in question, nominated by the relevant council;
 - (ii) a person appointed by the relevant member of the Executive Council to represent him or her;
 - (iii) a member of the council of each local municipality within the health district, nominated by the members of the relevant council; and
 - (iv) not more than five other persons, appointed by the relevant member of the Executive Council after consultation with the municipal council of the metropolitan or district municipality, as the case may be.
- (b) The member contemplated in paragraph (a) (i) is the chairperson of the district health council.
- (c) In the case of a cross-boundary district, the relevant members of the Executive Council may each appoint a member to represent them and the persons contemplated in paragraph (a) (iv) must be appointed by the relevant members of the Executive Council in consultation with each other.

- (3) A district health council must-
 - (a) promote co-operative governance;
 - (b) ensure co-ordination of planning, budgeting, provisioning and monitoring of all health services that affect residents of the health district for which the council was established; and
 - (c) advise the relevant members of the Executive Council, through the Provincial Health Councils, and the municipal council of the relevant metropolitan or district municipality, on any matter regarding health or health services in the health district for which the council was established.
- (4) A district health council may create one or more committees to advise it on any matter
- (5) Provincial legislation must at least provide for-³⁷
 - (a) the functioning of district health councils;
 - (b) the approval, after consultation with the relevant district health council, by the relevant member of the Executive Council and the municipal council of the metropolitan or district municipality, as the case may be, of the detailed budget and performance targets for health services in the health district to which both the provincial and municipal spheres of government must contribute; and
 - (c) (i) deadlock-breaking mechanisms for cases where agreement between the relevant member of the Executive Council and the municipal council on the budget or per-

³⁷ As of 9 September, 2008, no provinces had finalised legislation required by the NHA. Kwazulu-Natal published the draft Kwazulu-Natal Health Care Bill for comment on 21 August 2007. This draft bill is available at: <http://www.kznhealth.gov.za/healthcarebill.pdf>. The ALP made a submission on the draft bill which is available at: <http://www.alp.org.za/pdf/Provincial/KZNHealthBill-2007-ALP.pdf>

- formance targets contemplated in paragraph (b) cannot be reached within a period specified in the legislation; and
- (ii) corrective action to be taken if the agreement contemplated in subparagraph (i) is breached.
- (6) The relevant member of the Executive Council must ensure that each health district and each health subdistrict is effectively managed.

32 Health services to be provided by municipalities

- (1) Every metropolitan and district municipality must ensure that appropriate municipal health services are effectively and equitably provided in their respective areas.
- (2) The relevant member of the Executive Council must assign such health services to a municipality in his or her province as are contemplated in section 156(4) of the Constitution.³⁸
- (3) An agreement contemplated in section 156(4) of the Constitution is known as a service level agreement and must provide for-
- (a) the services to be rendered by the municipality;
 - (b) the resources that the relevant member of the Executive Council must make available;
 - (c) performance standards which must be used to monitor services rendered by the municipality; and
 - (d) conditions under which the agreement may be terminated.

³⁸Section 156(4) of the Constitution says that both the national and provincial governments must allow local governments to administer certain functions, including health services, if the local government is able to do so and can administer the services more effectively than the provincial or the national government.

33 Preparation of district health plans³⁹

- (1) Each district and metropolitan health manager must within the national budget cycle develop and present to the district health council in question and the relevant member of the Executive Council a district health plan drawn up in accordance with national guidelines issued by the Director-General with due regard to national and provincial health policies and the requirements of the relevant integrated development plan prepared in terms of section 25 of the Local Government: Municipal Systems Act, 2000 (Act 32 of 2000).⁴⁰
- (2) The relevant member of the Executive Council must ensure that each health district develops and implements a district human resource plan in accordance with national guidelines issued by the Director-General.

34 Transitional arrangements concerning municipal health services

Until a service level agreement contemplated in section 32(3) is concluded, municipalities must continue to provide, within the

³⁹The local health district office must provide you with a copy of the district health plan upon request. The contact information for each health district is available in appendix “C”. Additionally, the National Department of Health has issued Guidelines for District Health Planning and Reporting. These explain what must appear in the district health plan. The guidelines are on the DoH website at: <http://www.doh.gov.za/docs/factsheets/guidelines/dhp/index.html>

⁴⁰Section 25 of the Local Government: Municipal Systems Act, 2000 (Act 32 of 2000) requires all newly elected municipal councils to adopt a strategic plan for the development of the municipality. The plan must link all the relevant areas (such as health, infrastructure, and transportation) and be compatible with both national and provincial development plans for the municipality. Copies of these plans must be made available upon request by your local municipal council.

resources available to them, the health services that they were providing in the year before this Act took effect.

Chapter 6

HEALTH ESTABLISHMENTS⁴¹

35 Classification of health establishments⁴²

The Minister may by regulation-⁴³

- (a) classify all health establishments into such categories as may be appropriate, based on-
 - (i) their role and function within the national health system;
 - (ii) the size and location of the communities they serve;
 - (iii) the nature and level of health services they are able to provide;
 - (iv) their geographical location and demographic reach;
 - (v) the need to structure the delivery of health services in accordance with national norms and standards within an integrated and co-ordinated national framework; and
 - (vi) in the case of private health establishments, whether or not the establishment is for profit or not; and
- (b) in the case of a central hospital, determine the establishment of the hospital board and the management system of such central hospital.

⁴¹ As of 9 September, 2008, the whole of Chapter 6 (sections 35-47) had not yet been proclaimed by the President. In the Minister's briefing on the National Health Act on 19 August, 2004, she indicated that Chapter 6 would be proclaimed after necessary regulations to implement its provisions had been drafted. Finalised regulations cannot be published until after the President proclaims the relevant sections.

⁴² As of 9 September, 2008, section 35 had not yet been proclaimed by the President.

⁴³ As of 9 September, 2008, no regulations under this section had been released for public comment by the Minister. See note 41 for more on regulations under Chapter 6.

36 Certificate of need⁴⁴

- (1) A person may not-
 - (a) establish, construct, modify or acquire a health establishment or health agency;
 - (b) increase the number of beds in, or acquire prescribed health technology at, a health establishment or health agency;
 - (c) provide prescribed health services; or
 - (d) continue to operate a health establishment or health agency after the expiration of 24 months from the date this Act took effect,without being in possession of a certificate of need.
- (2) A person who wishes to obtain or renew a certificate of need must apply to the Director-General in the prescribed manner and must pay the prescribed application fee.⁴⁵
- (3) Before the Director-General issues or renews a certificate of need, he or she must take into account-
 - (a) the need to ensure consistency of health services development in terms of national, provincial and municipal planning;
 - (b) the need to promote an equitable distribution and rationalisation of health services and health care resources, and the need to correct inequities based on racial, gender, economic and geographical factors;
 - (c) the need to promote an appropriate mix of public and private health services;

⁴⁴ As of 9 September, 2008, section 36 had not yet been proclaimed by the President.

⁴⁵ As of 9 September, 2008, none of the provisions dealing with certificates of need had yet been proclaimed. Therefor, there is no current requirement or procedure for people to obtain a certificate of need.

- (d) the demographics and epidemiological characteristics of the population to be served;
 - (e) the potential advantages and disadvantages for existing public and private health services and for any affected communities;
 - (f) the need to protect or advance persons or categories of persons designated in terms of the Employment Equity Act, 1998 (Act 55 of 1998), within the emerging small, medium and micro-enterprise sector;
 - (g) the potential benefits of research and development with respect to the improvement of health service delivery;
 - (h) the need to ensure that ownership of facilities does not create perverse incentives for health service providers and health workers;
 - (i) if applicable, the quality of health services rendered by the applicant in the past;
 - (j) the probability of the financial sustainability of the health establishment or health agency;
 - (k) the need to ensure the availability and appropriate utilisation of human resources and health technology;
 - (l) whether the private health establishment is for profit or not; and
 - (m) if applicable, compliance with the requirements of a certificate of non-compliance.
- (4) The Director-General may investigate any issue relating to an application for the issue or renewal of a certificate of need and may call for such further information as may be necessary in order to make a decision upon a particular application.
- (5) The Director-General may issue or renew a certificate of need subject to-

- (a) compliance by the holder with national operational norms and standards for health establishments and health agencies, as the case may be; and
- (b) any condition regarding-
 - (i) the nature, type or quantum of services to be provided by the health establishment or health agency;
 - (ii) human resources and diagnostic and therapeutic equipment and the deployment of human resources or the use of such equipment;
 - (iii) public private partnerships;
 - (iv) types of training to be provided by the health establishment or health agency; and
 - (v) any criterion contemplated in subsection (3).
- (6) The Director-General may withdraw a certificate of need-
 - (a) on the recommendation of the Office of Standards Compliance in terms of section 79(7)(b);
 - (b) if the continued operation of the health establishment or the health agency, as the case may be, or the activities of a health care provider or health worker working within the health establishment, constitute a serious risk to public health;
 - (c) if the health establishment or the health agency, as the case may be, or a health care provider or health worker working within the health establishment, is unable or unwilling to comply with minimum operational norms and standards necessary for the health and safety of users; or
 - (d) if the health establishment or the health agency, as the case may be, or a health care provider or health worker working within the health establishment, persistently violates the

constitutional rights of users or obstructs the State in fulfilling its obligations to progressively realise the constitutional right of access to health services.

- (7) If the Director-General refuses an application for a certificate of need or withdraws a certificate of need the Director-General must within a reasonable time give the applicant or holder, as the case may be, written reasons for such refusal or withdrawal.

37 Duration of certificate of need⁴⁶

A certificate of need is valid for a prescribed period, but such prescribed period may not exceed 20 years.

38 Appeal to Minister against Director-General's decision⁴⁷

- (1) Any person aggrieved by a decision of the Director-General in terms of section 36 may appeal in writing to the Minister against such decision.
- (2) Such appeal must-
- (a) be lodged within 60 days from the date on which written reasons for the decision were given by the Director-General or such later date as the Minister permits; and
 - (b) set out the grounds of appeal.
- (3) After considering the grounds of appeal and the Director-General's reasons for the decision, the Minister must as soon as practicable-

⁴⁶ As of 9 September, 2008, section 37 had not yet been proclaimed by the President.

⁴⁷ As of 9 September, 2008, section 38 had not yet been proclaimed by the President.

- (a) confirm, set aside or vary the decision; or
 - (b) substitute any other decision for the decision of the Director-General.
- (4) The Minister must within a reasonable time after reaching a decision give the appellant written reasons for such decision.

39 Regulations relating to certificates of need⁴⁸

- (1) The Minister may, after consultation with the National Health Council, make regulations relating to-⁴⁹
- (a) the requirements for the issuing or renewal of a certificate of need;
 - (b) the requirements for a certificate of need for health establishments and health agencies existing at the time of commencement of this Act;
 - (c) the requirements for a certificate of need for health establishments and health agencies coming into being after the commencement of this Act; and
 - (d) any other matter relating to the granting of a certificate of need and the inspection and administration of health establishments and health agencies.
- (2) Regulations made under subsection (1)-
- (a) must ensure the equitable distribution and rationalisation of health, with special regard to vulnerable groups such as woman, older persons, children and people with disabilities;

⁴⁸ As of 9 September, 2008, section 39 had not yet been proclaimed by the President.

⁴⁹ As of 9 September, 2008, no regulations under this section had been released for public comment by the Minister. See note 41 for more on regulations under Chapter 6.

- (b) may prescribe the fees payable in respect of applications for the issuing and renewal of certificates of need;
- (c) must prescribe the formats and procedures to be used in applications for the issuing and renewal of certificates of need, and the information that must be submitted with such applications;
- (d) must ensure and promote access to health services and the optimal utilisation of health care resources, with special regard to vulnerable groups such as woman, older persons, children and people with disabilities;
- (e) must ensure compliance with the provisions of this Act and national operational norms and standards for the delivery of health services;
- (f) must seek to avoid or prohibit business practices or perverse incentives which adversely affect the costs or quality of health services or the access of users to health services;
- (g) must avoid or prohibit practices, schemes or arrangements by health care providers or health establishments that directly or indirectly conflict with, violate or undermine good ethical and professional practice; and
- (h) must ensure that the quality of health services provided by health establishments and health agencies conforms to the prescribed norms and standards.

40 Offences and penalties in respect of certificate of need⁵⁰

- (1) Any person who performs any act contemplated in section 36(1) without a certificate of need required in terms of that

⁵⁰ As of 9 September, 2008, section 40 had not yet been proclaimed by the President.

section is guilty of an offence.

- (2) Any person convicted of an offence in terms of subsection (1) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

41 Provision of health services at public health establishments⁵¹

- (1) The Minister, in respect of a central hospital, and the relevant member of the Executive Council, in respect of all other public health establishments within the province in question, may-
- (a) determine the range of health services that may be provided at the relevant public health establishment;
 - (b) prescribe the procedures and criteria for admission to and referral from a public health establishment or group of public health establishments;
 - (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) various forms of treatment; and
 - (iii) various categories of public health establishments; and
 - (d) in consultation with the relevant Treasury, determine the proportion of revenue generated by a particular public health establishment classified as a 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

⁵¹ As of 9 September, 2008, section 41 had not yet been proclaimed by the President.

ordinarily resident in a province.

- (3) Despite subsection (2), a province whose residents make use of another province's services must compensate that province for health services provided to such residents in the manner and to the extent prescribed by the Minister in consultation with, in the case of a central hospital, the National Treasury and, in the case of any other hospital, the relevant Treasury.
- (4) The Minister must appoint a representative hospital board for each central hospital or group of central hospitals.⁵²
- (5) The functions of a central hospital board must be prescribed by the Minister.⁵³
- (6) (a) The relevant member of the Executive Council must-
 - (i) appoint a representative board for each public health establishment classified as a hospital or for each group of such public health establishments within the relevant province;
 - (ii) prescribe the functions of such boards; and
 - (iii) prescribe procedures for meetings of the board.
- (b) A hospital contemplated in paragraph (a) does not include a central hospital.
- (7) The boards contemplated in subsections (4) and (6) must be composed of-
 - (a) one representative from each university associated with the hospital;

⁵²Once hospital boards are appointed in terms of this section, contact information for them must be made available upon request at a central hospital or from the local health district office. See Appendix "C" for contact information for each local health district.

⁵³As of 9 September, 2008, the Minister had not yet prescribed the functions of central hospital boards.

- (b) in the case of a board contemplated in subsection (4), one representative from the national department;
 - (c) in the case of boards contemplated in subsections (4) and (6), one representative from the provincial department in the province in which the relevant hospital is situated;
 - (d) not more than three representatives of the communities served by the hospital, including special interest groups representing users; and
 - (e) not more than five representatives of staff and management of the hospital but such representatives may not vote at a meeting of the board.
- (8) The boards contemplated in subsections (4) and (6) may include not more than five persons with expertise in areas such as accounting, financial management, human resources management, information management and legal matters.
- (9) Members of a hospital board are 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 any member on good cause shown.

42 Clinics and community health centre committees⁵⁴

- (1) Provincial legislation must at least provide for the establishment in the province in question of a committee for-⁵⁵
- (a) a clinic or a group of clinics;

⁵⁴ As of 9 September, 2008, section 42 had not yet been proclaimed by the President.

⁵⁵ As of 9 September, 2008, no provinces had finalised legislation required by the NHA. For further information on the status of draft Kwazulu-Natal legislation, see note 37 above. Unfortunately, because section 42 isn't proclaimed and no provinces have finalised legislation, these committees – which are meant to include community representatives – have not yet been established in the manner intended.

- (b) a community health centre; or
 - (c) a clinic and a community health centre or a group of clinics and community health centres.
- (2) Any committee contemplated in subsection (1) must at least include-
- (a) one or more local government councillors;
 - (b) one or more members of the community served by the health facility; and
 - (c) the head of the clinic or health centre in question.
- (3) The functions of a committee must be prescribed in the provincial legislation in question.

43 Health services at non-health establishments and at public health establishments other than hospitals⁵⁶

- (1) The Minister may prescribe-
- (a) minimum standards and requirements for the provision of health services in locations other than health establishments, including schools and other public places; and
 - (b) penalties for any contravention of or failure to comply with any such standards or requirements.
- (2) Provincial legislation must provide for the provision of health services at health establishments in the province in question other than hospitals.
- (3) (a) The Minister may, in the interests of the health and wellbeing of persons attending an initiation school and subject to the provisions of any other law, prescribe conditions under

⁵⁶ As of 9 September, 2008, section 43 had not yet been proclaimed by the President.

which the circumcision of a person as part of an initiation ceremony may be carried out.

(b) For the purposes of this subsection-

(i) 'initiation school' means any place at which one or more persons are circumcised as part of an initiation ceremony; and

(ii) 'initiation ceremony' means a traditional ritual or practice in terms of which a person is inducted into an order or accorded a certain status or recognition within a community.

(4) The Minister may, subject to the provisions of any other law, prescribe conditions relating to traditional health practices to ensure the health and well-being of persons who are subject to such health practices.

44 Referral from one public health establishment to another⁵⁷

(1) Subject to this Act, a user may attend any public health establishment for the purposes of receiving health services.

(2) If a public health establishment is not capable of providing the necessary treatment or care, the public health establishment in question must transfer the user concerned to an appropriate public health establishment which is capable of providing the necessary treatment or care in such manner and on such terms as may be determined by the Minister or the relevant member of the Executive Council, as the case may be.

⁵⁷ As of 9 September, 2008, section 44 had not yet been proclaimed by the President.

45 Relationship between public and private health establishments⁵⁸

- (1) The Minister must prescribe mechanisms to enable a co-ordinated relationship between private and public health establishments in the delivery of health services.⁵⁹
- (2) The national department, any provincial department or any municipality may enter into an agreement with any private practitioner, private health establishment or nongovernmental organisation in order to achieve any object of this Act.
- (3) An agreement contemplated in subsection (2) must comply with the Public Finance Management Act, 1999 (Act 1 of 1999), or any municipal finance management legislation, as the case may be.

46 Obligations of private health establishments⁶⁰

Every private health establishment must maintain insurance cover sufficient to indemnify a user for damages that he or she might suffer as a consequence of a wrongful act by any member of its staff or by any of its employees.

⁵⁸ As of 9 September, 2008, section 45 had not yet been proclaimed by the President.

⁵⁹ As of 9 September, 2008, the Minister had not yet prescribed the mechanisms necessary for public and private co-operation in the delivery of health care services. These regulations will be essential for structuring health care delivery in the country and ensuring that the health care capacity in the country is fully utilised.

⁶⁰ As of 9 September, 2008, section 46 had not yet been proclaimed by the President.

47 Evaluating services of health establishments⁶¹

- (1) All health establishments must comply with the quality requirements and standards prescribed by the Minister after consultation with the National Health Council.
- (2) The quality requirements and standards contemplated in subsection (1) may relate to human resources, health technology, equipment, hygiene, premises, the delivery of health services, business practices, safety and the manner in which users are accommodated and treated.
- (3) The Office of Standards Compliance and the Inspectorate for Health Establishments must monitor and enforce compliance with the quality requirements and standards contemplated in subsection (1).

Chapter 7

HUMAN RESOURCES PLANNING AND ACADEMIC HEALTH COMPLEXES

48 Development and provision of human resources in national health system⁶²

- (1) The National Health Council must develop policy and guidelines for, and monitor the provision, distribution, development, management and utilisation of, human resources within the national health system.

⁶¹ As of 9 September, 2008, section 47 had not yet been proclaimed by the President.

⁶² The Department of Health's most recent human resources for health plan was published in 2006. This plan sets out a number of principles that must be considered by provincial governments when creating their own provincial human resources for health plan. The National Human Resources Plan for Health is available online at: <http://www.doh.gov.za/docs/factsheets/guidelines/hrplan/index.html>

- (2) The policy and guidelines contemplated in subsection (1) must amongst other things facilitate and advance-
 - (a) the adequate distribution of human resources;
 - (b) the provision of appropriately trained staff at all levels of the national health system to meet the population's health care needs; and
 - (c) the effective and efficient utilisation, functioning, management and support of human resources within the national health system.

49 Maximising services of health care providers

The Minister, with the concurrence of the National Health Council, must determine guidelines to enable the provincial departments and district health councils to implement programmes for the appropriate distribution of health care providers and health workers.

50 Forum of Statutory Health Professional Councils⁶³

- (1) A forum to be known as the Forum of Statutory Health Professional Councils is hereby established on which all the statutory health professional councils must be represented.
- (2) The Forum of Statutory Health Professional Councils consists of the chairpersons of the statutory health professional councils and the registrars or chief executive officers, as the case may be, of the statutory health professional councils.
- (3) (a) In addition to the representatives contemplated in subsection (2), the Minister must appoint-
 - (i) two representatives of the national department;

⁶³ As of 9 September, 2008, section 50 had not yet been proclaimed by the President.

- (ii) three community representatives who have been appointed to any of the statutory health professional councils contemplated in subsection (1); and
 - (iii) two representatives of tertiary education institutions, to the Forum of Statutory Health Professional Councils.
- (b) (i) The Minister must appoint a suitable person as chairperson of the Forum of Statutory Health Professional Councils
- (ii) The chairperson holds office for such period, but not exceeding two years, as the Minister may determine at the time of his or her appointment, and may be reappointed at the expiry of his or her term of office.
- (c) Any member of the Forum of Statutory Health Professional Councils, including the chairperson, must vacate his or her office if-
 - (i) his or her estate is sequestrated;
 - (ii) he or she becomes disqualified from practising his or her profession in terms of any law;
 - (iii) he or she becomes mentally ill to such a degree that it is necessary that he or she be detained, supervised or controlled;
 - (iv) he or she is convicted in the Republic or elsewhere of an offence involving dishonesty or an offence in respect whereof he or she is sentenced to imprisonment without the option of a fine;
 - (v) he or she ceases to be a South African citizen;
 - (vi) he or she has been absent from more than two consecutive ordinary meetings of the Forum without leave from the Forum;
 - (vii) he or she tenders his or her resignation in writing and

- the Minister accepts the resignation;
 - (viii) he or she ceases to hold any qualification necessary for his or her appointment; or
 - (ix) the Minister, in the public interest, terminates his or her membership.
- (4) The Forum of Statutory Health Professional Councils must-
- (a) protect the interests of the public and users;
 - (b) ensure communication and liaison between the statutory health professional councils upon matters affecting more than one of the registered professions;
 - (c) in the interests of the public, promote interprofessional liaison and communication between registered professions;
 - (d) promote good practice in health services and sharing of information between the statutory health professional councils;
 - (e) ensure consistency in the actions and decisions of the statutory health professional councils;
 - (f) consult and liaise with any relevant authority on matters collectively affecting all registered health professions;
 - (g) investigate and report on, of its own accord, at the request of one or more of the statutory health professional councils or at the request of the Minister, any matter of relevance to more than one statutory health professional council;
 - (h) in the prescribed manner, act as ombudsperson in respect of complaints by members of the public and other persons concerning the councils referred to in subsection (1);
 - (i) advise the Minister on the development of coherent policies relating to the education and training and optimal utilisation and distribution of health care providers;
 - (j) monitor and advise the Minister on the implementation of

- health policy in so far as it impacts on health care providers and the registered professions;
- (k) hold the statutory health professional councils explicitly to account for their performance as competent public authorities;
 - (l) publish an annual report on the performance of the statutory health professional councils;
 - (m) set performance improvement targets with the statutory health professional councils and monitor their progress; and
 - (n) advise the Minister and the individual statutory health professional councils concerning-
 - (i) the scopes of practice of the registered professions;
 - (ii) common educational and training requirements of health care providers;
 - (iii) new professions to be regulated;
 - (iv) targets, priorities, norms and standards relating to the equitable distribution of health care providers;
 - (v) development, procurement and use of health service technology;
 - (vi) perverse incentives within the registered professions;
 - (vii) the recruitment, evaluation and registration of foreign health care professionals;
 - (viii) effective co-ordination of the objectives and responsibilities of the various statutory health professional councils;
 - (ix) responsibilities of health care providers in promoting and maintaining public health;
 - (x) interprofessional communication and relationships; and
 - (xi) any other matter that may be prescribed.
- (5) (a) In performing its duties the Forum of Statutory Health

Professional Councils may-

- (i) consult or hear representations by any person, body or authority; and
 - (ii) establish a committee to advise it on any matter.
- (b) A committee contemplated in paragraph (a) (ii) may consist of not more than seven persons who must have the relevant knowledge, expertise, skills and experience to enable the committee to give the required advice.
- (c) The chairperson of the Forum must be a member of the committee.
- (6) (a) A decision of the Forum of Statutory Health Professional Councils must be taken by the votes of a majority of at least two thirds of the members of the Forum present at the meeting of the Forum.
- (b) A quorum for any meeting of the Forum is at least half of the members of the Forum plus one.
- (c) In the event of an equality of votes, the chairperson of the Forum has a casting vote in addition to his or her deliberative vote.
- (7) The Forum of Statutory Health Professional Councils may determine the procedure for its meetings.
- (8) The Forum of Statutory Health Professional Councils must meet at least three times a year.
- (9) The Forum of Statutory Health Professional Councils is funded through prescribed membership fees paid by the statutory health professional councils.
- (10) The members of the Forum of Statutory Health Professional Councils may agree that a person employed by one of the statutory health professional councils represented on the Forum must act as secretary at a meeting of the Forum.

51 Establishment of academic health complexes⁶⁴

The Minister may, in consultation with the Minister of Education, establish-

- (a) academic health complexes, which may consist of one or more health establishments at all levels of the national health system, including peripheral facilities, and one or more educational institutions working together to educate and train health care personnel and to conduct research in health services; and
- (b) any co-ordinating committees that may be necessary in order to perform such functions as may be prescribed.

52 Regulations relating to human resources

The Minister may make regulations regarding human resources within the national health system in order to-⁶⁵

- (1) (a) ensure that adequate resources are available for the education and training of health care personnel to meet the human resources requirements of the national health system;
- (b) ensure the education and training of health care personnel to meet the requirements of the national health system;
- (c) create new categories of health care personnel to be educated or trained;

⁶⁴ As of 9 September, 2008, section 51 had not yet been proclaimed by the President.

⁶⁵ As of 9 September, 2008, no regulations under this section had been finalised or released for public comment by the Minister. The DoH has produced guidelines on human resources planning, but guidelines cannot create the same level of obligations for government or the private sector that regulations are able to. The process for creating guidelines also does not ordinarily include as much opportunity for public participation, as is required when departments draft new regulations.

- (d) identify shortages of key skills, expertise and competencies within the national health system and to prescribe strategies which are not in conflict with the Higher Education Act, 1997 (Act 101 of 1997), for the-
 - (i) recruitment of health care personnel from other countries; and
 - (ii) education and training of health care providers or health workers in the Republic,to make up the deficit in respect of scarce skills, expertise and competencies;
- (e) prescribe strategies for the recruitment and retention of health care personnel within the national health system;
- (f) ensure the existence of adequate human resources planning, development and management structures at national, provincial and district levels of the national health system;
- (g) ensure the availability of institutional capacity at national, provincial and district levels of the national health system to plan for, develop and manage human resources;
- (h) ensure the definition and clarification of the roles and functions of the national department, provincial departments and municipalities with regard to the planning, production and management of human resources; and
- (i) prescribe circumstances under which health care personnel may be recruited from other countries to provide health services in the Republic.

Chapter 8

CONTROL OF USE OF BLOOD, BLOOD PRODUCTS, TISSUE AND GAMETES IN HUMANS⁶⁶

53 Establishment of national blood transfusion service⁶⁷

- (1) The Minister must establish a blood transfusion service for the Republic by granting a licence to a non-profit organisation, which is able to provide a blood transfusion service throughout the territory of the Republic.
- (2) The holder of the licence granted in terms of subsection (1)-
 - (a) must comply with prescribed norms and standards and must provide the prescribed blood transfusion and related services;
 - (b) may establish regional units, for the delivery of blood transfusion services, which must function under the control of the licence holder; and
 - (c) has the sole right to provide a blood transfusion service in the Republic.
- (3) Any person other than the holder of the licence granted in terms of subsection (1) who provides a blood transfusion service in the Republic, is guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

⁶⁶Several regulations relating to chapter 8 have been published for comment, but as of 9 September, 2008, most sections of Chapter 8 had not yet been proclaimed. The regulations under Chapter 8 cannot be finalised until after the President proclaims the relevant sections. See Appendix "A" for information on where to get copies of the draft regulations.

⁶⁷The President published a proclamation on 27 June, 2008 in terms of which, section 53 came into effect on 30 June, 2008.

54 Designation of authorised institution⁶⁸

- (1) The Minister may, by notice in the Gazette, designate any institution other than an institution contemplated in section 63 as an authorised institution.
- (2) An authorised institution may-
 - (a) acquire, use or supply the body of a deceased person for any of the purposes referred to in section 64;
 - (b) acquire or use any tissue lawfully imported or removed from the body of a living or deceased person for any of the purposes referred to in section 56 or 64, as the case may be;
 - (c) supply any tissue preserved by it to an institution or person contemplated in section 63 for any of the purposes referred to in section 58 or 64; and
 - (d) acquire, use and supply blood products for any of the purposes referred to in section 56 or 64.
- (3) The Minister may, in the notice contemplated in subsection (1), impose conditions in respect of the exercise of a power referred to in subsection (2).

55 Removal of tissue, blood, blood products or gametes from living persons⁶⁹

A person may not remove tissue, blood, a blood product or gametes from the body of another living person for the purpose referred to in section 56 unless it is done-

⁶⁸ As of 9 September, 2008, section 54 had not yet been proclaimed by the President.

⁶⁹ As of 9 September, 2008, section 55 had not yet been proclaimed by the President.

- (1) with the written consent of the person from whom the tissue, blood, blood product or gametes are removed granted in the prescribed manner; and
- (2) in accordance with prescribed conditions.

56 Use of tissue, blood, blood products or gametes removed or withdrawn from living persons⁷⁰

- (1) A person may use tissue or gametes removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribed.
- (2) (a) Subject to paragraph (b), the following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purpose contemplated in subsection (1):
 - (i) Tissue, blood, a blood product or a gamete from a person who is mentally ill within the meaning of the Mental Health Care Act, 2002 (Act 17 of 2002);
 - (ii) tissue which is not replaceable by natural processes from a person younger than 18 years;
 - (iii) a gamete from a person younger than 18 years; or
 - (iv) placenta, embryonic or foetal tissue, stem cells and umbilical cord, excluding umbilical cord progenitor cells.
- (b) The Minister may authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph (a) and may impose any condition which may be necessary in respect of such removal or withdrawal.

⁷⁰ As of 9 September, 2008, section 56 had not yet been proclaimed by the President.

57 Prohibition of reproductive cloning of human beings⁷¹

- (1) A person may not-
 - (a) manipulate any genetic material, including genetic material of human gametes, zygotes or embryos; or
 - (b) engage in any activity, including nuclear transfer or embryo splitting,
for the purpose of the reproductive cloning of a human being.
- (2) The Minister may, under such conditions as may be prescribed, permit therapeutic cloning utilising adult or umbilical cord stem cells.
- (3) No person may import or export human zygotes or embryos without the prior written approval of the Minister.
- (4) The Minister may permit research on stem cells and zygotes which are not more than 14 days old on a written application and if-
 - (a) the applicant undertakes to document the research for record purposes; and
 - (b) prior consent is obtained from the donor of such stem cells or zygotes.
- (5) Any person who contravenes a provision of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.
- (6) For the purpose of this section-
 - (a) reproductive cloning of a human being' means the manipulation of genetic material in order to achieve the repro-

⁷¹ As of 9 September, 2008, section 57 had not yet been proclaimed by the President.

duction of a human being and includes nuclear transfer or embryo splitting for such purpose; and

- (b) 'therapeutic cloning' means the manipulation of genetic material from either adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues.

58 Removal and transplantation of human tissue in hospital or authorised institution⁷²

- (1) A person may not remove tissue from a living person for transplantation in another living person or carry out the transplantation of such tissue except-
 - (a) in a hospital or an authorised institution; and
 - (b) on the written authority of-
 - (i) the medical practitioner in charge of clinical services in that hospital or authorised institution, or any other medical practitioner authorised by him or her; or
 - (ii) in the case where there is no medical practitioner in charge of the clinical services at that hospital or authorised institution, a medical practitioner authorised thereto by the person in charge of the hospital or authorised institution.
- (2) The medical practitioner contemplated in subsection (1) (b) may not participate in a transplant for which he or she has granted authorisation in terms of that subsection.

⁷²As of 9 September, 2008, section 58 had not yet been proclaimed by the President.

59 Removal, use or transplantation of tissue, and administering of blood and blood products by medical practitioner or dentist⁷³

- (1) For the purposes of this Chapter, only a registered medical practitioner or dentist may remove any tissue from a living person, use tissue so removed for any of the purposes contemplated in section 56 or transplant tissue so removed into another living person.
- (2) Subject to the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), only a registered medical practitioner or dentist, or a person acting under the supervision or on the instructions of a medical practitioner or dentist, may for the purposes of this Chapter administer blood or a blood product to, or prescribe blood or a blood product for, a living person.

60 Payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes⁷⁴

- (1) No person, except-
 - (a) a hospital or an institution contemplated in section 58 (1)
 - (a), a person or an institution contemplated in section 63 and an authorised institution or, in the case of tissue or gametes imported or exported in the manner provided for in the regulations, the importer or exporter concerned, may receive payment in respect of the acquisition, supply, importation or export of any tissue or gamete for or to another

⁷³ As of 9 September, 2008, section 59 had not yet been proclaimed by the President.

⁷⁴ As of 9 September, 2008, section 60 had not yet been proclaimed by the President.

- person for any of the purposes contemplated in section 56 or 64;
- (b) a person or an institution contemplated in section 63 or an authorised institution, may receive any payment in respect of the importation, export or acquisition for the supply to another person of blood or a blood product.
- (2) The amount of payment contemplated in subsection (1) may not exceed an amount which is reasonably required to cover the costs involved in the importation, export, acquisition or supply of the tissue, gamete, blood or blood product in question.
 - (3) This section does not prevent a health care provider registered with a statutory health professional council from receiving remuneration for any professional service rendered by him or her.
 - (4) It is an offence for a person-
 - (a) who has donated tissue, a gamete, blood or a blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and
 - (b) to sell or trade in tissue, gametes, blood or blood products, except as provided for in this Chapter.
 - (5) Any person convicted of an offence in terms of subsection (4) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

61 Allocation and use of human organs⁷⁵

- (1) Human organs obtained from deceased persons for the purpose of transplantation or treatment, or medical or dental training or research, may only be used in the prescribed manner.
- (2) Human organs obtained in terms of subsection (1) must be allocated in accordance with the prescribed procedures.
- (3) An organ may not be transplanted into a person who is not a South African citizen or a permanent resident of the Republic without the Minister's authorisation in writing.
- (4) The Minister must prescribe-
 - (a) criteria for the approval of organ transplant facilities; and
 - (b) procedural measures to be applied for such approval.
- (5)
 - (a) A person who contravenes a provision of this section or fails to comply therewith or who charges a fee for a human organ is guilty of an offence.
 - (b) Any person convicted of an offence in terms of paragraph (a) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

62 Donation of human bodies and tissue of deceased persons⁷⁶

- (1)
 - (a) A person who is competent to make a will may-
 - (i) in the will;
 - (ii) in a document signed by him or her and at least two competent witnesses; or

⁷⁵ As of 9 September, 2008, section 61 had not yet been proclaimed by the President.

⁷⁶ As of 9 September, 2008, section 62 had not yet been proclaimed by the President.

- (iii) in an oral statement made in the presence of at least two competent witnesses,
 - donate his or her body or any specified tissue thereof to be used after his or her death, or give consent to the post mortem examination of his or her body, for any purpose provided for in this Act.
 - (b) A person who makes a donation as contemplated in paragraph (a) must nominate an institution or a person contemplated in section 63 as donee.
 - (c) If no donee is nominated in terms of paragraph (b), the donation is null and void.
 - (d) Paragraph (b) does not apply in respect of an organ donated for the purposes contemplated in section 61 (1) and the donee of such organ must be determined in terms of section 61 (2).
- (2) In the absence of a donation under subsection (1) (a) or of a contrary direction given by a person whilst alive, the spouse, partner, major child, parent, guardian, major brother or major sister of that person, in the specific order mentioned, may, after that person's death, donate the body or any specific tissue of that person to an institution or a person contemplated in section 63.
- (3) (a) The Director-General may, after the death of a person and if none of the persons contemplated in subsection (2) can be located, donate any specific tissue of that person to an institution or a person contemplated in section 63.
- (b) The Director-General may only donate the specific tissue if all the prescribed steps have been taken to locate the persons contemplated in subsection (2).

63 Human bodies, tissue, blood, blood products or gametes may be donated to prescribed institution or person⁷⁷

A human body, tissue, blood, blood products or gametes may be donated by any person contemplated in section 55 (a) or 62 to any prescribed institution or person for any purpose contemplated in section 56 or 64 (1).

64 Purposes of donation of body, tissue, blood or blood products of deceased persons⁷⁸

- (1) A donation in terms of section 62 may only be made for-
 - (a) the purposes of the training of students in health sciences;
 - (b) the purposes of health research;
 - (c) the purposes of the advancement of health sciences;
 - (d) therapeutic purposes, including the use of tissue in any living person; or
 - (e) the production of a therapeutic, diagnostic or prophylactic substance.
- (2) This Act does not apply to the preparation of the body of a deceased person for the purposes of embalming it, whether or not such preparation involves the-
 - (a) making of incisions in the body for the withdrawal of blood and the replacement thereof by a preservative; or
 - (b) restoration of any disfigurement or mutilation of the body before its burial.

⁷⁷ As of 9 September, 2008, section 63 had not yet been proclaimed by the President.

⁷⁸ As of 9 September, 2008, section 64 had not yet been proclaimed by the President.

65 Revocation of donation⁷⁹

A donor may, prior to the transplantation of the relevant organ into the donee, revoke a donation in the same way in which it was made or, in the case of a donation by way of a will or other document, also by the intentional destruction of that will or document.

66 Post mortem examination of bodies⁸⁰

- (1) Subject to subsection (2), a post mortem examination of the body of a deceased person may be conducted if-
 - (a) the person, while alive, gave consent thereto;
 - (b) the spouse, partner, major child, parent, guardian, major brother or major sister of the deceased, in the specific order mentioned, gave consent thereto; or
 - (c) such an examination is necessary for determining the cause of death.
- (2) A post mortem examination may not take place unless-
 - (a) the medical practitioner in charge of clinical services in the hospital or authorised institution or of the mortuary in question, or any other medical practitioner authorised by such practitioner, has authorised the post mortem examination in writing and in the prescribed manner; or
 - (b) in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorised by the person in charge of such hospital or authorised institution, has authorised the post mortem examination in writing and in the prescribed manner.

⁷⁹ As of 9 September, 2008, section 65 had not yet been proclaimed by the President.

⁸⁰ As of 9 September, 2008, section 66 had not yet been proclaimed by the President.

67 Removal of tissue at post mortem examinations and obtaining of tissue by institutions and persons⁸¹

- (1) (a) The Minister may, on the written application of an institution or person requiring tissue for a purpose contemplated in section 64 (1), authorise that institution or person, in writing, to obtain such tissue from a medical practitioner contemplated in subsection (3) or a person or an institution contemplated in section 63.
- (b) The Minister may impose any condition on the institution or person to which or to whom he or she has granted an authorisation in terms of paragraph (a).
- (c) This Act does not prevent persons or institutions from acquiring tissue in terms of the National Heritage Resources Act, 1999 (Act 25 of 1999), for the purposes of that Act.
- (2) The medical practitioner in charge of clinical services in the hospital or authorised institution or of the mortuary in question, or any other medical practitioner authorised by such practitioner, or, in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorised by the person in charge of such hospital or authorised institution, may, in writing and in the prescribed manner, authorise-
 - (a) a prescribed institution or person contemplated in section 63; or
 - (b) an authorised institution making application therefor in writing,to remove any specified tissue from the body concerned before burial thereof.

⁸¹ As of 9 September, 2008, section 67 had not yet been proclaimed by the President.

- (3) Despite anything to the contrary in any other law, a medical practitioner who conducts a post mortem examination in terms of-
- (a) section 3 of the Inquests Act, 1959 (Act 58 of 1959);⁸² or
 - (b) section 71 (1) (a) or (b),
- must remove or cause to be removed from a body such tissue as may be specified in an authorisation under subsection (1) and must hand it over to the institution or person in possession of the authorisation.
- (4) The removal contemplated in subsection (3) may not be effected if-
- (a) the removal of the tissue is likely to affect the outcome of the examination; or
 - (b) the body or tissue in question has been donated or if the removal would be contrary to a direction given by the deceased before his or her death.

68 Regulations relating to tissue, cells, organs, blood, blood products and gametes⁸³

- (1) The Minister may make regulations regarding-⁸⁴
- (a) the post mortem examination of bodies of deceased persons;

⁸²Section 3 of the Inquests Act allows a police officer who believes a person died from something other than natural causes (such as poison or an accident) to investigate the cause of death and have the district surgeon or other medical practitioner examine the body to determine the cause of death.

⁸³As of 9 September, 2008, section 68 had not yet been proclaimed by the President.

⁸⁴See appendix “A” for a list of draft regulations issued under section 68. As of 9 September, 2008, no final regulations had yet been issued. See note 66 for more on regulations under Chapter 8.

- (b) the preservation, use and disposal of bodies, including unclaimed bodies;
- (c) the removal of donated tissue or cells from persons, tissue or cells obtained from post mortem examinations and the procurement, processing, storage, supply and allocation of tissue or human cells by institutions and persons;
- (d) tissue transplants;
- (e) the production, packaging, sealing, labelling, storage and supplying of therapeutic, diagnostic and prophylactic substances from tissue;
- (f) the supply of tissue, organs, oocytes, human stem cells and other human cells, blood, blood products or gametes;
- (g) the importation and exportation of tissue, human cells, blood, blood products or gametes;
- (h) the withdrawal of blood from living persons and the preservation, testing, processing, supply or disposal of withdrawn or imported blood;
- (i) the administering of blood and any blood product to living persons;
- (j) the production, packaging, sealing, labelling and supplying of blood and blood products;
- (k) the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes;
- (l) the artificial fertilisation of persons;
- (m) the appointment and functions of inspectors of anatomy and investigating officers;
- (n) the records and registers to be kept by persons and institutions;
- (o) the returns and reports, including extracts from registers, to

- be submitted to specified persons and institutions;
 - (p) the acquisition, storage, harvesting, utilisation or manipulation of tissue, blood, blood products, organs, gametes, oocytes or human stem cells for any purpose;
 - (q) the appointment and functions of inspectors of the national blood transfusion service and progenitor cell transplant institutions; and
 - (r) any other matter relating to regulating the control and the use of human bodies, tissue, organs, gametes, blood and blood products in humans.
- (2) The Minister, with the concurrence of the Cabinet member responsible for finance, may make regulations concerning the payment of persons or institutions in connection with procurement, storage, supply, import or export of human bodies, tissue, blood, blood products or gametes.
- (3) The Minister may, if it is consistent with the objects of this Act and upon such conditions as the Minister may deem fit, by notice in the Gazette exempt any person or category of persons from any or all of the regulations made under this section.

Chapter 9

NATIONAL HEALTH RESEARCH AND INFORMATION

69 National Health Research Committee⁸⁵

- (1) The Minister must establish a committee to be known as the National Health Research Committee.
- (2) (a) The National Health Research Committee consists of not more than 15 persons, appointed by the Minister after consultation with the National Health Council.
 - (b) A person appointed in terms of paragraph (a)-
 - (i) serves for a term of not more than three years and may be reappointed for one or more terms; and
 - (ii) ceases to be a member on resignation or if requested by the Minister for good cause to resign.
 - (c) A vacancy in the National Health Research Committee must be filled by the appointment of a person for the unexpired portion of the term of office of the member in whose place the person is appointed, and in the same manner in which the member was appointed in terms of paragraph (a).
- (3) The National Health Research Committee must-
 - (a) determine the health research to be carried out by public health authorities;
 - (b) ensure that health research agendas and research resources focus on priority health problems;

⁸⁵While the National Health Research Committee has been formed, as of 9 September, 2008, no regulations had been finalised to govern its actions. Draft Regulations Relating to the National Health Research Committee were published on 23 February, 2007. Please see appendix “A” for information on where to get a copy of the draft regulations.

- (c) develop and advise the Minister on the application and implementation of an integrated national strategy for health research; and
 - (d) coordinate the research activities of public health authorities.
- (4) The Minister must prescribe the manner in which the National Health Research Committee must conduct its affairs and the procedure to be followed at meetings of the Committee, including the manner in which decisions must be taken.
- (5) A member of the National Health Research Committee who is not in the full-time employment of the State must in respect of his or her service as a member be paid such remuneration as the Minister may determine with the concurrence of the Minister of Finance.

70 Identification of health research priorities

- (1) The National Health Research Committee must identify and advise the Minister on health research priorities.
- (2) In identifying health research priorities, the National Health Research Committee must have regard to-
- (a) the burden of disease;
 - (b) the cost-effectiveness of interventions aimed at reducing the burden of disease;
 - (c) the availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities;
 - (d) the health needs of vulnerable groups such as woman, older persons, children and people with disabilities; and
 - (e) the health needs of communities.

71 Research on or experimentation with human subjects⁸⁶

- (1) Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted-
 - (a) in the prescribed manner; and
 - (b) with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.
- (2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted-
 - (a) if it is in the best interests of the minor;
 - (b) in such manner and on such conditions as may be prescribed;
 - (c) with the consent of the parent or guardian of the child; and
 - (d) if the minor is capable of understanding, with the consent of the minor.
- (3) (a) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted-
 - (i) in such manner and on such conditions as may be prescribed;

⁸⁶ As of 9 September, 2008, section 71 had not yet been proclaimed by the President. Draft Regulations Relating to Research on Human Subjects were published on 23 February 2007, but had not yet been finalised as of the date of publication. See appendix “A” for information on where to get a copy of the draft regulations.

- (ii) with the consent of the Minister;
 - (iii) with the consent of the parent or guardian of the minor; and
 - (iv) if the minor is capable of understanding, the consent of the minor.
- (b) The Minister may not give consent in circumstances where-
- (i) the objects of the research or experimentation can also be achieved if it is conducted on an adult;
 - (ii) the research or experimentation is not likely to significantly improve scientific understanding of the minor's condition, disease or disorder to such an extent that it will result in significant benefit to the minor or other minors;
 - (iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy;
 - (iv) the research or experimentation poses a significant risk to the health of the minor; or
 - (v) there is some risk to the health or wellbeing of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk.

72 National Health Research Ethics Council⁸⁷

- (1) A council to be known as the National Health Research Ethics Council is hereby established.

⁸⁷While the National Health Research Ethics Council has been formed, as of 9 September, 2008, no regulations had been finalised to govern its actions. Draft Regulations Relating to the National Health Research Ethics Council were published on 23 February, 2007. Please see appendix "A" for information on where to get a copy of the draft regulations.

- (2) The Minister must-
 - (a) after consultation with the National Health Council, appoint as members of the National Health Research Ethics Council not more than 15 persons nominated by interested parties at the invitation of the Minister by notice in the Gazette; and
 - (b) publish the list of appointees in the Gazette.
- (3) A member of the National Health Research Ethics Council is appointed for three years but may be reappointed for one or more further terms.
- (4) A member of the National Health Research Ethics Council must vacate his or her office if he or she resigns or if requested by the Minister for good cause to resign.
- (5) If a member of the National Health Research Ethics Council vacates office or dies, the Minister may fill the vacancy by appointing a person in accordance with subsection (2) for the unexpired portion of the term of office of his or her predecessor.
- (6) The National Health Research Ethics Council must-
 - (a) determine guidelines for the functioning of health research ethics committees;
 - (b) register and audit health research ethics committees;
 - (c) set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials;
 - (d) adjudicate complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he or she has been discriminated against by a health research ethics committee;
 - (e) refer to the relevant statutory health professional council

- matters involving the violation or potential violation of an ethical or professional rule by a health care provider;
- (f) institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards, or guidelines, set for the conducting of research in terms of this Act; and
 - (g) advise the national department and provincial departments on any ethical issues concerning research.
- (7) For the purposes of subsection (6)(c), 'clinical trials' means a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment.

73 Health research ethics committees

- (1) Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.
- (2) A health research ethics committee must-
 - (a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and
 - (b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.

74 Co-ordination of national health information system

- (1) The national department must facilitate and co-ordinate the establishment, implementation and maintenance by provincial departments, district health councils, municipalities and the private health sector of health information systems at national, provincial and local levels in order to create a comprehensive national health information system.
- (2) The Minister may, for the purpose of creating, maintaining or adapting databases within the national health information system contemplated in subsection (1), prescribe categories or kinds of data for submission and collection and the manner and format in which and by whom the data must be compiled or collated and must be submitted to the national department.

75 Provincial duties in relation to health information

The relevant member of the Executive Council must establish a committee for his or her province to establish, maintain, facilitate and implement the health information systems contemplated in section 74 at provincial and local level.

76 Duties of district health councils and municipalities

Every district health council and every municipality which provides a health service must establish and maintain a health information system as part of the national health information system contemplated in section 74.

Chapter 10

HEALTH OFFICERS AND COMPLIANCE PROCEDURES

77 Establishment of Inspectorate for Health Establishments⁸⁸

- (1) The relevant member of the Executive Council must establish an inspectorate in his or her province to be known as the Inspectorate for Health Establishments.
- (2) An Inspectorate for Health Establishments must-
 - (a) monitor and evaluate compliance with this Act by health establishments and health agencies in the province for which it is established; and
 - (b) submit a quarterly report on its activities and findings to the relevant member of the Executive Council.
- (3) The relevant member of the Executive Council must submit an annual report to the Minister on the activities and findings of the Inspectorate for Health Establishments established in his or her province.

78 Office of Standards Compliance⁸⁹

- (1) The Director-General must establish an Office of Standards Compliance within the national department which must include

⁸⁸ As of 9 September, 2008, section 77 had not yet been proclaimed by the President.

⁸⁹ As of 9 September, 2008, section 78 had not yet been proclaimed by the President. The DoH has recently appointed someone to head the Office of Standards Compliance under the Deputy Director-General for Health Service Delivery. Contact information for the Office is available in Appendix “C”, but until this section and section 79 are proclaimed, the Office has no legal authority to carry out inspections or issue notices of non-compliance in terms of the Act.

a person who acts as ombudsperson in respect of complaints in terms of this Act.

(2) The Office of Standards Compliance must-

- (a) keep the Minister informed of the quality of the health services provided throughout the Republic as measured against prescribed health standards;
- (b) advise the Minister on norms and standards for quality in health services;
- (c) advise the Minister on norms and standards for the certificate of need processes;
- (d) recommend to the Minister any changes which should be made to the prescribed health standards;
- (e) recommend to the Minister new systems and mechanisms to promote quality of health services;
- (f) monitor compliance with prescribed health standards by health establishments, health care providers, health workers and health agencies;
- (g) monitor compliance by a health establishment, health agency, health worker and health care provider with any condition that may have been imposed on such establishment, agency, worker or provider, as the case may be, in respect of certificates of need issued in terms of this Act;
- (h) report to the Minister any violation of a prescribed health standard where such violation poses an immediate and serious threat to public health and make recommendations to the Minister on the action to be taken in order to protect public health;
- (i) prepare an annual report to the Minister concerning its findings with regard to compliance with prescribed standards and with conditions imposed in respect of certificates of

- need;
- (j) institute monitoring activities and processes for quality assurance in health establishments;
- (k) provide advice to the national department and to provincial departments on quality of care provided by health establishments, health agencies, health workers and health care providers;
- (l) inspect a health establishment or health agency in order to determine levels of compliance with prescribed health standards and conditions imposed by certificates of need; and
- (m) instruct a health officer or person designated by the National Commissioner of the South African Police Service in terms of section 80 (3) to inspect health establishments and health agencies in order to-
 - (i) investigate any complaint, allegation or suspicion relating to the observation of prescribed health standards; and
 - (ii) report to the Director-General on the findings of any investigation contemplated in subparagraph (i).

79 Inspections by Office of Standards Compliance⁹⁰

- (1) The Office of Standards Compliance or its agents must inspect every health establishment and health agency at least once every three years to ensure compliance with this Act, and may conduct announced or unannounced inspections of a health establishment and a health agency at any time.

⁹⁰ As of 9 September, 2008, section 79 had not yet been proclaimed by the President.

- (2) (a) The Office of Standards Compliance may order the total or partial closure of a health establishment or a health agency if a certificate of need was not issued in respect of that health establishment or health agency prior to any activities contemplated in section 36 being undertaken.
- (b) An order issued in terms of paragraph (a) must be in writing and issued to the head of the health establishment or health agency in question.
- (3) If the Office for Standards Compliance orders the total or partial closure of a health establishment, the Minister must ensure, within a reasonable period from the date of such closure, that reasonable alternative and accessible health services are available to any community affected by the closure.
- (4) The Office of Standards Compliance must issue a written notice of non-compliance to the head of a health establishment if the Office of Standards Compliance 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 or health worker associated with the health establishment is engaged in certain prescribed business or health service practices upon the basis of perverse incentives.
- (5) A notice of non-compliance must be issued to the person determined to be responsible for any condition contemplated in subsection (3) (a) or (b) stating the nature and extent of the non-compliance and directing the appropriate corrective action

to be taken within a specified period in respect of the prescribed business or health service practice or to minimise or rectify the non-compliance.

- (6) A notice of non-compliance contemplated in subsection (3) remains in force until the relevant provision of the Act has been complied with and the Office of Standards Compliance has issued a compliance certificate in respect of that notice.
- (7) The Office of Standards Compliance, in the event of failure to comply with the requirements of a notice of non-compliance, may-
 - (a) temporarily suspend the operation of, or shut down, the whole or a part of the health establishment or health agency, pending compliance with the notice of non-compliance;
 - (b) recommend to the Director-General that the certificate of need of the health establishment or health agency be withdrawn; or
 - (c) recommend to the Director-General that an application for the renewal of a certificate of need in respect of the health establishment or health agency be refused.

80 Appointment of health officers

- (1) Subject to any other law-
 - (a) the Minister may appoint any person in the employ of the national department as a health officer of the national department;
 - (b) the relevant member of the Executive Council may appoint any person in the employ of the provincial department in question, as a health officer for the province in question; and

- (c) the mayor of a metropolitan or district council may appoint any person in the employ of the council in question as a health officer for the municipality in question.
- (2) An appointment under subsection (1) may be general or for a specific purpose.
- (3) The relevant member of the Executive Council may request the National Commissioner of the South African Police Service to designate a member of the Service as a health officer for the province in question.
- (4) The Minister or the relevant member of the Executive Council, as the case may be, must issue to every health officer a document in the prescribed form certifying that he or she has been appointed or designated as a health officer for the national department or provincial department in question.

81 Duty of health officers

A health officer must monitor and enforce compliance with this Act.

82 Routine inspections

- (1) A health officer may enter any premises, excluding a private dwelling, at any reasonable time and-
 - (a) inspect such premises in order to ensure compliance with this Act;
 - (b) question any person who he or she believes may have information relevant to the inspection;
 - (c) require the person in charge of such premises to produce, for inspection or for the purpose of obtaining copies or extracts thereof or therefrom, any document that such person

- is required to maintain in terms of any law; and
- (d) take samples of any substance that is relevant to the inspection.
- (2) A health officer may be accompanied by an interpreter and any other person reasonably required to assist him or her in conducting the inspection.
 - (3) A health officer may issue a compliance notice to the person in charge of the premises if a provision of this Act has not been complied with.
 - (4) A compliance notice remains in force until the relevant provision of the Act has been complied with and the health officer has issued a compliance certificate in respect of that notice.
 - (5) A health officer who removes any item other than that contemplated in subsection (1) (d) must-
 - (a) issue a receipt for it to the person in charge of the premises; and
 - (b) subject to the Criminal Procedure Act, 1977 (Act 51 of 1977), return it as soon as practicable after achieving the purpose for which it was removed.

83 Environmental health investigations⁹¹

- (1) (a) If a health officer has reasonable grounds to believe that any condition exists which-
 - (i) constitutes a violation of the right contained in section 24(a) of the Constitution;⁹²
 - (ii) constitutes pollution detrimental to health;

⁹¹ As of 9 September, 2008, section 83 had not yet been proclaimed by the President.

⁹² Section 24(a) of the Constitution says that everyone has the right to an environment that is not harmful to their health or well-being.

- (iii) is likely to cause a health nuisance; or
 - (iv) constitutes a health nuisance,
- the health officer must investigate such condition.
- (2) If the investigation reveals that a condition contemplated in subsection (1) exists, the health officer must endeavour to determine the identity of the person responsible for such condition.
- (3) The health officer must issue a compliance notice to the person determined to be responsible for any condition contemplated in subsection (1) to take appropriate corrective action in order to minimise, remove or rectify such condition.
- (4) Any person aggrieved by a determination or instruction in terms of subsection (2) or (3) may, within a period of 14 days from the date on which he or she became aware of the determination or instruction, lodge an appeal with the head of the relevant provincial department.

84 Entry and search of premises with warrant

- (1) A health officer accompanied by a police official may, on the authority of a warrant issued in terms of subsection (5) and subject to section 85, enter any premises specified in the warrant, including a private dwelling, and-
 - (a) inspect, photograph, copy, test and examine any document, record, object or material, or cause it to be inspected, photographed, copied, tested and examined;
 - (b) seize any document, record, object or material if he or she has reason to suspect that it might be used as evidence in a criminal trial; and
 - (c) examine any activity, operation or process carried out on the premises.

- (2) A health officer who removes anything from the premises being searched must-
 - (a) issue a receipt for it to the owner or person in control of the premises; and
 - (b) unless it is an item prohibited in terms of this Act, return it as soon as practicable after achieving the purpose for which it was removed.
- (3) Upon the request of a health officer acting in terms of a warrant issued in terms of subsection (5), the occupant and any other person present on the premises must-
 - (a) make available or accessible or deliver to the health officer any document, record, object or material which pertains to an investigation contemplated in subsection (1) and which is in the possession or under the control of the occupant or other person;
 - (b) furnish such information as he or she has with regard to the matter under investigation; and
 - (c) render such reasonable assistance as the health officer may require to perform his or her functions in terms of this Act efficiently.
- (4) Before questioning any person at the premises in question, the health officer or police official must advise that person of his or her right to be assisted at the time by an advocate or attorney, and allow that person to exercise that right.
- (5) A warrant contemplated in subsection (1) may be issued by a judge or a magistrate-
 - (a) in relation to premises on or from which there is reason to believe that a contravention of this Act has been or is being committed; and

- (b) if it appears from information on oath or affirmation that there are reasonable grounds to believe that there is evidence available in or upon such premises of a contravention of this Act.
- (6) The warrant may impose restrictions on the powers of the health officer.
- (7) A warrant issued in terms of this section-
 - (a) remains in force until-
 - (i) it is executed;
 - (ii) it is cancelled by the person who issued it or, if such person is not available, by any person with like authority;
 - (iii) the expiry of one month from the day of its issue; or
 - (iv) the purpose for the issuing of the warrant has lapsed, whichever occurs first; and
 - (b) must be executed by day unless the person who issues the warrant authorises the execution thereof by night.
- (8) No person is entitled to compensation for any loss or damage arising out of any bona fide action by a police official or health officer under this section.

85 Identification prior to entry, and resistance against entry

- (1) A health officer who has obtained a warrant in terms of section 84 (5) or the police official accompanying him or her must immediately before entering the premises in question-
 - (a) audibly announce that he or she is authorised to enter the premises and demand admission to the premises; and

- (b) notify the person in control of the premises of the purpose of the entry,

unless there are reasonable grounds to believe that such announcement or notification might defeat the purpose of the search.

- (2) The health officer must-

- (a) hand to the person in control of the premises a copy of the warrant or, if such person is not present, affix such a copy to a prominent place on the premises; and

- (b) on request of the person in charge of such premises, show his or her certificate of appointment as health officer to that person.

- (3) A health officer or police official contemplated in subsection (1) may overcome resistance to the entry and search by using such force as is reasonably required, including the breaking of a door or window of the premises.
- (4) Before using force, the health officer or police official must audibly demand admission and must announce the purpose of the entry, unless there are reasonable grounds to believe that doing so might defeat the purpose of the search.

86 Entry and search of premises without warrant

A health officer accompanied by a police official may without a warrant exercise any power referred to in section 84 (1) if-

- (a) the person who is competent to do so consents to such exercise; or
- (b) there are reasonable grounds to believe that a warrant would be issued in terms of section 84 (5) and that the delay in obtaining

the warrant would defeat the object of the warrant.

87 Disposal of items seized by health officer

- (1) The health officer must deliver anything seized in terms of section 84 or 86 without delay to a police official contemplated in section 30 of the Criminal Procedure Act, 1977 (Act 51 of 1977),⁹³ who must deal with and dispose of the seized item in the manner provided for in Chapter 2 of that Act.
- (2) When a police official acts in terms of section 30 (a) or (b) of the Criminal Procedure Act, 1977 (Act 51 of 1977), in respect of an item contemplated in subsection (1), he or she must do so after consultation with the health officer.

88 Miscellaneous provisions relating to health officers, inspectors and compliance procedures

For the purposes of this Act, the heads of national and provincial departments, and the head of a health department of a municipality must be regarded as being-

- (a) the owner and occupier of any premises that the national or provincial department or the municipality occupies or uses; and
- (b) the employer of persons in the service of that national or provincial department or municipality if, as an employer, the national or provincial department or municipality-

⁹³Section 30 of the Criminal Procedure Act governs how property seized from an alleged offender is disposed. A police official can dispose of the property if the situation warrants, return stolen property to the original owner with permission of the alleged offender, or can have it marked and placed into police storage for later use as evidence.

- (i) performs any duty imposed upon an employer by or under this Act; or
- (ii) exercises any power conferred upon an employer by or under this Act.

89 Offences

- (1) A person is guilty of an offence if he or she-
 - (a) obstructs or hinders a health officer who is performing a function under this Act;
 - (b) refuses to provide a health officer with such information as that person is required to provide under this Act;
 - (c) knowingly gives false or misleading information to a health officer;
 - (d) unlawfully prevents the owner of any premises, or a person working for the owner, from entering the premises in order to comply with a requirement of this Act;
 - (e) impersonates a health officer;
 - (f) fails to comply with a compliance notice issued to him or her by a health officer in terms of this Act; or
 - (g) discloses any information, which was acquired in the performance of any function in terms of this Act and which relates to the financial or business affairs of any person, to any other person, except if-
 - (i) the other person requires that information in order to perform any function in terms of this Act;
 - (ii) the disclosure is ordered by a court of law; or
 - (iii) the disclosure is in compliance with the provisions of any law.
- (2) Any person convicted of an offence in terms of subsection (1) is

liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

Chapter 11

REGULATIONS

90 Regulations⁹⁴

- (1) The Minister, after consultation with the National Health Council, may make regulations regarding-
 - (a) anything which may or must be prescribed in terms of this Act;
 - (b) the fees to be paid to public health establishments for health services rendered;
 - (c) the norms and standards for specified types of protective clothing and the use, cleaning and disposal of such clothing;
 - (d) the development of an essential drugs list and medical and other assistive devices list;
 - (e) human resource development;
 - (f) co-operation and interaction between private health care providers and private health establishments on the one hand and public health care providers and public health establishments on the other;
 - (g) returns, registers, reports, records, documents and forms to be completed and kept by the national department, provincial departments, district health councils, health care providers, private health establishments and public health establishments;

⁹⁴For a list of all regulations and draft regulations that had been published as of 9 September, 2008, see appendix "A".

- (h) the functions of persons who render voluntary, charitable or similar services in connection with a public health establishment;
- (i) the rendering of forensic pathology, forensic medicine and related laboratory services, including the provision of medico-legal mortuaries and medico-legal services;⁹⁵
- (j) communicable diseases;
- (k) notifiable medical conditions;
- (l) rehabilitation;
- (m) emergency medical services and emergency medical treatment, both within and outside of health establishments;
- (n) health nuisances and medical waste;
- (o) the import and export of pathogenic micro-organisms;
- (p) health laboratory services, including-
 - (i) the classification, accreditation and licensing of health laboratories; and
 - (ii) setting, monitoring and enforcing quality control standards applicable to health laboratories;
- (q) non-communicable diseases;
- (r) health technology;
- (s) health research;
- (t) the national health information system contemplated in section 74;
- (u) the processes and procedures to be implemented by the Director-General in order to obtain prescribed information from stakeholders relating to health financing, the pricing of health services, business practices within or involving health establishments, health agencies, health workers and

⁹⁵ See Appendix "A": Regulations Regarding the Rendering of Forensic Pathology Service (Gazette 30075, RG 8718, Notice 636), 20 July 2007.

health care providers, and the formats and extent of publication of various types of information in the public interest and for the purpose of improving access to and the effective and efficient utilisation of health services;⁹⁶

- (v) the processes of determination and publication by the Director-General of one or more reference price lists for services rendered, procedures performed and consumable and disposable items utilised by categories of health establishments, health care providers or health workers in the private health sector which may be used-
 - (i) by a medical scheme as a reference to determine its own benefits; and
 - (ii) by health establishments, health care providers or health workers in the private health sector as a reference to determine their own fees,but which are not mandatory; and
- (w) generally, any other matter which it is necessary or expedient to prescribe in order to implement or administer this Act.

- (2) The Minister, subject to the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), and after consultation with the National Health Research Ethics Council, may make regulations regarding research on human subjects.⁹⁷
- (3) The Minister may, in any regulation made under this Act-

⁹⁶See Appendix "A": Obtainment of Information and the Processes of Determination and Publication of Reference Price List Regulations (Gazette 30110, GN 8722, Notice 681), 23 July 2007.

⁹⁷See Appendix "A". As of 9 September, 2008, no final regulations had been published by the Minister. Draft Regulations Relating to Research on Human Subjects were released for public comment on 23 April 2007.

- (a) designate as authoritative any methodology, procedure, practice or standard that is recognised as authoritative by internationally recognised health bodies within the relevant profession; and
 - (b) require any person or body to comply with the designated methodology, procedure, practice or standard.
- (4) (a) The Minister must publish all regulations proposed to be made under this Act in the Gazette for comment at least three months before the date contemplated for their commencement.
- (b) If the Minister alters the draft regulations, as a result of any comment, he or she need not publish those alterations before making the regulations.
- (c) The Minister may, if circumstances necessitate the immediate publication of a regulation, publish that regulation without the consultation contemplated in paragraph (a).

Chapter 12

GENERAL PROVISIONS

91 Minister may appoint committees

- (1) The Minister may, after consultation with the National Health Council, establish such number of advisory and technical committees as may be necessary to achieve the objects of this Act.
- (2) When establishing an advisory or technical committee, the Minister may determine by notice in the Gazette-
 - (a) its composition, functions and working procedure;

- (b) in consultation with the Minister of Finance, the terms, conditions, remuneration and allowances applicable to its members; and
- (c) any incidental matters relating to that advisory or technical committee.

92 Assignment of duties and delegation of powers

Subject to the Public Finance Management Act (Act 1 of 1999)-

- (a) the Minister may assign any duty and delegate any power imposed or conferred upon him or her by this Act, except the power to make regulations, to-
 - (1) any person in the employ of the State; or
 - (2) any council, board or committee established in terms of this Act;
- (b) the relevant member of the Executive Council may assign any duty and delegate any power imposed or conferred upon him or her by this Act, except the power to make regulations, or assigned or delegated to him or her by the Minister, to any officer in the relevant provincial department or any council, board or committee established in terms of this Act;
- (c) the Director-General may assign any duty and delegate any power imposed or conferred upon him or her by this Act to any official in the national department; and
- (d) the head of a provincial department may assign any duty and delegate any power imposed or conferred upon him or her in terms of this Act to any official of that provincial department.

93 Repeal of laws, and savings

- (1) Subject to this section, the laws mentioned in the second column of the Schedule are hereby repealed to the extent set out in the third column of the Schedule.
- (2) Anything done before the commencement of this Act under a provision of a law repealed by subsection (1) and which could have been done under a provision of this Act must be regarded as having been done under the corresponding provision of this Act.
- (3) The Minister may prescribe such further transitional arrangements as may be necessary to effect a smooth transition between the laws referred to in the Schedule and this Act.

94 Short title and commencement

This Act is called the National Health Act, 2003, and takes effect on a date fixed by the President by proclamation in the Gazette.

SCHEDULE: LAWS REPEALED⁹⁸**(Section 93)**

Number and Year of Act	Short Title	Extent of Repeal
Act 63 of 1977	Health Act, 1977	The whole
Act 18 of 1979	Health Amendment Act, 1979	The whole
Act 33 of 1981	Health Amendment Act, 1981	The whole
Act 37 of 1982	Health Amendment Act, 1982	The whole
Act 21 of 1983	Health Amendment Act, 1983	The whole
Act 65 of 1983	Human Tissue Act, 1983	The whole
Act 2 of 1984	Health Amendment Act, 1984	The whole
Act 106 of 1984	Human Tissue Amendment Act, 1984	The whole
Act 70 of 1985	Health Amendment Act, 1985	The whole
Act 51 of 1989	Human Tissue Amendment Act, 1989	The whole
Act 116 of 1990	National Policy for Health Act, 1990	The whole
Act 86 of 1993	Academic Health Centres Act, 1993	The whole
Act 118 of 1993	Health and Welfare Matters Amendment Act, 1993	Sections 1, 2, 4, 5, 6, 7, 8, 9 and 10

⁹⁸Despite the repeal of these acts or sections, the savings clause in section 93 does allow any conduct done before the commencement of the NHA, which could have been done under a corresponding provision of the NHA, to be considered as having been done under the NHA. Thus, certain regulations under these acts, despite their repeal, may remain in effect if the NHA allows for similar regulations to be created.

Appendix “A”

Regulations published under the National Health Act

Finalised Regulations

- 20 July 2007 – Regulations Regarding the Rendering of Forensic Pathology Service (*Gazette 30075, RG 8718, Notice 636*)
<http://www.info.gov.za/view/DownloadFileAction?id=72280>
- 23 July 2007 – Obtainment of Information and the Processes of Determination and Publication of Reference Price List Regulations (*Gazette 30110, GN 8722, Notice 681*)
<http://www.info.gov.za/view/DownloadFileAction?id=72288>

Published Draft Regulations

- 5 January 2007 – Regulations Regarding the Use of Human DNA, RNA, Cultured Cells, Stem Cells, Blastomeres, Polar Bodies, Embryos, Embryonic Tissue and Small Tissue Biopsies for Diagnostic Testing, Health Research and Therapeutics (*Gazette 29526*)
<http://www.info.gov.za/view/DownloadFileAction?id=72123>
- 5 January 2007 – Regulations Regarding Artificial Fertilisation and Related Matters (*Gazette 29527*)
<http://www.info.gov.za/view/DownloadFileAction?id=72124>
- 23 February 2007 – Regulations Relating to the National Health Research Ethics Council (*Gazette 29637*)

- <http://www.info.gov.za/view/DownloadFileAction?id=72154>
- 23 February 2007 – Regulation Relating to Research on Human Subjects (*Gazette 29637*)
<http://www.info.gov.za/view/DownloadFileAction?id=72155>
 - 23 February 2007 – Regulations Relating to the National Health Research Committee (*Gazette 29637*)
<http://www.info.gov.za/view/DownloadFileAction?id=72156>
 - 4 May 2007 – Regulation Relating to Human Stem Cells (*Gazette 29840*)
<http://www.info.gov.za/view/DownloadFileAction?id=72211>
 - 25 January 2008 – Regulations Regarding Communicable Diseases (*Gazette 30681*)
<http://www.info.gov.za/view/DownloadFileAction?id=77000>
 - 4 February 2008 – Regulations Relating to the Obtainment of Information and the Process of Determination and Publication of Reference Price Lists (*Gazette 30727*)
<http://www.info.gov.za/view/DownloadFileAction?id=78099>
 - 7 March 2008 – Regulations Regarding the General Control of Human Bodies, Tissue and Organs for Transplantation (*Gazette 30828*)
<http://www.info.gov.za/view/DownloadFileAction?id=78099>

Appendix “B”

Other Important Health Legislation and Policy Documents

Legislation

Choice of Termination of Pregnancy Act 92 of 1996

The Choice of Termination of Pregnancy Act sets the conditions and procedures to be followed for a woman to obtain a termination of pregnancy. In terms of section 2 the Act, a pregnancy may be terminated:

- (a) upon the request of a woman during the first 12 weeks of ... her pregnancy;
- (b) from the 13th up to and including the 20th week [of pregnancy] if a medical practitioner, after consultation with the pregnant woman, is of the opinion that -
 - (i) the continued pregnancy would pose a risk of injury to the woman's physical or mental health; or
 - (ii) there exists a substantial risk that the fetus would suffer from a severe physical or mental abnormality; or
 - (iii) the pregnancy is the result of rape or incest; or
 - (iv) the continued pregnancy would significantly affect the social or economic circumstances of the woman;
- (c) after the 20th week [of pregnancy] if a medical practitioner, after consultation with another medical practitioner or a registered midwife, is of the opinion that the continued pregnancy

-

- (i) would endanger the woman’s life;
- (ii) would result in a severe malformation of the fetus; or
- (iii) would pose a risk of injury to the fetus.

For information on access to and consent for a termination of pregnancy, see footnotes 18 and 22.

Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972⁹⁹

The Foodstuffs, Cosmetics and Disinfectants Act (Foodstuffs Act) governs the advertising, labelling, safety standards and selling of foodstuffs and other products which have the potential to negatively impact the health of people consuming them. It provides the Minister of Health the authority to prescribe for such things as testing of foodstuffs to ensure there are no dangerous toxins or to require warning labels to be included on disinfectants which may be dangerous if used incorrectly.

It is important to note that the Foodstuffs Act and the Medicines Act do not cover the same products, even if a particular item could

⁹⁹The ALP and TAC have made two submissions on draft regulations issued under the Foodstuffs Act. Draft Regulations Relating to Foodstuffs for Infants, Young Children and Children were published for comment on 26 October 2007. As of 9 September, 2008, the draft regulations had not yet been finalised. The draft regulations are available at: <http://www.info.gov.za/gazette/regulation/2007/30402.pdf> and the submission made by the ALP and TAC focusing on issues surrounding advertising and promotion of breastfeeding for infants in the context of South Africa’s high HIV prevalence is available at: <http://www.alp.org.za/pdf/Departments/RegulationsRelatingtoFoodstuffsforInfantsandYoungChildren-2003-ALP.pdf>

Draft Regulations Relating to the Labelling and Advertising of Foodstuffs were published for comment on 20 July 2007. As of 9 September, 2008, the draft regulations had not yet been finalised. The draft regulations are available at: <http://www.info.gov.za/gazette/regulation/2007/30075t.pdf> and the submission made by the ALP and TAC is available at: <http://www.alp.org.za/pdf/Departments/RegulationsRelatingtotheLabellingandAdvertisingofFoodstuffs-2007-TACALP.pdf>

be sold under both. This is because anything which falls within the definition of a medicine in the Medicines Act is exclusively governed by the Medicines Act. For instance, while a multivitamin can be sold as a nutritional supplement under the Foodstuffs Act, if the same multivitamin is advertised as preventing heart disease, it must meet all the requirements of the Medicines Act, even if it still claims to only be a nutritional supplement.¹⁰⁰

Health Professions Act 56 of 1974

The Health Professions Act regulates the registration and practice of most health professionals in the country, with the exception of nurses and traditional health practitioners. The Health Professions Act establishes the Health Professions Council of South Africa which oversees the conduct of different professional boards. The professional boards each represent and regulate a different field of health practitioners. The professional boards are responsible for receiving complaints and investigating those practicing in their field. Practicing in any of these fields without a license is a criminal offence under the Act. The professional boards which have been established in terms of the Act are:

- Medical and Dental Professional Board
- Professional Board for Dental Therapy and Oral Hygiene
- Professional Board for Emergency Care Practitioners
- Professional Board for Environmental Health Practitioners
- Professional Board for Medical Technology
- Professional board for Occupational Therapy and Medical Orthotics / Prosthetics
- Professional board for Optometry and Dispensing Opticians

¹⁰⁰For more on the definition of a medicine, see footnote 103 below

- Professional board for Physiotherapy, Podiatry and Biokinetics
- Professional board for Psychology
- Professional board for Radiography and Clinical Technology
- Professional board for Speech, Language and Hearing Professions

Medical Schemes Act 131 of 1998¹⁰¹

The Medical Schemes Act governs the terms of regulation and registration of medical schemes in the country. All medical schemes must be registered with the Council for Medical Schemes in terms of this Act prior to being sold to the public. As part of the requirements for registration, all medical schemes cover the costs of certain minimum standards of care to be provided called Prescribed Minimum Benefits (PMBs). The PMBs are set out in the Regulations under Medical Schemes Act.

¹⁰¹A Draft Medical Schemes Amendment Bill was published on 2 June, 2008 along with amendment bills for the Medicines and Related Substances Act and the National Health Act. The draft bill is available at: <http://www.info.gov.za/view/DownloadFileAction?id=83813>

Medicines and Related Substances Act 101 of 1965¹⁰²

The Medicines and Related Substances Act (Medicines Act) creates the regulatory structure which oversees all registration of medicines in the country. This is done primarily through the Medicines Control Council (MCC). Under the Medicines Act, anything which falls within the definition of a medicine¹⁰³ may not be sold or advertised in South Africa unless it has been proven to be safe for use in humans, effective at treating a stated condition and the manufacturer is able to consistently deliver a good quality product.

Criminal penalties may be enforced against anyone who sells or advertises a medicine in contravention of the Act. Unfortunately, the government has been reluctant to prosecute for violations of the Act. Recently, the Treatment Action Campaign (TAC) and the South African Medical Association (SAMA) won a judgment in the Western Cape in *Treatment Action Campaign and Another v*

¹⁰²The DoH released a Medicines and Related Substances Amendment Bill for comment on 18 April, 2008. Initially, the ALP and TAC made a submission to the department recommending the entire amendment bill be withdrawn as it further undermined scientific integrity in the registration of medicines. However, after Parliamentary hearings on the Bill in August, 2008, the ALP and TAC made a further submission for the reformulation of contentious aspects of the Bill. It is not clear which, if any, of these submissions were accepted. The draft bill is available at: <http://www.info.gov.za/view/DownloadFileAction?id=83233>, the ALP and TAC's initial submission on the bill is available at: <http://www.alp.org.za/Submissions/Department/MaRSABSubmission.pdf> and the ALP and TAC's submission proposing reformulations is available at: <http://www.alp.org.za/Submissions/Parliament/MaRSABProposedAmendments.pdf>

¹⁰³“Medicine,” in terms of the Act, means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in -

- (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or
- (b) restoring, correcting or modifying any somatic or psychic or organic function in man,

and includes any veterinary medicine.

Rath and Others (12156/05) [20080 ZAWCHC 34 (13 June 2008)] which held that the products being distributed by Mathias Rath as treatments for HIV were being unlawfully distributed. Additionally, the TAC and SAMA filed suit against the Minister of Health and the Director-General of the DoH to compel them to ensure the enforcement of the Medicines Act against those distributing products in contravention to the Act. The court clearly held that the Minister of Health and the Director-General are under a duty to take reasonable measures to prevent unauthorised clinical trials and the distribution of such unauthorised products.¹⁰⁴

In late 2008, Parliament was considering amendments to this Act, including the replacing of the MCC with the South African Health Products Regulatory Authority. It is probable that this Amendment will come into force in 2009.

Nursing Act 33 of 2005¹⁰⁵

The Nursing Act, like the Health Professions Act, regulates the registration and practice of nursing in the country. All practicing nurses must be registered with the South African Nursing Council.¹⁰⁶ Practicing without a license is a criminal offence under the Act.

¹⁰⁴For more information on *Treatment Action Campaign and Another v Rath and Others* see: <http://www.tac.org.za/community/rath>

¹⁰⁵The Nursing Act 33 of 2005 repealed and replaced the Nursing Act 50 of 1978 seen referenced in the NHA.

¹⁰⁶The Regulations relating to the Nomination and Appointment of the Members of Council were published on 16 January 2008. The ALP made a submission on these regulations when they were in draft form and believes these regulations as finalised are unconstitutional because they effectively deprive members of the community their statutory right to nominate members to the council. The ALP's submission on the draft regulations, which set out these concerns, is available at: <http://www.alp.org.za/pdf/Departments/NursingCouncilRegulations-2007-ALP.pdf>

Pharmacy Act 53 of 1974

The Pharmacy Act regulates the registration, training, and practice of pharmacists in South Africa. All practicing pharmacists, including pharmacy students, interns, technicians and assistants must be registered in terms of the Act in order to practice in South Africa. The Act also provides for the South African Pharmacy Council which, much like the South African Nursing Council and the professional boards established in the Health Professions Act, has a responsibility to register, investigate complaints regarding pharmacists, and, if necessary, take appropriate actions against a pharmacist if there has been a violation of the Act. Practicing as a pharmacist without a licence is a criminal offence under the Act.

Traditional Health Practitioners Act 22 of 2007

The Traditional Health Practitioners Act creates a regulatory framework similar to the Health Professions Act. The Act is meant to ensure the efficacy, safety and quality of traditional health care services. In terms of the Act, no person is permitted to practice as a traditional healer unless he or she has been registered with the Interim Traditional Health Practitioner’s Council. To do so, even as a student is criminally punishable. The Council has the authority and responsibility to register and investigate the practice of traditional healers and to receive and investigate complaints of misconduct by a traditional healer.¹⁰⁷

¹⁰⁷Regulations Relating to the Appointment by the Minister as Members of the Interim Traditional Health Practitioners Council of South Africa were published on 16 May, 2008. A copy of these regulations is available at: <http://www.info.gov.za/view/DownloadFileAction?id=81737> and includes the form by which nominations for membership may be submitted. The council has yet to be appointed.

Policy Documents and Guidelines

The Department of Health has developed policies and guidelines covering many aspects of health care and disease management. These can be found at: <http://www.doh.gov.za/docs/> Below, are links to some of the most important policies.

Draft Policy on African Traditional Medicine in South Africa, 2008

<http://www.doh.gov.za/docs/policy/atm.pdf>

Guidelines for the Management of HIV-infected Children, 2005

<http://www.doh.gov.za/docs/factsheets/guidelines/hiv/index.html>

HIV & AIDS and STI National Strategic Plan 2007-2011

<http://www.doh.gov.za/docs/misc/stratplan/2007-2011/index.html>

National Antiretroviral Treatment Guidelines, 2004

<http://www.doh.gov.za/docs/factsheets/guidelines/artguidelines04/index.html>

National Drugs Policy for South Africa, 1996

<http://www.doh.gov.za/docs/policy/drugsjan1996.pdf>

The National Infection Prevention and Control Policy & Strategy, 2007

<http://www.doh.gov.za/docs/policy/ipc/ipc-policy.pdf>

The National Infection Prevention and Control Policy for TB, MDRTB & XDRTB, 2007

<http://www.doh.gov.za/docs/policy/tb/index.html>

A National Human Resources Plan for Health, 2006

<http://www.doh.gov.za/docs/factsheets/guidelines/hrplan/index.html>

Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment in South Africa, 2003

<http://www.info.gov.za/otherdocs/2003/aidsplan/index.html>

Policy and Guidelines for the Implementation of the PMTCT Programme, 2008

<http://www.doh.gov.za/docs/policy/pmtct.pdf>

Tuberculosis Strategic Plan for South Africa, 2007-2011

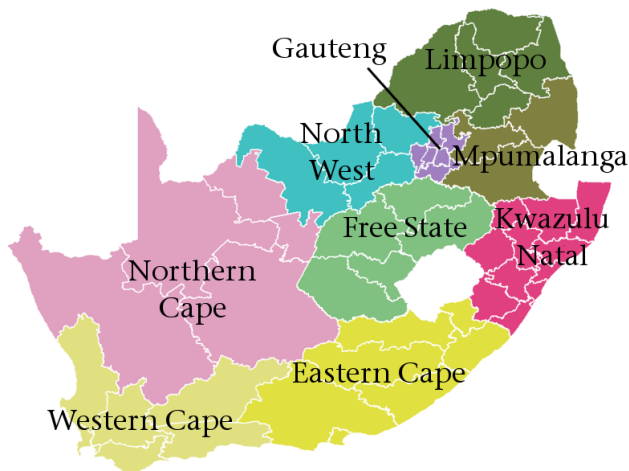
<http://www.doh.gov.za/tb/docs/stratplan/2007-2011/tb/index.html>

**White Paper for the Transformation of the Health System
in South Africa, 1997**

[http://www.doh.gov.za/docs/policy/white_paper/
healthsys97_01.html](http://www.doh.gov.za/docs/policy/white_paper/healthsys97_01.html)

Appendix “C”
*Contact information for important
regulatory councils, oversight
bodies, and other health
organisations*¹⁰⁸

NATIONAL STRUCTURES



¹⁰⁸The ALP has attempted to establish contact details for all health districts, oversight bodies, and provincial health councils. However, much of this information is hard to locate and we cannot vouch for its ongoing accuracy.

Ministry of Health

Mail: Private Bag X399, Pretoria, 0001

Mail: Private Bag X9070, Cape Town, 8000

Tel: (012) 312 0546 / (021) 466 7260

Fax: (012) 325 5526 / (021) 465 1575

National Department of Health

Mail: Private Bag X828, Pretoria, 0001

Tel: (012) 312 0000

Fax: (012) 326 4395

Website: www.doh.gov.za

National Health Research Ethics Council

Current Members:

Prof D. du Toit (Chairperson),

Prof. A. Dhai (Deputy Chairperson),

Ms C. Slack, Mr N Ramuthaga, Dr M. Groenewald, Ms D. Biyela,
Dr D. Pearmain, Dr L. Makubalo, Dr N. Khaole, Dr N. Khomo,
Prof L. Mazwai, Ms M. Haskins, Prof. L. London, & Ms E.
Levendal

Secretariat of the NHREC:

Ms P. Netshidzivhani

Tel: (012) 312 0995

Fax: (012) 312 0784

E-mail: nhrec@health.gov.za

Website: www.doh.gov.za/nhrec/

Office of Standards Compliance¹⁰⁹

Mail: Private Bag X828, Pretoria, 0001

Tel: (012) 312 0947 / 0492

Council for Medical Schemes

Mail: Private Bag X34, Hatfield, 0028

Tel: (012) 431 0500

Fax: (012) 430 7644

Website: www.medicalschemes.com

South African National AIDS Council (SANAC)

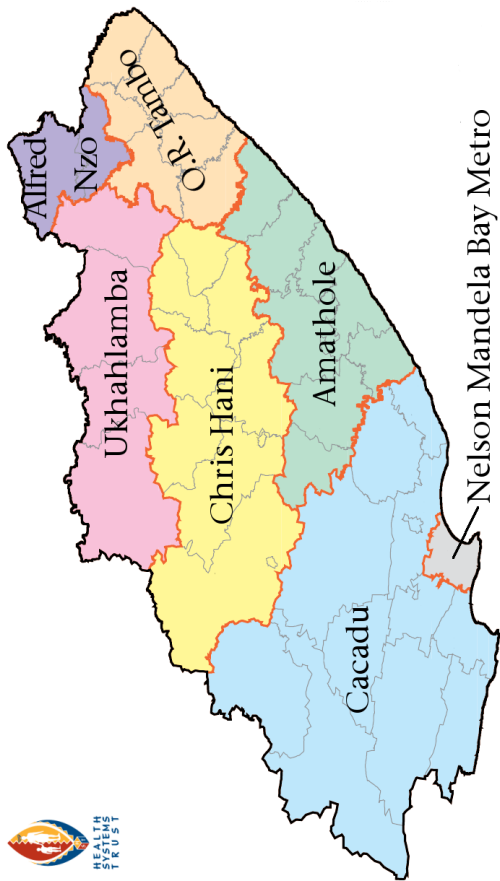
Tel (012) 312-0131

Fax (012) 312-0644

Website: <http://www.sanac.org.za>

¹⁰⁹ See sections 78 and 79 and the corresponding footnotes for more on the Office of Standards Compliance.

EASTERN CAPE



Eastern Cape Department of Health

Mail: Private Bag X0038, Bisho, 5605

Tel: (040) 609 3998

Fax: (040) 609 3892

Alfred Nzo Health District

Tel: (039) 727 4462

Fax: (039) 727 1044

Amathole Health District

Tel: (043) 707 6700

Fax: (043) 707 6520

Cacadu Health District

Tel: (041) 408 8152

Fax: (041) 408 8176

Chris Hani Health District

Tel: (045) 807 1100

Fax: (045) 807 1154

Nelson Mandela Bay Metro Health District

Tel: (041) 391 8000

Fax: (041) 374 5766

O.R. Tambo Health District

Tel: (047) 531 0797

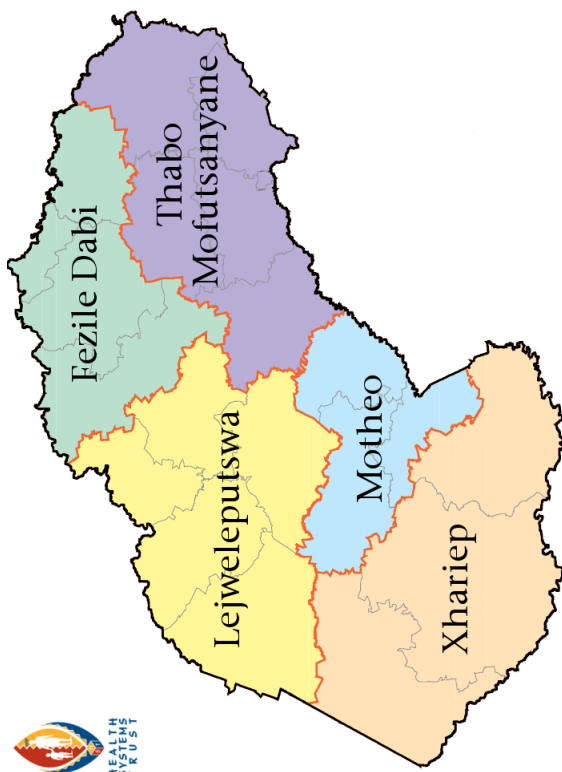
Fax: (047) 532 3995

Ukhahlamba Health District

Tel: (051) 634 1899

Fax: (051) 634 2062

FREE STATE



Free State Department of Health

Mail: PO Box 227, Bloemfotein, 9300

Tel: (051) 408 1106

Fax: (051) 408 1566

Fezile Dabi Health District

Tel: (016) 970 9371

Fax: (016) 970 9333

Lejweleputswa Health District

Tel: (057) 325 1452

Fax: (057) 352 9277

Motheo Health District

Tel: (051) 447 2195

Fax: (051) 447 6477

Thabo Mofutsanayne Health District

Tel: (058) 713 2154

Fax: (058) 713 2154

Xhariep Health District

Tel: (051) 447 2777

Fax: (051) 447 1036

GAUTENG



Gauteng Department of Health

Mail: Private Bag X085, Marshalltown, 2107

Tel: (011) 355 3870 / 3235

Fax: (011) 355 3259

Ekurhuleni Health District

Tel: (011) 876 1700

Fax: (011) 876 1818

Johannesburg Metro Health District

Tel: (011) 407 7513

Fax: (011) 339 2866

Metsweding Health District

Tel: (013) 933 3486

Fax: (013) 933 3487

Sedibeng Health District

Tel: (016) 950 6000

Fax: (016) 950 6016

Tshwane Health District

Tel: (012) 303 9012

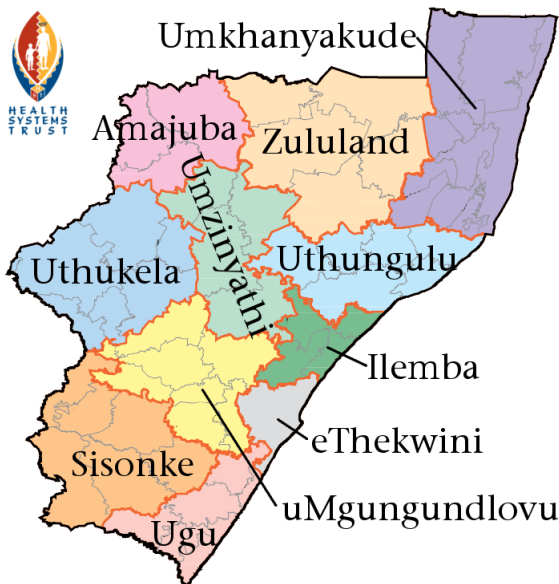
Fax: (012) 323 2259

West Rand Health District

Tel: (011) 953 2152

Fax: (011) 953 4519

KWAZULU-NATAL



Kwazulu-Natal Department of Health

Mail: Private Bag X9051, Pietermaritzburg, 3200

Tel: (033) 395 3028

Fax: (033) 395 2258

Amajuba Health District

Tel: (034) 328 7000

Fax: (034) 312 3123

eThekwini (Durban) Health District

Tel: (031) 240 5300

Fax: (031) 240 5501/2/3/4/5/6

Ilembe Health District

Tel: (032) 437 3500

Fax: (032) 551 1590

Sisonke Health District

Tel: (039) 834 8300

Fax: (039) 834 1301

Ugu Health District

Tel: (039) 688 3000

Fax: (039) 682 6296

uMgungundlovu Health District

Tel: (033) 897 1000

Fax: (033) 394 3235

Umkhanyakude Health District

Tel: (035) 572 1327

Fax: (035) 572 1251

Umzinyathi Health District

Tel: (034) 299 9100

Fax: (034) 212 3139

Uthukela Health District

Tel: (036) 631 2202

Fax: (036) 631 2217

Uthungulu Health District

Tel: (035) 787 0631

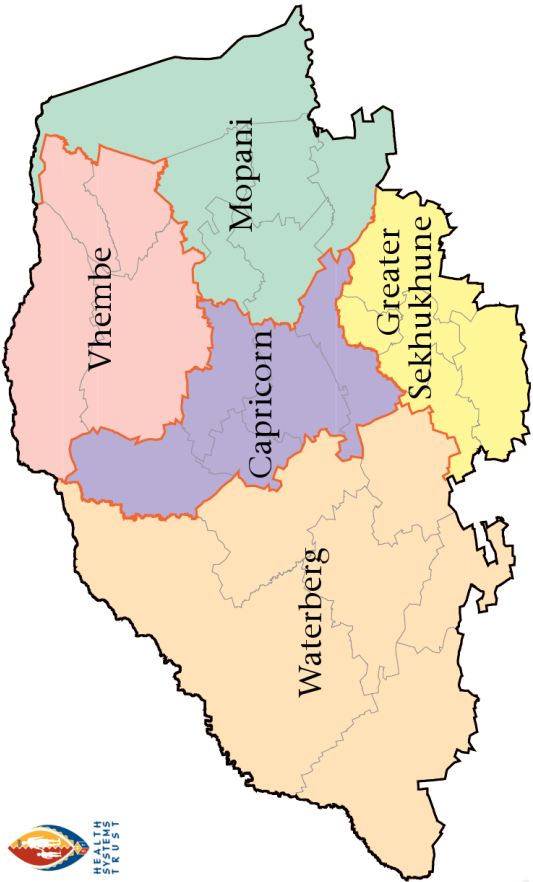
Fax: (035) 787 0646

Zululand Health District

Tel: (035) 874 2381

Fax: (035) 874 2457

LIMPOPO



Limpopo Department of Health and Social Development

Mail: Private Bag X9302, Polokwane, 0700

Tel: (015) 293 6005

Fax: (015) 293 6150

Capricorn District

Tel: (015) 290 9000

Fax: (015) 291 3260

Greater Sekhukhune District

Tel: (015) 633 2410

Fax: (015) 633 7927

Mopani District

Tel: (015) 811 6501

Fax: (015) 812 3162/1257

Vhembe District

Tel: (015) 962 1001

Fax: (015) 962 2373/4

Waterberg District

Tel: (015) 718 1700

Fax: (014) 717 2954

MPUMALANGA



Mpumalanga Department of Health and Social Development

Mail: Private Bag X11285, Nelspruit, 1200

Tel: (013) 766 3098

Fax: (013) 766 3475

Ehlanzeni District

Tel: (013) 752 3585

Fax: (013) 752 7498

Gert Sibande District

Tel: (017) 811 3292

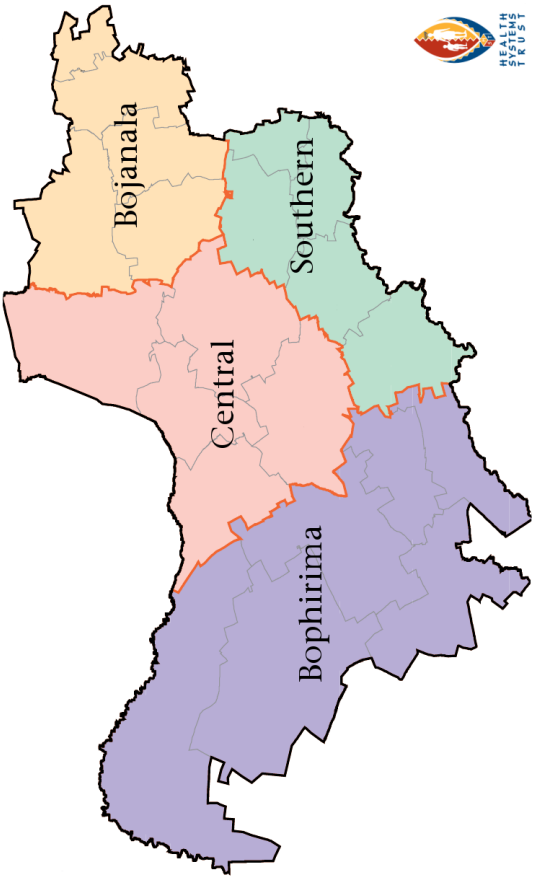
Fax: (017) 819 2505

Nkangala District

Tel: (013) 690 3307

Fax: (013) 656 1800

NORTH WEST PROVINCE



North West Province Department of Health

Mail: PO Box 124, Rooigrond, 2743

Tel: (018) 387 5784

Fax: (018) 387 5726

Bojanala Health District

Tel: (014) 592 3472

Fax: (014) 592 7319

Bophirima Health District

Tel: (053) 927 0456

Fax: (053) 927 0009

Central Health District

Tel: (018) 384 0240

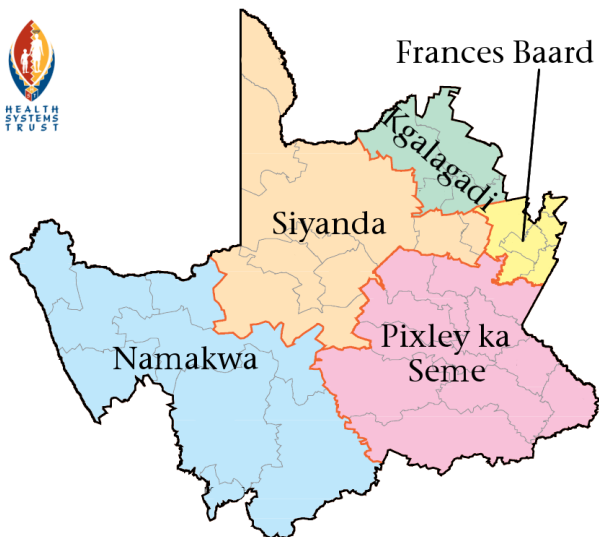
Fax: (018) 392 1655

Southern Health District

Tel: (018) 462 7734

Fax: (018) 464 4075

NORTHERN CAPE



Northern Cape Department of Health

Mail: Private Bag X5049, Kimberley, 8300

Tel: (053) 830 2000

Fax: (053) 833 1925

Frances Baard Health District

Tel: (053) 831 4695

Fax: (053) 833 7201

Kgalagadi Health District

Tel: (053) 712 0775

Fax: (053) 712 0656

Namakwa Health District

Tel: (027) 712 1601

Fax: (027) 712 3421

Pixley ka Seme Health District

Tel: (054) 331 2120

Fax: (054) 332 2642

Siyanda Health District

Tel: (053) 631 1575

Fax: (053) 631 0777

WESTERN CAPE



Western Cape Department of Health

Mail: PO Box 2060, Cape Town, 8000

Tel: (021) 483 5417

Fax: (021) 483 4143

Western Cape Provincial Health Council

Secretariat:

Tel: (021) 483 5619

Western Cape Provincial Consultative Body

According to the MEC for Health in the Western Cape, consultative bodies in the WC are *ad-hoc* with membership varying depending on the subject matter to be discussed. This appears to be at odds with the consultative body that is envisaged in section 28 of the NHA which calls for a standing consultative body in each province.

Consultative Body Contact:

Mr Phillip Grobler

Tel: (021) 483 5417

E-mail: Pigrobler@pgwc.gov.za

Boland/Overberg Health District

Tel: (023) 348 8101

Fax: (023) 342 8501

Cape Town Metro Health District

Tel: (021) 483 2518

Fax: (021) 483 6033

Cape Winelands Health District

Tel: (022) 487 9210

Fax: (022) 487 1775

Central Karoo Health District

Tel: (044) 803 2707

Fax: (044) 873 5929

Eden Health District

Tel: (044) 803 2707

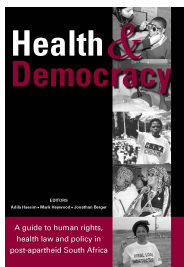
Fax: (044) 873 5929

West Coast Winelands Health District

Tel: (022) 487 9210

Fax: (022) 487 1775

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