SECOND EDITION

THE NATIONAL HEALTH ACT

A GUIDE

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The National Health Act 61 of 2003

A Guide

- Second Edition -

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Contents

* Section not yet proclaimed

List of Acronyms

AFSA:	AIDS Foundation of South Africa
AHPCSA:	Allied Health Professions Council of South Africa
AIDS:	Acquired Immune Deficiency Syndrome
ALP:	AIDS Law Project
ANC:	African National Congress
ARV:	Antiretroviral
BEMF:	Budget and Expenditure Monitoring Forum
CEO:	Chief Executive Officer
CMS:	Council for Medical Schemes
DHB:	District Health Barometer
DHMIS:	District Health Management Information System
DR-TB:	Drug-Resistant Tuberculosis
HCT:	HIV Counseling and Testing
HIV:	Human Immunodeficiency Virus
HPCSA:	Health Professions Council of South Africa
HRH:	Human Resources for Health
IST:	Integrated Support Team
MCC:	Medicines Control Council
MDR-TB:	Multi-Drug-Resistant Tuberculosis
MEC:	Member of the Executive Council
MRC:	Medical Research Council
NDoH:	National Department of Health
NHA:	National Health Act
NHI:	National Health Insurance
NHLS:	National Health Laboratory Service
NHRC:	National Health Research Committee
NHREC:	National Health Research Ethics Council
NSDA:	Negotiated Service Delivery Agreement

PDoH:	Provincial Department of Health
PEP:	Post-Exposure Prophylaxis
PFMA:	Public Finanace Management Act
PMB:	Prescribed Minimum Benefit
PMTCT:	Prevention of Mother-to-Child Transmission of HIV
SAHPRA:	South African Health Products Regulatory Authority
SALGA:	South African Local Government Association
SAMA:	South African Medical Association
SANAC:	South African National AIDS Council
SOP:	Standard Operating Procedure
STI:	Sexually Transmitted Infection
TAC:	Treatment Action Campaign
TB:	Tuberculosis
XDR-TB:	Extensively Drug-Resistant Tuberculosis

Editors' Introduction

Since the first edition of this Guide was published in 2008, there have been many important changes in law and policy governing health. There have been new legislation and regulations, as well as the commitment by the government to implement a national health insurance (NHI) scheme. The appointment of Dr Aaron Motsoaledi as Minister of Health in 2009 signaled a renewed prioritisation of health by the government, and was accompanied by a public commitment to implement a 10-point plan to improve health services. This plan is incorporated into the Negotiated Service Delivery Agreement (NSDA) signed in October 2010 between the Minister of Health and President Zuma.

In South Africa, one characteristic of most of the legislation, regulations and policies relating to health is the emphasis they place on community involvement in the management of the health system. This is one of the reasons why it is so important that users and providers of health care understand the legal framework.

This second edition of the Guide aims to make the National Health Act (NHA) accessible, easily understandable and up to date. It is written for a range of readers, from individuals accessing health care services to communities, from health care practitioners to civil society activists, from non-governmental organizations to public servants, from National Department of Health (NDoH) officials to lawyers.

We hope that you find it useful.

Inter-relationship of rights and laws

The National Health Act 61 of 2003 was 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, which places express obligations on the state to progressively realise socio-economic rights, including access to health care.

Section 27 of the Constitution states 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 realisation of each of these rights; and

(3) No one may be refused emergency medical treatment.

Section 27 obviously refers to health. But all the rights in our Constitution are indivisible, interrelated and mutually supporting. This means that it is important to achieve the realisation of some rights in order to enjoy other rights. For example:

- Human dignity, equality and privacy are denied to those who have no or limited access to health, food and shelter.
- Patients should be afforded the necessary privacy when being examined and should not be physically exposed in front of others. Their medical information should not be disclosed to others, and they should have access to decent ablution facilities.

There are also important rights for vulnerable groups such as children. Section 28 provides that every child has the right to 'basic nutrition, shelter, basic health care services and social services'.

In terms of section 9, everyone has the right to equality, including access to health care services, which means that individuals should not be unfairly excluded in the provision of health care. This includes prisoners, who in terms of section 35(2)(e), are entitled to 'medical treatment at state expense'.

People also have the right to access information that is held by another person if it is required for the exercise or protection of a right – this may arise in relation to accessing one's own medical records from a health facility for the purposes of lodging a complaint or for giving consent for medical treatment. This right also enables people to exercise their autonomy in decisions related to their own health, an important part of the right to human dignity and bodily integrity in terms of sections 9 and 12 respectively. Security of the person also means that patients and health care professionals should have sufficient security in facilities.

In other words, the imperatives of section 27 should not be seen in isolation but as a necessary part of the achievement of all the rights in the Bill of Rights. Importantly, the right to equality includes the full and equal enjoyment of all rights and freedoms.

Background of the NHA

To understand the NHA it helps to understand its historical background. The NHA is the culmination of key health system policies dating from 1994. It reflects elements of the African National Congress (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 efficient human resource planning and development, and increasing access to health care services for everyone.

But whilst the NHA creates the foundations of the health care system, it must be understood alongside other laws and policies which relate to health, such as the registration and regulation of medicines. The most important of these laws and policies are described briefly in Appendix "B", including:

- The Choice on 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

The NHA sets out the structure of the national, provincial, and district health care system. It is designed to create the framework for delivering health care services, including the duty to 'promote the inclusion of health services in the socio-economic development plan of the Republic.' Thus the National Development Plan: 2030, which was approved by Cabinet in 2012, includes a chapter on health, which is an important guide to health policy and objectives.

Since publication of the first edition of this Guide the majority of the then outstanding provisions of the NHA have been promulgated. But there are still some important provisions and regulations which have not yet been made law.

The sections that the President has yet to proclaim, or in respect of which regulations have yet to be finalised, are marked throughout

the text. Until these remaining provisions and regulations are brought into effect the NHA will not fully comply with the duty that rests on the government to fulfill its obligations under section 27.

Further, as we describe below, whilst there have been many improvements to policy and legislation since 1994, very few of them have been properly implemented. Below we draw attention to some important areas of law and policy and the challenges that remain for ensuring their proper implementation.

Rights of Access to Quality Health Care

Free Health Care Services

Since 1994 there has been a marked improvement in people's access to health care services. Section 4 of the NHA, for example, sets out categories of people who are entitled to free health care services. 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 on Termination of Pregnancy Act 92 of 1996.

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

The Planned National Health Insurance (NHI)

Although access to health care services has improved, the quality of those services has not. In fact, inequality in access to quality health care has grown. People who are poor and totally dependant on public health services complain that they are often not able to get the care they need, that queues are long, and the clinics are dirty. On the other hand, people who can afford to pay for privately run health care services receive a better standard of care.

To begin to remedy these inequalities, in 2010 the Minister appointed an Advisory Committee on National Health Insurance, tasked with researching and developing proposals for an NHI system. In 2011, the Ministry published a National Health Insurance Policy Paper – known as a Green Paper[1] and requested public comments. It is expected that a White Paper reflecting those comments will be available in early 2013.

The government's objective for introducing NHI is to eliminate the current tiered health system, to improve access to quality healthcare services and provide financial risk protection against health-related catastrophic expenditures. An NHI system provides a mechanism for improving cross-subsidisation in the overall health system.

In 2012, the NDoH identified ten pilot health districts for the development of frameworks and models which can be scaled up when NHI is implemented nationally. Each pilot site has a business plan to which the public should have access.

The introduction of NHI is going to be one of the most important reforms to health care. It needs to be monitored in the coming years. The Green Paper and the business plans for the pilot districts

[1] Available at: http://www.section27.org.za/nha/

can be accessed via the SECTION27 website.[2] We will make the White Paper available as soon as it is published.

Emergency Medical Treatment

In line with section 27(3) of the Constitution, section 5 of the NHA 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 a person needs emergency medical treatment, they should be admitted to any hospital and receive appropriate care and treatment.

There are a large number of people in South Africa who need emergency medical treatment because of motor accidents or violence. Usually they require urgent attention from the nearest health facility. But unfortunately some private hospitals insist on payment before any treatment is provided, even if it is an emergency. Others provide only very limited treatment before an uninsured patient is passed on to a public facility.

Despite this practice, regulations have not yet been published regarding the definition and provision of emergency services. Neither are there any official guidelines or protocols governing payments for emergency care or the levels of treatment required in different emergency situations.

Rights Inside the Health System

Sometimes people complain about the way they are treated by doctors and nurses. This makes some people unwilling to seek the

[2] http://www.section27.org.za/nha/

care they need. It is therefore important to know about the rights that the NHA recognises. Some of these are explained below.

Consent to Medical Treatment

Section 6 of the NHA gives you the right – before you are given any medical treatment – to be told 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 a 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. Likewise, if a person has a dangerous communicable disease that could pose a public health risk – such as Ebola – that person may have to be isolated and 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 is the least restrictive method 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, 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 people the right to complain about how they have been treated by a health facility. Procedures to follow in laying a formal complaint are supposed to be clearly displayed in all health facilities and must be provided to a person who asks 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. In addition, both the Office of Health Standards Compliance and the Ombud will accept complaints regarding quality and access to health care services once they have been set up.

Community Involvement in the Health Care System

National and Provincial Health Councils

The National Health Council is made up of all the provincial MECs for health and is meant to advise the Minister of Health. Its composition is mirrored by the provincial health councils created by sections 26 and 27 of the NHA. The provincial councils are responsible for advising the provincial department on health policy and include members of municipalities, local and provincial government. They may also consider representations from any person, organisation, institution or authority.

National and Provincial Consultative Bodies on Health

Section 28 of the NHA requires that each province establish a consultative body to promote and facilitate 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 bodies must include relevant stakeholders, such as community health organisations, and must meet at least every 12 months.

District Health Councils

Section 31 of the NHA instructs the member of the executive council for health (known as the MEC for Health) in each province to create a District Health Council in 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 health activists to monitor since they help set district and provincial policy.

But until each province passes its own health legislation, it won't be known how each district health council will function.

Contact information for all district health offices is included in Appendix C.

National, Provincial and District Health Plans

Section 33 of the NHA requires each district or metropolitan health manager to create annual district health and human resource plans. These health plans must be developed according to guidelines published by the NDoH.

At a national level, sections 21(3)–(5) of the NHA require that the Director General produces an annual national health plan; and that he or she should 'integrate the health plans of the national department and provincial departments annually and submit the integrated plans to the National Health Council.'

Knowing the contents of these plans is very important. It provides the ability to monitor what those responsible for health at national, provincial and district level are meant to accomplish and to hold them accountable for failure to meet their mandates.

If individuals, communities and organisations are more aware of health plans and budgets, they can measure these plans against a proper needs-based health assessment of a community or district.

Hospital Boards

Section 41 of the NHA requires the Minister to appoint hospital boards for each central hospital or group of hospitals. These boards must include up to three representatives of the communities served by the hospitals. They provide community members with the

opportunity to provide input into the governing of the hospitals that serve them.

Section 41 of the NHA was only implemented in March 2012. Therefore it is essential that the Minister speedily appoint these boards.

Clinic and Community Health Centre Committees

The NHA says that clinic committees should be created and must include members of the community. As with section 41, section 42 was only proclaimed by President Zuma in March 2012.

Unfortunately, the powers and responsibilities of these committees remain unclear. Another challenge is that the NHA requires that provincial legislation be passed before these committees are set up. As far as we know, provincial legislation on health has only been passed in two provinces, KwaZulu Natal and the Eastern Cape.

Planning and Budgeting for Health Services

The NHA is silent on the issue of health financing and management. Instead, guidance on the law regarding budgeting and expenditure has to be sought in the Public Finance and Management Act (PFMA) whose object is 'to secure transparency, accountability, and sound management of the revenue, assets and liabilities of [public/state] institutions'.

Since the first edition of this Guide, one of the greatest challenges facing the implementation of health policy has been inadequate planning, oversight and management of public finances for health.

In 2008/09, for example, massive budgetary shortfalls overwhelmed several provincial departments of health (PDoHs). This

reached crisis levels when in November 2008 the Free State Department of Health issued a moratorium on the initiation of new patients onto antiretroviral treatment which lasted until February 2009, causing many preventable deaths from AIDS.

As a result of the Free State crisis, Barbara Hogan, then the Minister of Health, set up special integrated support teams (ISTs) to investigate the management of finances in all the provincial health departments. In 2009 the NDoH published their report (Consolidated Report of the Integrated Support Team: Review of health overspending and macro-assessment of the public health system in South Africa[3]).

These reports contain a sobering assessment of the inadequate financial capacity of provincial departments of health. Their findings reveal deep failures in political and bureaucratic leadership, inappropriate financial management systems, inadequate monitoring and evaluation systems, and a failure to plan appropriately for human resources, amongst others.

The reports made detailed recommendations of what steps must be taken to resolve these systemic failings. These weaknesses help explain the widespread corruption that has taken hold in the health system and drains its resources.

Unfortunately, few of these recommendations appear to have been implemented. At the time of publication of this second edition, a crisis exists in the Eastern Cape Department of Health, which is facing a shortfall of between R2.5 and R3 billion. A similar crisis confronts the Limpopo and Gauteng Health departments.

For these reasons the National Health Department has had to take over all or parts of several provincial departments, including by using powers under section 100 of the Constitution.

[3] Available at: http://www.section27.org.za/nha/

The problems of efficient financial management of health are multi-layered. They include the difficulty of fiscal planning created by the concurrent jurisdiction for health between provinces and the national government. Thus, whilst the national government may determine health policies and priorities, the determination of budgets falls upon provincial governments.

But whatever the reason, the problem manifests itself in ways that negatively affect health services, such as an insufficient supply of medicines, the failure of provinces to spend according to national health priorities and a failure to plan for, train and retain sufficient health care workers.

Because of the importance of monitoring health financing and budgeting, in 2009, civil society organisations set up a body called the Budget Expenditure and Monitoring Forum (BEMF), which is currently co-ordinated by SECTION27.[4]

Human Resources

Chapter 7 of the NHA, in particular sections 48 and 52, requires the Minister to make plans for human resources training, retention and distribution throughout the country. Similarly, sections 25(3) and 33 require the development of provincial and district level human resources plans.

These plans are essential because, without the training and retention of health care workers, health services cannot function.

As with any governmental plan, knowing the contents and objectives of the plan makes it possible to review them and ensure that they are adequately supported by budgets.

[4]The BEMF can be contacted at bemf@section27.org.za.

The 2011 Human Resources for Health South Africa, published by the NDoH, is guided by the NDoH's 10-Point Plan which incorporates human resources planning, development and management as one of its priorities.[5]

Provincial and district level human resources plans should be made public. They can be 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.

Conclusion

This Guide reflects the progress in the development of the legal framework for health since it was first published in 2008. However, the legal framework remains incomplete.

For example:

- Most provincial governments have not fulfilled their duty to pass provincial health legislation and establish legally required bodies, such as the provincial consultative bodies.
- At a national level the NDoH needs to quickly establish statutory oversight bodies, such the Office of Health Standards Compliance (section 78, as amended by the National Health Amendment Bill passed by Parliament in November 2012, but not yet signed by the President).
- Finally, it is urgent that outstanding regulations such as those on human resources, communicable diseases and primary health care services, are finalised and that the remaining provisions of the NHA are proclaimed by the President.

[5] These documents can be found at: http://www.section27.org.za/nha/

We hope that by putting the text of the NHA into the hands of people in communities and organisations, they can start to mobilise to demand full implementation of their rights under the NHA and under the Constitution.

NATIONAL HEALTH ACT 61 OF 2003 [6]

(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

[6] President 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. In three subsequent proclamations, the majority of the remaining sections of the Act have been proclaimed. As of 22 February, 2013, 10 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:–

ARRANGEMENT OF SECTIONS

CHAPTER 3
NATIONAL HEALTH

CHAPTER 4
PROVINCIAL HEALTH

CHAPTER 5
DISTRICT HEALTH SYSTEM FOR REPUBLIC

CHAPTER 6
HEALTH ESTABLISHMENTS

CHAPTER 7
HUMAN RESOURCES PLANNING AND ACADEMIC HEALTH COMPLEXES

CHAPTER 8
CONTROL OF USE OF BLOOD, BLOOD PRODUCTS, TISSUE AND GAMETES IN HUMANS

CHAPTER 9
NATIONAL HEALTH RESEARCH AND INFORMATION

CHAPTER 10
OFFICE OF HEALTH STANDARDS COMPLIANCE, BOARD, INSPECTIONS AND ENVIRONMENTAL HEALTH INVESTIGATIONS, HEALTH OFFICERS AND INSPECTORS, COMPLAINTS AND APPEAL PROCEDURES[7]

[7] At the time of publishing, Parliament is processing new legislation amending the NHA. The National Health Amendment Bill has been considered by both the National Assemply and National Council of Provinces and seems likely to pass. Because of the importance of the changes to the NHA and the health system, we have included the amendments being proposed in the text of this guide in shaded boxes. For more on the National Health Amendment Bill, see note 100.

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;

'Board' means the Office of Health Standards Compliance Board established in terms of section 79A;[8]

'central hospital' means a public hospital designated by the Minister to provide health services to users from more than one province;[9]

'certificate of need' means a certificate contemplated in section 36;[10]

'Chief Executive Officer' means the person appointed as Chief Executive Officer in terms of section 79H(1);[11]

'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;

[8] See note 7 above.

[9] See note 66 on the significance of the classification of health facilities.

[10] Section 36 of the Act sets out certain actions – such as building new hospitals and clinics, or providing certain health services – which require a certificate of need. The section has not yet come into effect.

[11] See note 7 above.

'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;[12]

'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;[13]

[12] As of 22 February, 2013, the Minister had not yet published regulations defining 'essential health services'. For more information on the significance of a definition for 'essential health services', see note 36 below.

[13] According 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]-

'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);
(b) Health Professions Act, 1974 (Act 56 of 1974);
(c) Nursing Act, 1978 (Act 50 of 1978);[14]
(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 the person appointed as Health Officer in terms of section 80(1);[15]

'health research' includes any research which contributes to knowledge of–

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

[14] The Nursing Act of 1978 has been repealed and replaced by the Nursing Act 33 of 2005.

[15] See note 7 above.

(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;

'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;[16]
(b) basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution;[17]

[16] Section 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.

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

(c) medical treatment contemplated in section 35(2)(e) of the Constitution;[18] and
(d) municipal health services;[19]

'health technology' means machinery or equipment that is used in 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);[20]

'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;

[18] According 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 the argument made by the respondents who had been detained that persons detained in terms of the NHA are also entitled to the protections contained in section 35(2) of the Constitution. The Court did, however, not consider this point from a legal perspective and another court may make a different decision. For more on the *Goliath* case, see footnote 39.

In addition, in *Dudley Lee v Minister for Correctional Services* [2012] ZACC 30, the Constitutional Court considered certain legal questions around Mr Lee's contracting TB while he was an awaiting trial prisoner at Pollsmoor for six years. Mr Lee sued the Minister for damages on the basis that poor prison health management resulted in his being infected with TB. Although the judgment does not rely on the NHA, this is an important health-related judgment because it affirmed that there is a legal duty on the responsible authorities to provide adequate health care services as part of the constitutional right of all prisoners to conditions of detention that are consistent with human dignity and that there was, in this case, a probable chain of causation between the negligent omissions by the responsible authorities and Mr Lee's infection with TB.

[19] See the definition of 'municipal health services' below.

[20] According 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 NHA's definition.

'hospital' means a health establishment which is classified as a hospital by the Minister in terms of section 35;[21]

'inspector' means any person appointed as an inspector in terms of section 80(2);[22]

'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;[23]

'municipal health services', for the purposes of this Act, includes–

(a) water quality monitoring;
(b) food control;
(c) waste management;

[21] The Minister, in consultation with the National Health Council, promulgated regulations on 2 March 2012 which classify categories of hospital as well as listing all public hospitals. The regulations specify what services different categories of hospitals must provide. Any public hospitals which require time to comply with the regulations must ensure that the relevant Member of the Executive Council has requested this extension and that the extension is approved by the Minister.

[22] See note 7 above.

[23] According to the Constitution, a municipal council is the elected body that is given both administrative and legislative powers in respect of a particular municipality. Section 157(1) of the Constitution sets out the requirements for the composition and election of the municipal councils.

(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);[24]

'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);

'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;

[24] 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'.

'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' means the Office of Health Standards Compliance established by section 77(1);

'Ombud' means the person appointed as Ombud in terms of section 81(1);[25]

'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;[26]

'pollution' means pollution as defined in section 1 of the National Environmental Management Act, 1998 (Act 107 of 1998);[27]

'premises' means any building, structure or tent together with the land on which it is situated and the adjoining land used in

[25] See note 7 above.

[26] According 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 NDoH, 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.

[27] Section 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.

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;[28]

'primary health care services' means such health services as may be prescribed by the Minister to be primary health care services;[29]

'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;[30]

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[28] Since the NHA came into effect, 16 regulations have been promulgated by the Minister or the Director-General of Health under section 90. See Appendix 'A' for links to these regulations.

[29] While the Minister has not prescribed regulations regarding primary health care service, there are a number of policies that have been implemented, including: 'Policy on the Management of Public Hospitals', March 2012; 'Integrated School Health Programme', April 2012; 'District Health Management Information System (DHMIS) Policy', 2011; 'National Department of Health: Strategic Plan 2010/11-2012/13' (10-Point Plan), February 2010; 'National Core Standards for Health Establishments in South Africa', 2011; 'Primary Health Care Package for South Africa: A set of norms and standards', March 2000; 'Standard Treatment Guidelines and Essential Drugs List for Primary Health Care', revised in 2012; and 'A User's Guide to Primary Health Care Services', 2006. All these documents can be found at http://www.section27.org.za/nha/. See footnote 29 for more on the significance of a definition for 'primary health care services'.

[30] All 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

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

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and principles enshrined in the Constitution, including the following principles:

(a) A high standard of professional ethics must be promoted and maintained.
(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.

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

'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);[31]

(b) the South African Nursing Council established by section 2 of the Nursing Act, 1978 (Act 50 of 1978);[32]

(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;

[31] The functions of the HPCSA include a duty to 'uphold and maintain professional and ethical standards within health professions in order to protect the interest of the public'. Section 53 of the Health Professions Act requires health professionals to disclose to patients the fee that will be charged prior to rendering a service on request or if the fee exceeds what is usually charged for such services. This is an important way to ensure that patients are not over-charged for health care services, particularly in the private sector.

[32] See note 14 above.

'user' means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a 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),[33] 'user' includes the person's parent or guardian or another person authorised by law to act on the firstmentioned 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.

[33] The Child Care Act was repealed by the Children's Act 38 of 2005. Section 129 of the new Children's Act sets out 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. The Act also governs HIV-testing of children in Section 130. Children can consent to HIV-tests at age 12 or younger if of sufficient maturity to understand the benefits, risk and social implications of the HIV-test. Section 133 prohibits anyone from disclosing a child's HIV status without consent whilst section 134 governs children's access to contraceptives. Consent for the termination of pregnancy is different. Section 5 of the Choice on Termination of Pregnancy Act 92 of 1996 says that a minor must be advised by a medical practitioner, registered midwife or registered nurse to speak to a parent, guardian, family member or friend before terminating a pregnancy. Importantly, however, she cannot be denied a termination if – after being so advised – she chooses not to talk to anyone else. The UCT Children's Institute has published a helpful guide to the Children's Act for health professionals. The 2010 fourth edition is available at: http://www.section27.org.za/nha/.

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;[34] and

(iv) vulnerable groups such as women, children, older persons and persons with disabilities.

[34] According 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;[35]

(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; and[36]

(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

[35] In *Treatment Action Campaign and Another v Rath and Others* (12156/05) [2008] 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.

[36] Even 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 22 February, 2013, the Minister had not yet published a definition for either. This means that section 3 is difficult to enforce. The Minister's failure to provide a definition 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.[37]

(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–

(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;

[37] As of 22 February, 2013, the Minister had not yet published any conditions regarding eligibility for free health services. This means that there are no restrictions on the list of people eligible for free health services or free primary health services set out in subsection 3 and these categories of people must be provided with the relevant free services. The Minister could further extend the range of free services currently available, in consultation with the Minister of Finance. These may be subject to conditions as determined by the Ministers.

(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.[38]

[38]The Constitutional Court in *Soobramoney v Minister of Health (Kwazulu-Natal)*, (CCT32/97) [1997] ZACC 17; 1998 (1) SA 765 (CC); [1998] 1 All SA 268 (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;[39]

(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

[39]The NDoH has twice published draft Regulations Regarding Communicable Diseases – most recently in April 2010 – but the regulations have not yet been promulgated. The 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 and what the compulsory measure is likely to entail
- It must be highly likely that, without intervention, the disease will be spread to others.

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

In *Minister of Health of the Province of the Western Cape v Goliath and Others* (13741/07) [2008] ZAWCHC 41; 2009 (2) SA 248 (C), the Minister applied in the Cape High Court 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 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. There have also been no subsequent cases dealing with either section 7 or section 9.

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.

(2) A health care provider must take all reasonable steps to obtain the user's informed consent.[40]

(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

[40] For 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* (181/2004) [2005] ZASCA 81; 2006 (2) SA 161 (SCA); [2006] 1 All SA 197 (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).

service in question unless the disclosure of such information would be contrary to the user's best interest.

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 purposes

(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.[41]

(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, ade-

[41] As of 22 February, 2013, regulations regarding the prescribed manner to inform the user had not been published.

quate 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;
(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 Confidentiality[42]

(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

[42] In *Tshabalala-Msimang and Another v Makhanya and Others* (18656/07) [2007] ZAGPHC 161; 2008 (6) SA 102 (W); [2008] 1 All SA 509 (W), 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 stigmatised when they go to a health facility for a medical assessment or treatment for a cause of illness such as infection with HIV.

establishment as is necessary for any legitimate purpose within 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).[43]

[43] 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–[44]

(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;

[44] See footnote 42.

(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.[45]

[45] Section 17 is one of a few provisions in the NHA which impose criminal liability on those responsible for the management of health facilities. As of 22 February, 2013, there are no recorded successful prosecutions under the NHA.

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 cooperate 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) facilitate and promote the provision of port health service and participate in intersectoral and interdepartmental collaboration;[46]
(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. [47]

[46] See note 7 above.

[47] The NDoH Strategic Plan 2010/11 – 2012/13 and the Annual National Health Plan 2010/2011 are available at:http://www.section27.org.za/nha/.

(b) The national health plans referred to in paragraph (a) must form the basis of–

(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. [48]

22 Establishment and composition of National Health Council[49]

(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;

[48] The integration of national and district (provincial) health plans is discussed in the Annual National Health Plan mentioned in note 47 above. One of the priorities of the Plan is to strengthen service delivery in all districts starting with 18 priority districts. An analysis of the District Health Plans in these priority districts reflected adverse performance on key coverage, health systems performance and outcome indicators. For links to the provincial Annual Plans, see Appendix B.

[49] Although the National Health Council is referred to in NDoH documents, information on the Council is not readily available. Nor could anyone in the Minister's office provide contact details for the Council.

(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;
(g) one person employed and appointed by the national organisation contemplated in section 163(a) of the Constitution;[50] 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;

[50] Section 163 of the Constitution requires that legislation be enacted by Parliament to 'provide for the recognition of national and provincial organisations 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.

(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;

(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 representations 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[51]

(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.

[51] The National Consultative Health Forum has convened meetings but – as with the National Health Council – it is difficult to locate current information on the Forum. The last meeting of the Forum was in November 2011, meaning it has not met its statutory obligation to meet once every 12 months in terms of section 24(3)(c).

(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[52]

[52]Health services is a functional area in which national and provincial government share legislative competence, while the only health-related functional area which is the exclusive domain of provincial government is ambulance services. Concurrent legislative competence means that both provincial and national government may pass legislation that fits into the functional area of health services. If there is a conflict between the provincial health services legislation and the national health services legislation, section 146 of the Constitution governs the resolution of these conflicts. In order for the national legislation to prevail, certain requirements must be met such as the national legislation providing uniformity by establishing norms and standards, frameworks and policies. There have not yet been any cases dealing with conflicts between the NHA and provincial health legislation. It should be reiterated that concurrent legislative competence allows provinces to enact health-services related legislation and it does not mean that the provinces must rely exclusively on the NHA.

Another important provincial consideration is the power of the national executive to intervene when a province cannot or does not fulfil an executive obligation in terms of legislation or the Constitution. The terms for such interventions are in section 100 of the Constitution. In December 2011, Limpopo's Department of Health was placed under section 100(1)(b) national executive administration and remained so at the time of publication. There is no case law relating to interventions in provincial departments of health but in *Centre for Child Law and Others v Minister of Basic Education and Others* (1749/02) [2012] ZAECGHC 60; [2012] 4 All SA 35 (ECG) the Eastern Cape Department of Basic Education had been placed under the administration of the national government in terms of section 100(1)(b) of the Constitution. The Court reiterated Constitutional Court jurisprudence that in intervening in terms of section 100(1)(b), the national government takes on the powers of the provincial administration as well as its obligations. The case dealt with the Minister's obligation to fill certain non-teaching staff posts at schools. The Court held that the Minister is obliged to both declare post establishments and fill those posts.

The South African Local Government Association has published a position paper on the provincialisation of Personal Primary Health Care Services (2009). This document includes useful information on health care services at a provincial level. It is available at http://www.section27.org.za/nha/.

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 comprehensive primary health services and community hospital services;[53]

(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.

[53] See note 7 above.

26 Establishment and composition of Provincial Health Council[54]

(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.[55]

27 Functions of Provincial Health Council

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

[54] Provincial Health Councils have not been established in any provinces. This means that section 27(7) of the NHA which requires the Councils to have met within a certain time period after the proclamation of this section has not been complied with.

[55] For more on section 163 of the Constitution see note 50 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[56]

(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[57]

29 Establishment of district health system

(1) A district health system is hereby established.

[56] As with Provincial Health Councils, provinces have not established Provincial consultative bodies meaning that they are in contravention of their obligations in terms of section 28 of the NHA.

[57] The Health Systems Trust publishes an annual District Health Barometer ('DHB') which is a tool designed to assist in making functional information available for monitoring progress in health services delivery at the district level. The DHB is available at: http://www.hst.org.za/district-health-barometer-dhb-2.

(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 27[58] and 195[59] of the Constitution and the criteria laid down in section 25 of the Local Government: Municipal Demarcation Act, 1998 (Act 27 of 1998),[60] particularly in so far as they relate to–

[58] Section 27 of the Constitution covers the right to have access to health care, food, water, and social security. The text of section 27 is set out in note 12 above.

[59] Section 195 of the Constitution sets out the basic principles governing public administration. The entire text of section 195 is set out in note 26 above.

[60] Section 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.

(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
(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–[61]

[61] The Free State Provincial Health Act 3 of 2009 came into effect on 30 March 2009 while Kwazulu-Natal has promulgated the KwaZulu-Natal Health Act 1 of 2009 but the Act has not yet come into effect. Most recently, the Western Cape District Health Councils Act 5 of 2010 came into effect on 24 August 2011. The North West Province published a draft bill inviting written representations on 29 September 2008.

(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 performance 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

It is unclear whether there has been any progress with this bill. None of the remaining 5 provinces have initiated or finalised any legislation required in term of section 31. The Eastern Cape Provincial Health Act 10 of 1999 is still in effect, but it pre-dates the NHA.

as are contemplated in section 156(4) of the Constitution.[62]

(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.

33 Preparation of district health plans[63]

(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

[62] Section 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.

[63] The 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 NDoH has issued Guidelines for District Health Planning and Reporting. These explain what must appear in the district health plan. The guidelines are available at: http://www.section27.org.za/nha/.

Systems Act, 2000 (Act 32 of 2000).[64]

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

[64] Section 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.

Chapter 6
HEALTH ESTABLISHMENTS[65]

35 Classification of health establishments[66]

The Minister may by regulation–

(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

[65] Six of the 13 sections of Chapter 6 have not yet been proclaimed. Sections 36 – 40, which remain unproclaimed, relate to the certificate of need which is required in order to establish, construct, modify or acquire a health establishment or health agency as well as to provide prescribed health services. Section 47 – which also remains unproclaimed – sets out the requirement that all health establishments must comply with prescribed quality requirements and standards and that the Office of Health Standards Compliance (in terms of the National Health Amendment Act) must monitor and enforce compliance with the quality requirements and standards. Section 47, once proclaimed, could be an important and effective tool to ensure access to quality healthcare.

[66] The Minister has categorised public hospitals as district, regional, tertiary, central and specialised. Each category has a certain maximum number of beds and the regulations set out which services must and may be provided at each category of hospital.

(b) in the case of a central hospital, determine the establishment of the hospital board and the management system of such central hospital.

36 Certificate of need[67]

(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.

(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

[67] As of 22 February, 2013, none of the provisions dealing with certificates of need had been proclaimed. It seems unlikely that these provisions will be proclaimed as there has been a shift away from this concept by the NDoH.

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;

(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 need[68]

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 decision[69]

(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.

[68] As of 22 February, 2013, section 37 had not yet been proclaimed by the President.

[69] As of 22 February, 2013, section 38 had not yet been proclaimed by the President.

(3) After considering the grounds of appeal and the Director-General's reasons for the decision, the Minister must as soon as practicable–

(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 need[70]

(1) The Minister may, after consultation with the National Health Council, make regulations relating to–[71]

(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)–

[70] As of 22 February, 2013, section 39 had not yet been proclaimed by the President.
[71] As of 22 February, 2013, no regulations under this section had been released for public comment by the Minister.

(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;
(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 need[72]

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

(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

[72] As of 22 February, 2013, section 40 had not yet been proclaimed by the President.

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 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.[73]

(5) The functions of a central hospital board must be prescribed by the Minister.[74]

(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;

[73] Once 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.

[74] As of 22 February, 2013, the Minister had not yet prescribed the functions of central hospital boards. However, in March 2012 the NDoH published its Policy on the Management of Public Hospitals. At their core, hospital boards must advise on policy. The policy states that hospital boards are largely advisory governance structures that have a mandate to act honestly in the best interest of the public and the users. In addition, it is important that hospital boards develop a working knowledge of the hospital and are cognisant of the economic, social, and political milieu in which the hospital operates. The Policy is available at: http://www.section27.org.za/nha/.

(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;
(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 committees

(1) Provincial legislation must at least provide for the establishment in the province in question of a committee for–[75]

(a) a clinic or a group of clinics;
(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 hospitals

(1) The Minister may prescribe–[76]

(a) minimum standards and requirements for the provision of

[75] For further information on provincial legislation, see note 61 above. Unfortunately, because many provinces have not finalised legislation, these committees – which are meant to include community representatives – have not yet been established in the manner intended.

[76] Although the Minister has not prescribed any standards or requirements under this section, the NDoH has published the Integrated School Health Programme which is available at: http://www.section27.org.za/nha/.

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 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 another

(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.

45 Relationship between public and private health establishments

(1) The Minister must prescribe mechanisms to enable a co-ordinated relationship between private and public health establishments in the delivery of health services.[77]

(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.

[77] As of 22 February, 2013, 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. It is likely that the policy on NHI, once finalised, will have bearing on this issue.

46 Obligations of private health establishments

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.

47 Evaluating services of health establishments[78]

(1) All health establishments must comply with the quality requirements and standards prescribed by the Minister after consultation with the Office.[79]

(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 must monitor and enforce compliance with the quality requirements and standards contemplated in subsection (1).[80]

[78] As of 22 February, 2013, section 47 had not yet been proclaimed by the President.
[79] See note 7 above.
[80] See note 7 above.

Chapter 7
HUMAN RESOURCES PLANNING AND ACADEMIC HEALTH COMPLEXES

48 Development and provision of human resources in national health system[81]

(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.

(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.

[81] The NDoH's *Human Resources for Health South Africa: HRH Strategy for the Health Sector: 2012/13 – 2016/17* was published on 11 October 2011. This plan aims to consolidate a number of existing policy and research documents and plans. The Strategy is available at: http://www.section27.org.za/nha/.

50 Forum of Statutory Health Professional Councils[82]

(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;

(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;

[82] There is no information available from the NDoH regarding this forum. It does not appear to have been established.

(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 complexes[83]

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.

[83] Although section 51 formally came into effect on 1 March 2012, the Minister has not yet established any academic health complexes.

52 Regulations relating to human resources

The Minister may make regulations regarding human resources within the national health system in order to–[84]

(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;

(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;

[84] As of 22 February, 2013, no regulations under this section had been finalised or released for public comment by the Minister. The NDoH has produced a human resources strategy for the health sector (see note 81 above), but guidelines and strategy cannot create the same level of obligations for government or the private sector as regulations. Although there was a consultation process followed in drafting the Human Resources Strategy, the process for creating strategy also does not ordinarily include as much opportunity for public participation, as is required when departments draft new regulations.

(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 HUMANS[85]

53 Establishment of national blood transfusion service

(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.[86]

[85]The majority of sections in Chapter 8 came into effect on 1 March 2012. In conjunction with this the Minister published a number of regulations regulating the control of the use of human blood, blood products, tissue and gametes.

[86]This section imposes criminal liability on anyone found guilty of providing a blood transfusion service without the correct licence.

54 Designation of authorised institution[87]

(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 persons

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–

[87] Although section 54 came into effect on 1 March 2012, as of 22 February, 2013 the Minister has not designated any institutions in terms of this section.

(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 persons

(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.

57 Prohibition of reproductive cloning of human beings

(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.[88]

(6) For the purpose of this section–

[88] This is another one of the sections of the NHA imposing criminal liability. At date of publication, there have been no recorded successful prosecutions under any of the provisions of the NHA.

(a) 'reproductive cloning of a human being' means the manipulation of genetic material in order to achieve the reproduction 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 institution

(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.

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

(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 gametes

(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 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 organs

(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 persons[89]

(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

(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

[89] Donation of organs for transplantation is governed by regulations which came into effect on 1 March 2012. The Southern African Transplantation Society is a useful organization to contact regarding transplantation. Their website is http://www.sats.org.za

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 person[90]

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 persons[91]

(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

[90] Donation of human bodies or organs is governed by regulations which came into effect on 1 March 2012. These can be found in Appendix A.

[91] Donation of human bodies or organs is governed by regulations which came into effect on 1 March 2012. These can be found in Appendix A.

(b) restoration of any disfigurement or mutilation of the body before its burial.

65 Revocation of donation[92]

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 bodies

(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

[92]The regulations relating to donation also make provision for the process to be followed if a person has made conflicting donations. In those circumstances, the donation which was last made is the one which will be given effect to and if a person first donated her entire body to one institution and afterwards donated specific tissue to a different institution, the donation of her entire body will take precedence.

(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.

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

(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.[93]

(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–

[93] The National Heritage Resources Act recognises human remains to be included in the national estate, which are heritage resources of cultural significance or other special value for the present community and future generations.

(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.

(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);[94] 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.

[94] Section 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.

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

(1) The Minister may make regulations regarding–

(a) the post mortem examination of bodies of deceased persons;
(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.[95]

(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.[96]

[95] In terms of regulations which came into effect on 2 March 2012, an authorized tissue bank, organization or person may only receive payment for the activities listed in section 60 of the NHA and any payment must be recorded including the amount paid, to whom payment was made, the reason for the payments, and who made the payment.

[96] As of 22 February, 2013, no exceptions have been published.

Chapter 9
NATIONAL HEALTH RESEARCH AND INFORMATION

69 National Health Research Committee[97]

(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;

[97] Regulations governing the establishment and constitution of the National Health Research Committee (NHRC) were passed in 2010. The Committee has a website with additional information and contact details available at: http://www.nhrc.org.za/

(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 subjects

(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;

(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 Council[98]

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

(2) The Minister must–

(a) after consultation with the National Health Council, appoint as members of the National Health Research Ethics

[98] The National Health Research Ethics Council (NHREC) is governed by regulations which were gazetted on 23 September 2010. The Council's website is available at: http://www.nhrec.org.za/

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[99]

(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

[99] In line with the NDoH's obligations under this section, it has published the District Health Management Information System (DHMIS) Policy, 2011 which is available at: http://www.section27.org.za/nha/.

system as part of the national health information system contemplated in section 74.

Chapter 10
OFFICE OF HEALTH STANDARDS COMPLIANCE, BOARD, INSPECTIONS AND ENVIRONMENTAL HEALTH INVESTIGATIONS, HEALTH OFFICERS AND INSPECTORS, COMPLAINTS AND APPEAL PROCEDURE[100]

[100]The National Health Amendment Bill – which at the time of publication has been passed by the National Council of Provinces (NCOP) but must still be passed by the National Assembly and signed by the President – will replace Chapter 10 of the NHA. The text here reflects that passed by the NCOP – based on bill B24D-2011 – but may be subject to further amendments. Once the Bill is passed, we will update the guide and notify readers at http://www.section27.org.za/nha/.

The most important aspects of the new Chapter 10 is that it replaces the Inspectorate for Health Establishments and the Office of Standards Compliance (neither of which had been established) with the Office of Health Standards Compliance, and establishes an Ombud within the Office of Health Standards Compliance.

Once established, the Office of Health Standards Compliance will be a separate juristic entity and must be funded by money appropriated by Parliament directly as well as through the fees it receives for the services it provides. The Office is subject to the Public Finance Management Act 1 of 1999. The main object of the Office is to protect and promote the health and safety of people using health services. The Office will do this by monitoring compliance by the health establishments with the norms and standards prescribed by the Minister in relation to the national health system. In addition, the Office will also act as a mechanism for complaints to be investigated and handled. The Office will perform both advisory functions to the Minister as well as inspecting and certifying health establishments.

The Office will be run by a CEO appointed by the Minister. In addition, the Minister must appoint a suitably qualified and experienced person as Ombud. The Ombud – who is independent and impartial – may, after receiving a written or verbal complaint relating to norms and standards in a health establishment, investigate the complaint. The Ombud can also initiate an investigation herself. The Ombud must submit a report to the CEO recommending a course of action to resolve the complaint. If the CEO does not take the recommended steps, the Ombud may request that the Minister intervenes.

The chapter sets out in a fair amount of detail the way in which the health officers

77 Establishment of Office of Health Standards Compliance

(1) The Office of Health Standards Compliance is hereby established as a juristic person.
(2) The Office is funded by–

(a) money appropriated by Parliament; and
(b) fees received for services rendered.

(3) The Office is subject to the Public Finance Management Act, 1999 (Act No. 1 of 1999).

78 Objects of Office

The objects of the Office are to protect and promote the health and safety of users of health services by–

(a) monitoring and enforcing compliance by health establishments with norms and standards prescribed by the Minister in relation to the national health system; and
(b) ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

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from the Office must perform their duties, including a requirement that although the officers and inspectors have the power to enter and search premises, this must be done with strict regard to decency and good order and in line with all of their constitutional obligations such as respecting the right to privacy and dignity.

When the Act is passed, it will be important to monitor the speedy and proper establishment of the Office and ensure that it has a budget that is sufficient to perform its vital responsibilities.

79 Functions of Office

(1) The Office must–

(a) advise the Minister on matters relating to the determination of norms and standards to be prescribed for the national health system and the review of such norms and standards;
(b) inspect and certify health establishments as compliant or non-compliant with prescribed norms and standards or, where appropriate and necessary, withdraw such certification;
(c) investigate complaints relating to breaches of prescribed norms and standards;
(d) monitor indicators of risk as an early warning system relating to serious breaches of norms and standards and report any breaches to the Minister without delay;
(e) identify areas and make recommendations for intervention by a national or provincial department of health, a health department of a municipality or health establishment, where it is necessary, to ensure compliance with prescribed norms and standards;
(f) publish information relating to prescribed norms and standards through the media and, where appropriate, to specific communities;
(g) recommend quality assurance and management systems for the national health system to the Minister for approval;
(h) keep records of all its activities; and
(i) advise the Minister on any matter referred to it by the Minister.

(2) The Office may–

(a) issue guidelines for the benefit of health establishments on the implementation of prescribed norms and standards;
(b) collect or request any information relating to prescribed norms and standards from health establishments and users;
(c) liaise with any other regulatory authority and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority in respect of–
(i) matters of common interest; or
(ii) a specific complaint of investigation; and
(d) nogotiate cooperative agreements with any regulatory authority in order to–
(i) coordinate and harmonise the exercise of jurisdiction over health norms and standards; and
(ii) ensure the consistent application of the principles of this Act.

79A Establishment of Office

(1) The Office of Health Standards Compliance Board is hereby established.
(2) The Office functions under the control of the Board.
(3) The Board is the accounting authority of the Office and must–

(a) determine the policy of the Office;
(b) do the necessary planning in connection with the functions of the Office; and
(c) perform such other functions as may be assigned to it by this Act.

79B Composition of Board

(1) The Board consists of no less than 7 members and no more than 12 members appointed by the Minister, as follows:

(a) five members who have expertise in, among others, medicine, pharmacy, reproductive and maternal health, nursing, pediatrics, surgery, clinical governance and clinical risk management, occupational health and safety, infection control, and public health, nominated by institutions of higher learning or any other institution;
(b) one member appointed on account of his or her knowledge of the law;
(c) one member appointed on account of his or her knowledge of economics and financial matters or accounting;
(d) one member appointed on account of his or her knowledge of private healthcare sector;
(e) one member appointed on account of his or her knowledge of public healthcare and public administration;
(f) one member appointed on account of his or her knowledge of quality assurance;
(g) one representative from organised labour; and
(h) one representative from civil society or the community.

(2) The Chief Executive Officer and the Chief Financial Officer of the Office are *ex officio* members of the Board.

79C Appointment of members of Board

(1) The Minister must appoint the members contemplated in section 79B(1)(a) after consultation with the relevant bodies and institutions.

(2) The Minister must, before appointing the members contemplated in section 79B(1)(b) to (h), by notice in the *Gazette* and in two or more nationally circulating newspapers in the Republic, invite all interested persons to nominate, within the period specified in the notice, persons who in the opinion of such interested persons are fit to be so appointed, stating the grounds upon which such opinion is based.
(3) If a suitable person or the required number of persons is not nominated in terms of subsection (2), the Minister must appoint an appropriate person or persons who qualify to be appointed in terms of this Act.
(4) The members of the Board hold office for a term of at least three years, as the Minister may determine at the time of appointment, but are eligible for re-appointment for one additional term.
(5) A member of the Board, excluding a member who is in the full-time employment of the State or the Service, must be appointed on such conditions as the Minister may, with the concurrence of the Minister of Finance, determine.
(6) If the number of members of the Board is reduced to such an extent that a quorum cannot be obtained, the Minister may appoint any suitably qualified persons on a temporary basis to serve on the Board until new members are appointed in terms of this section.

79D Chairperson and vice-chairperson of Board

(1) The Minister must appoint a chairperson and vice-chairperson of the Board from the members contemplated in section 79B(1).

(2) Whenever the chairperson of the Board is absent or unable to perform his or her functions as chairperson, the vice-chairperson must act as chairperson and, if the vice-chairperson is absent or unable to act as chairperson the Minister must designate another member of the Board to act as chairperson until the chairperson or vice-chairperson is available.

(3) Any person acting as chairperson of the Board in terms of subsection (2), must exercise all the powers and perform all the duties of the chairperson.

79E Disqualification from membership of Board and vacation of office

(1) A person may not be appointed as a member of the Board if that person–

(a) is not a South African citizen and ordinarily resident in the Republic;
(b) is an unrehabilitated insolvent;
(c) has at any time been convicted of an offence involving dishonesty, whether in the Republic or elsewhere, and sentenced to imprisonment without the option of a fine; or
(d) has been removed from an office of trust.

(2) A member of the Board must vacate his or her office if–

(a) he or she becomes disqualified in terms of subsection (1) from being appointed as a member of the Board;
(b) he or she submits his or her resignation to the Minister in writing;
(c) he or she is declared by the High Court to be of unsound mind or mentally disordered or is detained under the

Mental Health Act, 1973 (Act No. 18 of 1973);

(d) he or she has, without the leave of the Board, been absent from more than two consecutive meetings of the Board;

(e) the Minister withdraws the appointment because in the opinion of the Minister, and after consultation with the Board, the member is incompetent or unfit to fulfil his or her duties; or

(f) he or she ceases to be ordinarily resident in the Republic.

(3) If a member of the Board dies or vacates his or her office in terms of subsection (2), the Minister may, subject to section 79C, appoint a person to fill the vacancy for the unexpired portion of the period for which that member was appointed.

79F Meetings of the Board

(1) The meetings of the Board and the conduct of business at meetings must be prescribed by the rules.

(2) A quorum for a meeting of the Board is the majority of its members.

(3) A decision of the majority of the members of the Board present at any meeting constitutes a decision of the Board and, in the event of an equality of votes, the member presiding at the meeting has a casting vote in addition to his or her deliberative vote.

(4) A decision taken by the Board or an act performed under the authority of the Board is not invalid by reason only of a vacancy on the Board, or that a person who is not entitled to sit as a member of the Board sat as a member at the time when the decision was taken or the act was authorised, if the decision was taken or the act was authorised by the requisite majority

of the members of the Board who were present at the time and entitled to sit as members.

(5) Minutes of the proceedings of every meeting of the Board must be prepared and entered in a book kept for that purpose.

(6) Minutes of the proceedings of each meeting must be submitted at the next meeting of the Board and, if passed as correct, must be confirmed by the signature of the chairperson or other member presiding thereat and may, when so confirmed, be evidence in a court of law of the proceedings of the first-mentioned meeting.

(7) In the absence of the chairperson or the person acting as the chairperson from a particular meeting of the Board, the members present at that meeting may elect one of their number to preside at that meeting.

79G Committees of Board

(1) The Board may appoint one or more committees from among its members to assist it with the performance of its functions and exercise of its powers.

(2) The Board may appoint one or more specialist advisory committees consisting of members other than members of the Board, to assist it with the performance of its functions and exercise of its powers.

79H Appointment of Chief Executive Officer

(1) The Board must, in consultation with the Minister, subject to the laws governing the public service, appoint a fit and proper and suitably qualified South African citizen as the Chief Executive Officer of the Office.

(2) The Chief Executive Officer holds office for a term of five years and may be reappointed for one additional term of five years.
(3) (a) The appointment of a person as the Chief Executive Officer is subject to the conclusion of a written performance agreement entered into between that person and the Board, in consultation with the Minister.
(b) The Board, in consultation with the Minister, and the Chief Executive Officer may, in writing and by agreement, amend the performance agreement.
(4) The Board may, in consultation with the Minister, remove the Chief Executive Officer from office on account of serious misconduct, incapacity or incompetence, after affording him or her reasonable opportunity to be heard and subject to applicable legislation.
(5) If the Chief Executive Officer is unable to perform the functions of the Office, or during a vacancy in the office of Chief Executive Officer, the Board may, after consultation with the Minister, designate another employee of the Office to act as Chief Executive Officer.
(6) No person may be designated as acting Chief Executive Officer for longer than 90 days at a time.
(7) The Chief Executive Officer is entitled to the pension and retirement benefits calculated on the same basis as those of a head of a department in the public service.

79I Functions of Chief Executive Officer

(1) The Chief Executive Officer–

(a) is the head and accounting officer of the Office;
(b) is responsible for the proper and diligent implementation

of the Public Finance Management Act, 1999 (Act No. 1 of 1999); and

(c) must appoint suitably qualified persons as employees of the Office in accordance with an organisational structure approved by the Board in consultation with the Minister.

(2) As head of the Office, the Chief Executive Officer is responsible for–

(a) the formation and development of an efficient administration;
(b) the organisation and control of staff;
(c) the maintenance of discipline; and
(d) the effective deployment and utilisation of staff to achieve maximum operational results.

(3) The Chief Executive Officer may, after consultation with the Board, enter into contracts with any person or organisation or appoint expert or technical committees to assist the Office in the performance of its functions, including the conducting of inspections.

(4) The Chief Executive Officer must take appropriate action to ensure the implementation of the findings of the report and the recommendations of the Ombud referred to in section 81A(9).

(5) The Chief Executive Officer may, subject to subsection (4), request the intervention of the Minister, a member of the executive council responsible for health in the province or a member of the municipal council responsible for health if the complaint relates to a matter falling under the national department or that particular province or municipality, as the case may be.

79J Delegation of powers and assignment of duties by Chief Executive Officer

(1) The Chief Executive Officer may–

(a) delegate to an employee of the Office any of his or her powers in terms of this Act; or

(b) assign to an employee of the Office any of his or her duties in terms of this Act.

(2) The delegation in terms of subsection (1)–

(a) must be in writing;

(b) may be subject to such terms and conditions the Chief Executive Officer may determine or impose;

(c) may at any time be amended or revoked by the Chief Executive Officer; and

(d) does not divest the Chief Executive Officer of the responsibility concerning the exercise of the power.

79K Accountability of and reporting by Chief Executive Officer

(1) The Chief Executive Officer must, subject to the Public Finance Management Act, 1999 (Act No. 1 of 1999)–

(a) cause the necessary accounting and other records to be kept;

(b) in consultation with the Board, prepare and submit to the Minister an annual report for approval by the Minister within five months after the end of the financial year.

(2) The annual report referred to in subsection (1) must include–

(a) audited annual financial statements by the Auditor-General;
(b) the Auditor-General's report; and
(c) a detailed report of the activities of the Office undertaken during the year to which the audit relates.

(3) The Minister must table in Parliament a copy of the annual report, financial statements and the audit report on those statements within one month after receipt thereof if Parliament is in session or, if Parliament is not in session, within one month after the commencement of its next ensuing session.

(4) The Chief Executive Officer must, once the annual report, financial statements and audit report have been tabled in Parliament, make the annual report, financial statements and audit report on those statements accessible to the public.

(5) Notwithstanding subsections (1) and (2), the Board or Chief Executive Officer, as the case may be, must, upon request by the Minister–

(a) furnish the Minister with information or a report in respect of any case, matter or subject dealt with by the Office; and
(b) provide the Minister with reasons for any decision taken by the Board, Chief Executive Officer, an inspector or any other employee of the Office.

80 Appointment of health officers and inspectors

(1) The Minister, relevant member of the Executive Council or mayor of a municipal council may designate any person in the employ of the national department, province or municipality, as the case may be, as a health officer.

(2) The Chief Executive Officer must, subject to section 79I(1)(c), appoint any suitably qualified person with appropriate prescribed expertise and skill as an inspector.
(3) A health officer designated or an inspector appointed in terms of this section must be issued with a certificate stating that he or she has been designated or appointed, as the case may be, as a health officer or as an inspector in terms of this Act.
(4) When a health officer or an inspector performs any function in terms of this Act, he or she–

(a) must be in possession of a certificate of designation or certificate of appointment, as the case may be, issued in terms of subsection (3);
(b) must show that certificate to any person who is affected by the action of the health officer or inspector in terms of this Act; and
(c) has the powers of a peace officer, as defined in section 1 of the Criminal Procedure Act, 1977 (Act No. 51 of 1977), and may exercise any of the powers conferred on a peace officer by law.

81 Appointment of Ombud

(1) The Minister must, after consultation with the Board, appoint a suitably qualified and experienced South African citizen as Ombud.
(2) The Minister must, before appointing the Ombud in terms of subsection (1), by notice in the *Gazette* and in two or more nationally circulating newspapers in the Republic, invite applications from suitable persons.
(3) The Ombud–

(a) holds office for a non-renewable term of seven years;
(b) is located within the Office;
(c) is assisted by persons designated and seconded by the Office with the concurrence of the Ombud; and
(d) reports to and is accountable to the Minister.

(4) The Minister, with the concurrence of the Minister of Finance, must determine the remuneration and other terms and conditions of service of the Ombud.
(5) The Ombud may at any time resign by submitting a written notice to the Minister at least 90 days prior to the intended date of vacation of office, unless the Minister allows for a shorter period.
(6) The Minister may terminate the employment of the Ombud on account of serious misconduct, incapacity or incompetence, after affording him or her reasonable opportunity to be heard and subject to applicable legislation.
(7) The Minister must, during a vacancy or when the Ombud is unable to fulfil any of his or her functions, appoint a person on a temporary basis in accordance with subsection (1) to act in the position until a permanent person is appointed.

81A Functions of Ombud

(1) The Ombud may, on receipt of a written or verbal complaint relating to norms and standards, or on his or her own initiative, consider, investigate and dispose of the complaint in a fair, economical and expeditious manner.
(2) A complaint referred to in subsection (1) may involve an act or omission by a person in charge of or employed by a health establishment or any facility or place providing a health service.

(3) In conducting an investigation, the Ombud may, subject to subsection (8)–

(a) be assisted by any person contemplated in section 81(2)(c);
(b) (i) obtain an affidavit or a declaration from any person;
(ii) direct any person to appear before him or her;
(iii) direct any person to give evidence or produce any document in his or her possession or under his or her control which has a bearing on the matter under consideration or being investigated; and
(iv) interrogate such person;
(c) request an explanation from any person whom he or she reasonably suspects of having information which has a bearing on a matter under consideration or which is being or to be investigated; and
(d) require any person appearing as a witness to give evidence under oath or after having made an affirmation.

(4) A direction contemplated in subsection (3)(b) may be by way of a subpoena containing particulars of the matter in connection with which the person subpoenaed is required to appear before the Ombud and served on the person subpoenaed either by a registered letter sent through the post or by delivery by a person authorised thereto by the Ombud.

(5) If it appears to the Ombud that any person is being implicated in the matter being investigated, the Ombud must afford such person an opportunity to be heard in connection therewith by way of the giving of evidence, and such person is entitled, through the Ombud, to question other witnesses, determined by the Ombud, who have appeared before the Ombud in terms of this section.

(6) The Ombud may, when considering or investigating a complaint in terms of this section, require the assistance of or refer the complaint to any other authority established in terms of legislation or any other appropriate and suitable body or entity to investigate similar complaints.

(7) The authority, body or entity, as the case may be, contemplated in subsection (6) must provide–

(a) the Ombud with the assistance required; and
(b) report to the Ombud on the progress made in relation to complaints referred to it.

(8) No self-incriminating answer given or statement made by any person to the Ombud exercising powers in terms of this Act, is admissible as evidence against that person in criminal proceedings against that person instituted in any court, except in criminal proceedings for perjury or in which that person is tried for an offence contemplated in this Act, and then only to the extent that the answer or statement is relevant to prove the offence charged.

(9) After each investigation, the Ombud must submit a report together with his or her recommendations on appropriate action to the Chief Executive Officer.

(10) Where the Chief Executive Officer fails to act in accordance with the findings and recommendations of the Ombud, the Ombud may request the intervention of the Minister.

(11) The Ombud must, after the conclusion of an investigation, inform the complainant or the respondent or both, as the case may be, of his or her findings and recommendations.

81B Independence, impartiality and accountability of Ombud

(1) The expenditure connected with the appointment and functions of the Ombud is paid out of funds appropriated by Parliament for that purpose, as part of the budget of the Office.

(2) When dealing with any complaint in terms of this Act, the Ombud, including any person rendering assistance and support to the Ombud–

(a) is independent and impartial; and

(b) must perform his or her functions in good faith and without fear, favour, bias or prejudice.

(3) The Minister, national department and Office must afford the Ombud such assistance and support as may be reasonably necessary for the Ombud to perform his or her functions effectively and efficiently.

(4) The Ombud must, within one month after the end of the financial year, prepare a report on the affairs and functions of the Ombud during the financial year in question, and submit such report to the Minister for tabling in Parliament.

82 Inspections

(1) A health officer may enter any premises, excluding a private dwelling, whereas an inspector may enter any health establishment, at any reasonable time, and–

(a) inspect such premises or health establishment, as the case may be, 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 or health establishment to produce, for inspection or for the purpose of obtaining copies or extracts thereof or therefrom, any document, including any health record contemplated in section 15, which such person is required to maintain in terms of any law; and

(d) take samples of any substance or photographs relevant to the inspection.

(2) A health officer or an inspector 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 or an inspector may issue a compliance notice to the person in charge of the premises or health establishment, as the case may be, if any norm and standard or 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 a compliance certificate has been issued by the relevant authority.

(5) A health officer or an inspector 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 or health establishment, as the case may be; and

(b) subject to the Criminal Procedure Act, 1977 (Act No. 51 of 1977), return it as soon as practicable after achieving the purpose for which it was removed.

(6) The provisions of section 86A apply with the necessary changes required by the context to inspections conducted in terms of this section.

(7) A compliance certificate issued by the Office shall be valid for a period of no more than four years and must be renewed before or on the expiry date in a manner prescribed.

82A Non-compliance with prescribed norms and standards

(1) An inspector may issue a compliance notice to a person in charge of any health establishment if such establishment does not comply with any prescribed norm and standard.

(2) The notice contemplated in subsection (1) must set out–

(a) the health establishment to which the notice applies;
(b) any prescribed norm and standard that have not been complied with;
(c) details of the nature and extent of non-compliance;
(d) any steps that are required to be taken and the period over which such steps must be taken; and
(e) the penalties that may be imposed in the event of continued non-compliance.

(3) A compliance notice issued in terms of this section remains in force until the Office, on the basis of information furnished by the inspector, issues a certificate of compliance or until it is appealed against and set aside by the tribunal appointed in terms of section 88A(2)(a).

(4) If a person in charge of a health establishment to whom a compliance notice has been issued, fails to comply with the notice, the Office may as appropriate and taking into account the nature, extent, gravity and severity of the contravention–

(a) issue a written warning to achieve compliance within a set

period of time in a manner prescribed;

(b) require a written response from the health establishment regarding the continued non-compliance;

(c) recommend to the relevant authority any appropriate and suitable action to be undertaken, including the institution of disciplinary proceedings against persons responsible for the non-compliance or continued non-compliance;

(d) revoke the compliance certificate and recommend to the Minister the temporary or permanent closure of the health establishment or part thereof that constitutes a serious risk to public health or to health service users;

(e) impose upon that person or health establishment a fine as determined by the Minister in the *Gazette* from time to time; or

(f) refer the matter to the National Prosecuting Authority for prosecution.

(5) The Chief Executive Officer must inform the head of a national or provincial department, the municipal manager or the head of a health establishment of any persistent non-compliance.

83 Environmental health investigations

(1) If a health officer has reasonable grounds to believe that any condition exists which–

(a) constitutes a violation of the right contained in section 24(a) of the Constitution;[101]

(b) constitutes pollution detrimental to health;

[101] 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.

(c) is likely to cause a health nuisance; or
(d) constitutes a health nuisance,
the health officer must investigate such condition.

(3) 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.

(4) 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.

(5) 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 person who appointed a health officer in terms of section 80(1).

(6) Only a health officer who is registered as an environmental health practitioner in terms of the Health Professions Act, 1974 (Act No. 56 of 1974), may exercise any of the powers conferred under this section.

84 Entry and search of premises or health establishment with warrant by health officer or inspector

(1) A health officer or inspector may, where necessary, be accompanied by a police official and may, on the authority of a warrant issued in terms of subsection (5) and subject to sections 85 and 86A, enter any premises, including a private dwelling, or health establishment, as the case may be, specified in the warrant, 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 or health establishment.

(2) A health officer or an inspector who removes anything from the premises or health establishment being searched, as the case may be, must–

(a) issue a receipt for it to the owner or person in control of the premises or health establishment; 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 or an inspector acting in terms of a warrant issued in terms of subsection (5), the occupant and any other person present on the premises or health establishment, as the case may be, must–

(a) make available or accessible or deliver to the health officer or inspector any document, record, object or material which pertains to an investigation or inspection 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 or inspection; and
(c) render such reasonable assistance as the health officer or

inspector may require to perform his or her functions efficiently in terms of this Act.

(4) Before questioning any person at the premises or health establishment in question, the health officer, inspector 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 the premises or health establishment on or from which there is reason to believe an act has been or is being committed in contravention of this Act; 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 or health establishment of a contravention of this Act.

(6) The warrant may impose restrictions on the powers of the health officer or inspector.

(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, a health officer or an inspector under this section.

85 Identification prior to entry, and resistance against entry, by health officer or inspector

(1) A health officer or an inspector 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 or health establishment in question, as the case may be–

(a) audibly announce that he or she is authorised to enter the premises or health establishment and demand admission to the premises or establishment; and

(b) notify the person in control of the premises or health establishment 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 or inspector, as the case may be, must–

(a) hand to the person in control of the premises or health establishment 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 or health establishment, show his or her certificate of appointment as health officer or inspector to that person.

(3) A health officer or an inspector, as the case may be, or a 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 or health establishment.
(4) Before using force, the health officer or inspector, as the case may be, 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 or health establishment without warrant by health officer or inspector

A health officer or an inspector may, subject to section 86A, 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.

86A Constitutional right to privacy

Any entry upon or search of any premises or health establishment in terms of this Act must be conducted with strict regard to decency and good order, including–

(a) the right of a person to dignity;
(b) the right of a person to freedom and security; and
(c) the right of a person to privacy.

87 Disposal of items seized by health officer or inspector

A health officer or an inspector may dispose of anything seized in terms of section 84 or 86 in the manner provided for in Chapter 2 of the Criminal Procedure Act, 1977 (Act No. 51 of 1977).[102]

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

For the purposes of this Act, the head of a national or provincial department, the municipal manager or the head of a health establishment must be regarded as being–

(1) the owner and occupier of any premises or health establishment that the national or provincial department or the municipality occupies or uses; and

(2) 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–

  (a) performs any duty imposed upon an employer by or under this Act; or

  (b) exercises any power conferred upon an employer by or under this Act.

[102] Section 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.

88A Appeals against decisions of Office or Ombud

(1) Any person aggrieved by any decision of the Office or any finding and recommendation of the Ombud in relation to a matter regulated by this Act, or a person acting on his or her behalf, may within 30 days of him or her gaining knowledge of that decision, lodge a written appeal with the Minister.

(2) The Minister must, upon receipt of the appellant's written appeal contemplated in subsection (1)–

(a) appoint an independent *ad hoc* tribunal in terms of subsection (3);

(b) submit the appeal to the tribunal for adjudication in the prescribed manner.

(3) A tribunal contemplated in subsection (2) must consist of not more than three persons, of whom–

(a) one must be a person who is a retired judge of a High Court or a retired magistrate, who must be the chairperson; and

(b) two must be persons appointed on account of their knowledge of the health care industry.

(4) A tribunal contemplated in subsection (2)–

(a) may confirm, set aside or vary the decision of the Office or Ombud; and

(b) must notify the parties of its decision.

89 Offences and penalties

(1) A person is guilty of an offence if he or she–

(a) obstructs or hinders a health officer or an inspector who is performing a function or any other person rendering assistance or support to a health officer or an inspector under this Act;

(b) refuses to provide a health officer or an inspector with such information as that person is required to provide under this Act;
(c) knowingly gives false or misleading information to a health officer or an inspector;
(d) unlawfully prevents the owner of any premises or health establishment, or a person working for the owner, from entering the premises or health establishment in order to comply with a requirement of this Act;
(e) impersonates a health officer or an inspector;
(f) fails to comply with a compliance notice issued to him or her by a health officer or an inspector in terms of this Act;
(g) discloses any information acquired in the performance of any function in terms of this Act which relates to the financial or business affairs of any person, to any other person, except if–
(i) such 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; or
(h) interferes with, hinders or obstructs the Ombud or any other person rendering assistance or support to the Ombud when he or she is performing or exercising a function or power under this Act.

(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 10 years or to both a fine and such imprisonment.

Chapter 11
REGULATIONS

90 Regulations[103]

(1) The Minister, after consultation with the National Health Council or the Office, as the case may be, may make regulations regarding–[104]

(a) anything which may or must be prescribed in terms of this Act;

(b) (i) the fees to be paid to public health establishments for health services rendered; or
(ii) the fees to be paid to the Office for services rendered;

(c) the norms and standards for–
(i) the national health systems; or
(ii) specified types of protective clothing and the use, cleaning and disposal of such clothing;

(cA) the performance of the functions of the Board and the Office;[105]

(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;

[103] For a list of all regulations and draft regulations that had been published as of 22 February, 2013, see Appendix A.

[104] See note 7 above.

[105] See note 7 above.

(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;[106]

(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;[107]

(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) environmental health, including health nuisances and medical waste;[108]

(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;

[106] See Appendix A: Regulations: Cancer Registration (*Gazette* 34248, RG 9527, Notice 380), 26 April 2011.

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

[108] See note 7 above.

(r) health technology;
(s) health research;[109]
(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 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;[110]
(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

[109] See Appendix A: Regulations: National Health Research Ethics Council (*Gazette* 33574, RG 9382, Notice 839), 23 September 2010; Regulations: Establishment of the National Health Research Committee (*Gazette* 33575, RN 9383, Notice 840), 23 September 2010.

[110] The Minister of Health promulgated Regulations Relating to the Obtainment of Information and the Processes of Determination and Publication of Reference Price List in July 2007. These regulations were issued in terms of section 90(1)(u) and 90(1)(v). In *Hospital Association of South Africa and Others v Minister of Health and Others* [2010] ZAGPPHC 69 (28 July 2010), the court found that the regulations were invalid on both procedural and substantial grounds. The Minister has not yet promulgated new regulations in this regard.

(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.

(1A) The Minister may, after consultation with relevant regulatory authorities, prescribe different norms and standards for different types of health establishments.[111]

(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.[112]

(3) The Minister may, in any regulation made under this Act–

(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.

[111] See note 7 above.

[112] See Appendix A. As of 22 February, 2013, 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.

(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).[113]

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.[114]

(2) When establishing an advisory or technical committee, the Minister may determine by notice in the *Gazette*–

(a) its composition, functions and working procedure;

[113]The Regulations Relating to the Taking of Buccal Sample or Withdrawl of Blood from a Living Person for Testing: Amendment (*Gazette* 34750, RG 9624, Notice 944), 11 November 2011 was promulgated in terms of section 90(4)(c).

[114]The Minister of Health has established three advisory committees under section 91(1): The Advisory Committee on Reference Price Lists (established 11 April 2008) – which is no longer relevant following *Hospital Association of SA Ltd v Minister of Health and another; ER24 EMS (Pty) Ltd and another v Minister of Health and another; SA Private Practitioners Forum and others v Director-General of Health and others* [2011] 1 All SA 47 (GNP) but has not officially been disbanded – the National Health Insurance Advisory Committee (established 11 September 2009), and the National Advisory Committee on the Prevention and Control of Cancer (established 15 June 2012). The terms of reference for these committees can be found in Appendix A.

(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–
  (i) any person in the employ of the State; or
  (ii) 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 REPEALED[115]

(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	Section 1
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

[115] Despite 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

- 2 March 2012 – Regulations Relating to Categories of Hospitals *(Gazette 35101, Notice 185)*

  http://www.info.gov.za/view/DownloadFileAction?id=161177

- 2 March 2012 – Regulations Relating to Stem Cell Banks *(Gazette 35099, Notice 183)*

  http://www.info.gov.za/view/DownloadFileAction?id=161171

- 2 March 2012 – Regulations Relating to Tissue Banks *(Gazette 35099, Notice 182)*

  http://www.info.gov.za/view/DownloadFileAction?id=161173

- 2 March 2012 – Regulations Relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes *(Gazette 35099, Notice 181)*

  http://www.info.gov.za/view/DownloadFileAction?id=161169

- 2 March 2012 – Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes *(Gazette 35099, Notice 180)*

  http://www.info.gov.za/view/DownloadFileAction?id=161168

- 2 March 2012 – Regulations Relating to Blood and Blood Products *(Gazette 35099, Notice 179)*

  http://www.info.gov.za/view/DownloadFileAction?id=161166

- 2 March 2012 – Regulations Relating to the Registration of Microbiological Laboratories and the Acquisition, Importation, Handling, Maintenance and Supply of Human Pathogens *(Gazette 35099, Notice 178)*

  http://www.info.gov.za/view/DownloadFileAction?id=161174

- 2 March 2012 – Regulations Relating to the Use of Human Biological Material *(Gazette 35099, Notice 177)*

  http://www.info.gov.za/view/DownloadFileAction?id=161175

- 2 March 2012 – Regulations Regarding the Rendering of Clinical Forensic Medicine Services *(Gazette 35099, Notice 176)*

  http://www.info.gov.za/view/DownloadFileAction?id=161170

- 2 March 2012 – Regulations Relating to Artificial Fertilization of Persons *(Gazette 35099, Notice 175)*

  http://www.info.gov.za/view/DownloadFileAction?id=161172

- 11 November 2011 – Regulations Relating to the Taking of Buccal Sample or Withdrawal of Blood from a Living Person for Testing: Amendment *(Gazette 34750, Notice 944)*

  http://www.info.gov.za/view/DownloadFileAction?id=154413

- 26 April 2011 – Regulations Relating to Cancer Registration *(Gazette 34248, Notice 380)*

  http://www.info.gov.za/view/DownloadFileAction?id=145819

- 23 September 2010 – Regulations Relating the the Establishment of the National Health Research Committee *(Gazette 33575, Notice 840)*

  http://www.info.gov.za/view/DownloadFileAction?id=132307

- 23 September 2010 – Regulations Relating to the National Health Research Ethics Council *(Gazette 33574, Notice 839)*

  http://www.info.gov.za/view/DownloadFileAction?id=132263

- 23 July 2007 – Regulations Relating to the Obtainment of Information and the Processes of Determination and Publication of Reference Price List[116] *(Gazette 30110, GN 8722, Notice 681)*

  http://www.info.gov.za/view/DownloadFileAction?id=72288

- 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

Published Draft Regulations

- 13 April 2010 – Regulations Relating to Communicable Diseases *(Gazette 33107, RG 9266, Notice 287)*

  http://www.info.gov.za/view/DownloadFileAction?id=78099

[116] While these regulations have not been formally withdrawn, they are no longer relevant in light of the judgment in *Hospital Association of South Africa and Others v Minister of Health and Others* [2010] ZAGPPHC 69 (28 July 2010) where the court ruled them invalid on both procedural and substantive grounds.

- 7 March 2008 – Regulations Regarding the General Control of Human Bodies, Tissue and Organs for Transplantation *(Gazette 30828, Notice 320)*

  http://www.info.gov.za/view/DownloadFileAction?id=78099

- 23 February 2007 – Regulation Relating to Research on Human Subjects *(Gazette 29637, Notice 135)*

  http://www.info.gov.za/view/DownloadFileAction?id=72155

Published Notices

- 15 June 2012 – Call for the Establishment of a National Advisory Committee on the Prevention and Control of Cancer *(Gazette 35447, Notice 462)*

  http://www.info.gov.za/view/DownloadFileAction?id=167418

- 2 March 2012 – Policy on the Management of Public Hospitals *(Gazette 35101, Notice 186)*

  http://www.info.gov.za/view/DownloadFileAction?id=161164

- 11 September 2009 – Establishment of the National Health Insurance Advisory Committee *(Gazette 32564, Notice 903)*

  http://www.info.gov.za/view/DownloadFileAction?id=107622

- 11 April 2008 – Advisory Committee: Reference Price Lists[117]

  http://www.info.gov.za/view/DownloadFileAction?id=112902

[117] While the committee has not been formally disbanded, it is no longer relevant. See note 116 for more information.

Appendix B
Health Related Legislation and Important Policy Documents

Legislation

Allied Health Professions Act 63 of 1982

The Allied Health Professions Act provides for the control of the practice of allied health professions, and for that purpose establishes an Allied Health Professions Council of South Africa (AHPCSA). Allied health professions include the practice of ayurveda, Chinese medicine and acupuncture, chiropractic, homeopathy, naturopathy, osteopathy, phytotherapy, therapeutic aromatherapy, therapeutic massage therapy or therapeutic reflexology.

Like the Health Professions Act, various professional boards may be established to regulate the conduct of the professions. The Council receives complaints from members of the public but can delegate any inquiries or disciplinary proceedings to the relevant professional board.

Choice on Termination of Pregnancy Act 92 of 1996

The Choice on 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 for a child, see footnote 33.

Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007

The Criminal Law (Sexual Offences and Related Matters) Amendment Act reviewed and amended all aspects of the laws relating to sexual offences. The Act includes the right to access post-exposure prophylaxis (PEP) for a person who has been the victim of a sexual offence and who may have been exposed to HIV. PEP is a treatment regimen of anti-retroviral drugs that prevents the transmission of HIV if it is administered within 72 hours of the incident. The service is free at designated public health facilities. While the law requires a person to report a case of sexual assault to the police, failure to do so does not prevent such a person from accessing PEP at a designated health facility first. The regulations promulgated under this Act include provisions relating to HIV testing of alleged sex offenders.

Provisions of the Amendment Act that had the effect of criminalising consensual sex and sexual acts between teenagers were declared unconstitutional by the High Court on 15 January 2013.[118] The provisions required any health care worker or other person who becomes aware of such activity to report it to the police. The judgment ensures that children can seek sexual and reproductive information and services without fear of criminal sanction. Sexual violence perpetrated by or against children will still be prosecuted according to existing law.

[118] *The Teddy Bear Clinic for Abused Children and RAPCAN v Minister of Justice and Constitutional Development and National Director of Public Prosecutions* (Case No 73300/10) North Gauteng High Court.

Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972[119]

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 regulate 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. 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.[120]

[119]Following the publication of draft regulations relating to foodstuffs for infants, young children and children in 2007 and the subsequent submissions process (during which, the ALP and TAC made two submissions) updated Draft Regulations Relating to Foodstuffs for Infants, Young Children and Children were published for comment on 17 April 2012. As of 22 February, 2013, the draft regulations had not yet been finalised. The draft regulations are available at: http://www.info.gov.za/view/DownloadFileAction?id=163722 and the prior submissions 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 are available at: http://www.section27.org.za/nha/.

Regulations Relating to the Labelling and Advertising of Foodstuffs were published for comment on 1 March 2010 and subsequently amended on 19 January 2012 and came into effect. No pre-packaged foodstuff for sale may be manufactured, imported, sold or offered unless the foodstuff container is labeled in accordance with the regulations.

[120]For more on the definition of a medicine, see footnote 123 below.

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, traditional health practitioners, and allied health practitioners such as chiropractors. The Health Professions Act establishes the Health Professions Council of South Africa[121] 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. Practising in any of these fields without a licence is a criminal offence under the Act. The professional boards which have been established in terms of the Act are:

- Medical and Dental (and Medical Science) Professional Board
- Professional Board for Dental Therapy and Oral Hygiene
- Professional Board for Dietetics and Nutrition
- 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 and Arts Therapy
- Professional Board for Optometry and Dispensing Opticians
- 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

[121] The HPCSA's website is available at http://www.hpcsa.co.za.

Medical Schemes Act 131 of 1998[122]

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 selling any medical aid products to the public. All registered medical schemes must pay in full for the costs of diagnosis and treatment of specified medical conditions and chronic conditions called Prescribed Minimum Benefits (PMBs). The PMBs are set out in the Regulations under Medical Schemes Act, and include HIV/AIDS and other chronic conditions.

Medicines and Related Substances Act 101 of 1965

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 medicine[123] may not be sold or

[122] A 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 but there have been no subsequent developments on the bill.

In *Board of Health Care Funders of the Southern Africa (Association Incorporated under section 21 of the Companies Act 61 of 1973) & another v Council for Medical Schemes & others* [2012] JOL 28806 (GNP), the Board of Health Care Funders (BHCF) brought an application against the Council for Medical Schemes (CMS) and a range of medical schemes arguing that payment for PMBs should be done on the basis of the scheme's own tariffs and not the full invoice of the health care provider. The CMS argued that schemes are required to pay the full invoice cost and that patients shouldn't have to pay. The case, however, was not decided on the merits and so the issue may come before the courts again at some point in the future.

[123] '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–

advertised in South Africa unless it is 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 violations of the Act. The Treatment Action Campaign (TAC) and the South African Medical Assosiation (SAMA) won a judgment in the Western Cape in *Treatment Action Campaign and Another v Rath and Others* (12156/05) [20080 ZAWCHC 34; [2008] 4 All A 360 (C); 2007 (4) SA 563 (C) (13 June 2008) which held that the products being distributed by Mathias Rath as treatments for HIV were being distributed unlawfully. Additionally, the TAC and SAMA filed suit against the Minister of Health and the Director-General of the NDoH 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.[124]

In late 2008, Parliament passed the Medicines and Related Substances Amendment Act 72 of 2008, which dissolves the MCC and replaces it with the South African Health Products Regulatory Authority (SAHPRA), which will have broader authority to regulate

(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 midifying any somatic or psychic or organic function in man,

and includes any veterinary medicine.

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

medical products – such as medical devices – than the current MCC. However, this Amendment Act has not yet come into force. On 15 March 2012, the Minister of Health published the Draft Medicines and Related Substances Amendment Bill, 2012 for public comment. It includes technical amendments relating to the regulation of medical devices and provides for transitional arrangements to address the transition from the MCC to SAHPRA.[125]

The Regulations Relating to Transparent Pricing System for Medicines and Scheduled Substances are promulgated under the Medicines Act and set the dispensing fee that pharmacists may charge.[126] These regulations are intended to make medicines more affordable for everyone.

National Health Laboratory Service Act 37 of 2000

The National Health Laboratory Services Act establishes the National Health Laboratory Service (NHLS)[127] which is the consolidation of a number of previous institutes and centres. The NHLS now makes up the backbone for health laboratory testing in the public sector – including testing required for diagnosing HIV and TB such as CD4 count tests, viral load tests, and TB sputum microscopy and culture. Unfortunately, the NHLS has faced severe funding shortfalls in the last few years, resulting in severe delays in diagnostics and treatment of HIV and TB. This has a serious impact on health outcomes as people in need of urgent medical intervention, such as people with TB, are often lost to the health system altogether. Forensic chemistry laboratories

[125]The Draft Bill is available at: http://www.info.gov.za/view/DownloadFileAction?id=161875.

[126]Government Notice R1090 in *Government Gazette* 33775 of 19 November 2010.

[127]The NHLS website is available at http://www.nhls.ac.za

under the control of the National Department of Health and the forensic pathology laboratories under the control of the provincial departments responsible for health are not governed by this Act.

Nursing Act 33 of 2005[128]

The Nursing Act, like the Health Professions Act, regulates the registration and practice of nurses in the country. All practising nurses must be registered with the South African Nursing Council (SANC).[129] Practising without a license is a criminal offence under the Act.[130] Draft Regulations Relating to the Keeping, Supply, Administering, Prescribing or Dispensing of Medicine by Registered Nurses – which will make it easier for nurses to dispense ARVs – were published on 14 December 2011. In addition, policy is being developed to allow nurses to initiate and managed antiretroviral treatment (Nurse Initiated Management of Antiretroviral Treatment) following the successful STRETCH (Streamlining Tasks and Roles to Expand Treatment and Care for HIV) programme in the Free State Province between 2007 and 2010.[131] This will greatly increase the capacity of both the public and private health sectors to initiate more people on treatment and manage their care, which

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

[129]The 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.section27.org.za/nha/.

[130]The SANC's website is available at: http://www.sanc.co.za.

[131]See http://www.implementationscience.com/content/7/1/66.

is especially important in rural areas where there are fewer medical staff available to serve the public.

Pharmacy Act 53 of 1974

The Pharmacy Act regulates the registration, training, and practise of pharmacists in South Africa. All practising pharmacists, including pharmacy students, interns, technicians and assistants must be registered in terms of the Act in order to practise in South Africa. The Act also establishes the South African Pharmacy Council[132] 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. Practising as a pharmacist without a licence is a criminal offence under the Act.

Refugees Act 130 of 1998

The Refugees Act has been amended by the Refugees Amendment Act 33 of 2008 which provides that a refugee is entitled to full legal protection, which includes the rights set out in Chapter 2 of the Constitution – including the right to access to health care – except those rights that only apply to citizens (such as voting). The Amendment Act also provides that the rights in the Constitution apply in so far as they are applicable to asylum seekers. The Amendment Act has, however, not come into effect as of the 22 February, 2013. A National Directive was issued by the NDoH in 2007 which clarified that refugees and asylum seekers – with

[132]The Council's website is available at: http://www.pharmcouncil.co.za

or without identity documents – are able to access certain public health services, including ARVs without payment. This is subject to the person not being a member of a medical aid scheme.

Sterilisation Act 44 of 1998

The Sterilisation Act provides for the right to access sterilsation services in a health facility. The Act sets out the circumstances in which sterilisation may be performed, namely with or without consent. The age of consent for sterilisation is 18 years. Sterilisation may only be performed on a person younger than 18 years if failure to do so would jeopardise that person's life or seriously impair his or her health. The Act also covers sterilisation of people who are incapable of consenting or are incompetent to consent due to mental disability. There is no provision for sterilisation on the basis of the person being HIV-positive. There have been reported cases outside South Africa, in which health care workers either forced or coerced HIV-positive mothers to undergo sterilization based on a moral judgment about their suitability to be parents. No similar cases have been litigated in South Africa, however, such conduct would be unlawful not only in terms of the Sterilisation Act, but on the basis of every person's right to make autonomous decisions about their reproductive health care. Any contravention of the Act is a criminal offence and may be prosecuted.

Tobacco Products Control Act 83 of 1993

The Tobacco Products Control Act prohibits and restricts smoking in public places as well as regulating the sale and advertising of tobacco products. This includes regulating what information must be reflected on the tobacco products packaging. Draft regulations

relating to smoking in public places and outdoor public places were published on 30 March 2012 and comments on these draft regulations have resulted in robust debate between interested parties and the NDoH. The regulations further restrict the areas where smoking in public places is allowed. In *British American Tobacco South Africa (Pty) Ltd v Minister of Health (National Council Against Smoking as amicus curiae)* [2012] JOL 29239 (SCA) an application was brought by British American Tobacco (BAT) alleging that the Act unconstitutionally limited its right to communicate information concerning its tobacco products. The court held that BAT's constitutional freedom of expression was justifiably limited as the seriousness of the hazards of smoking far outweigh the interests of smokers as a group.

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 practise 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.[133]

[133]Regulations 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 and again on 22 August 2011. A copy of the 2011 regulations is available at: http://www.info.gov.za/view/DownloadFileAction?id=149279 including the form for nominations. 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/list.php?type=Policy%20Documents. Below, are links to some of the most important policies.

National Health Policy

National Development Plan, 2030: Promoting Health

One of the chapters in the National Planning Commission Department's National Development Plan is Promoting Health. The key points of this chapter are that greater intersectoral and interministerial collaboration is central to the Commission's proposals to promote health in South Africa. The Commission has identified reducing the disease burden to a manageable level as a major goal. Furthermore, the Commission has identified that human capacity is key and that there needs to be appropriate training and management, that health care professionals need to be produced in adequate numbers and deployed where most needed. Importantly, the Commission has identified that governance must be improved and infrastructure backlogs must be eliminated in order to strengthen the national health system as a whole. Lastly, the Commission is of the view that a national health insurance system should be implemented in phases, complemented by a reduction in the relative costs of private medical care and supported by better human capacity and systems in the public health sector.

http://www.info.gov.za/view/DynamicAction?pageid=623&myID=348761

National Department of Health Strategic Plan 2010/11 – 2012/13 (10-Point Plan)

The 10-Point Plan contain the priorities that are intended to assist the country in meeting the Millennium Development Goals and monitoring improvements in the health system.

The 10-Point Plan consists of the following priorities:

i Provision of Strategic leadership and creation of a social compact for better health outcomes;
ii Implementation of National Health Insurance (NHI);
iii Improving the Quality of Health Services;
iv Overhauling the health care system and improve its management;
v Improving Human Resources Management, Planning and Development;
vi Revitalisation of infrastructure;
vii Accelerated implementation of HIV & AIDS and Sexually Transmitted Infections National Strategic Plan 2007–11 and increase focus on TB and other communicable diseases;
viii Mass mobilisation for better health for the population;
ix Review of the Drug Policy; and
x Strengthening Research and Development.

http://www.section27.org.za/nha/

National Health Insurance (NHI) Green Paper

The NHI Green Paper was made available to the public in August 2011. It lays out a plan to fundamentally change the health care system in South Africa. The intention is that NHI will make available to everyone appropriate, efficient and quality health care

services at a price that they can afford. The health care system will transform into a single payer system in which a NHI Fund, likely to be funded by tax revenue, will pay for the health care services provided to anyone attending health care facilities, both public and private. The implementation of NHI is planned over a period of 14 years, starting with improving the quality of care available in many facilities and the piloting of aspects of NHI in ten pilot districts. Numerous comments on the Green Paper have been submitted to the Department of Health and the White Paper and Treasury Discussion Paper on the funding of NHI is expected in the first quarter of 2013.

http://www.section27.org.za/nha/

Negotiated Service Delivery Agreement, 2010–2014

The President has entered into a number of Negotiated Service Delivery Agreements (NSDAs) with particular sectors of government, including the NDoH. An NSDA is a charter that reflects the commitment of key sectoral and intersectoral partners linked to the delivery of identified outputs as they relate to a particular sector of government. The Government has agreed on 12 key outcomes as the key indicators for its programme of action for the period 2010–2014. For the health sector, the priority is improving the health status of the entire population and to contribute to Government's vision of 'A Long and Healthy Life for All South Africans'.

http://www.info.gov.za/view/DownloadFileAction?id=135747

Human Resources for Health South Africa: HRH Strategy for the Health Sector 2012/13 – 2016/17

This strategy is intended to ensure adequate human resources to address the country's health needs. This document sets out a strategic framework for the implementation of an effective HR policy and management. The document emphasises the re-engineering of the primary health care as a priority for the improvement of access to health.

http://www.info.gov.za/view/DownloadFileAction?id=152486

District Health Management Information System (DHMIS) Policy, 2012

This is the policy developed to meet the requirement in terms of the NHA for the NDoH to facilitate and coordinate the establishment, implementation and maintenance of the information systems by provincial departments, district health councils, municipalities and the private health sector at all levels to create a comprehensive national health information system. To ensure uniformity in the implementation and use of the DHMIS, the NDoH identified a need for the development of an overarching national policy with associated processes, standard operating procedures (SOPs), and norms and standards. This is the overarching policy for the DHMIS and should be read in conjunction with the SOPs once these have been published by the NDoH.

http://www.doh.gov.za/docs/policy/2012/dhmis.pdf

The Aid Effectiveness Framework for Health in South Africa, 2012

This framework is intended to be a tool whereby the NDoH guides its partnership activities with other national government departments, the provincial health departments, development partners, civil society organizations, labour and business. It is in essence a framework relating to service delivery.

http://www.doh.gov.za/docs/policy/2012/aideffect.pdf

National Drug Policy for South Africa, 1996

This policy is intended to set out the approach by which pharmaceutical services in South Africa are managed in order to ensure adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all who access medicines in South Africa as well as the rational use of drugs by prescribers, dispensers and consumers.

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

South African Declaration on the Prevention and Control of Non-Communicable Diseases, 2011

Following a summit on prevention and control of non-communicable diseases hosted by the NDoH in 2011, the declaration sets out goals including the creation of an intersectoral stakeholder forum similar to the South African National AIDS Council (SANAC) to implement strategy aimed at preventing and controlling non-communicable diseases in South Africa with a focus on tobacco use, consumption of alcohol, salt intake, obesity, blood pressure, cervical and prostate cancer, mental health and hypertension, diabetes and asthma. The Minister appointed a Medical Advisory

Committee on the Prevention and Control of Cancer to advise the Minister on interventions to address cancer.

http://www.doh.gov.za/docs/dcl/2011/draft_declaration_sa.pdf

Tshwane declaration of support for breastfeeding in South Africa, 2012

The NDoH convened the National Breastfeeding Consultative Meeting in 2012 which adopted a position to actively promote, protect and support exclusive breastfeeding as a health intervention to optimise child survival, irrespective of the mother's HIV status.

http://www.sajcn.co.za/index.php/SAJCN/article/viewFile/586/820

Integrated School Health Policy, 2012

The objective of the Integrated School Health Policy is to guide the provision of a comprehensive package of health care services at schools, which will be provided as part of the Primary Health Care package at a district level. The policy envisages each district establishing a team which is responsible for overseeing school health services.

http://www.doh.gov.za/docs/policy/2012/Integrated_School_Health_Policy.pdf

Policy Governing Health System Standards

National Core Standards for Health Establishments in South Africa, 2011

The Office of Standards Compliance developed these standards to assist in setting benchmarks of quality care against which delivery of services can be monitored.

http://www.section27.org.za/nha/

Policy on the Management of Public Hospitals, 2012

This policy was published by the Minister of Health after consultation with the National Health Council and is in line with the 10-Point Plan's strategy of overhauling the health care system and improving its management. The classification of hospitals is an important part of this policy.

http://www.section27.org.za/nha/

Policy on HIV, TB, and Communicable Diseases

National Strategic Plan on HIV, STIs and TB, 2012–2016

This document sets out the key strategic interventions of the national response to HIV, STIs and TB in South Africa for the five years spanning 2012–2016. It provides details of targets and programmes to achieve the long term vision of zero new HIV and TB infections; zero preventable deaths associated with HIV and TB; and zero discrimination associated with HIV and TB. The Cabinet and SANAC have approved it. Each province also has a strategic plan.

http://www.doh.gov.za/docs/stratdocs/2012/NSPfull.pdf

National HIV Counselling and Testing (HCT) Policy Guidelines, 2010

These policy guidelines are linked to the National Strategic Plan for HIV, STIs and TB. The guidelines seek to ensure that HCT is conducted in the most sensitive and caring way with specific attention to issues of human rights, quality and access.

http://www.section27.org.za/nha/

The National Infection Prevention and Control Policy & Strategy, 2007

This policy aims to establish a framework for improving the management of health care associated infections at all levels of healthcare from national through to district level.

http://www.doh.gov.za/docs/policy/2007/ipc-policy.pdf

Policy and Guidelines for the Implementation of the Prevention of Mother-to-Child Transmission (PMTCT) Programme, 2008

The aim of the PMTCT programme is to ensure primary prevention of HIV especially among women of childbearing age and to integrate PMTCT interventions into routine maternal, child and women's health services.

http://www.doh.gov.za/docs/policy/2008/pmtct.pdf

Clinical Guidelines: PMTCT, 2010

The revised 2010 PMTCT Guidelines serve as a guide to health practitioners with regard to the comprehensive management of pregnant women who are HIV-positive.

http://www.section27.org.za/nha/

South African Antiretroviral Treatment Guidelines, 2010

The objectives of these guidelines are to ensure timely initiation of ARVs for treatment and prevention, to minimise unnecessary drug toxicities and to contribute to strengthening the health sector's capacity to delivery health services.

http://www.section27.org.za/nha/

Guidelines for the Management of HIV in Children, 2010

These guidelines serve as guidance to health practitioners with regard to comprehensive management of children living with HIV. ART regimens are described in the guidelines as well as laboratory and clinical monitoring at diagnosis, initiation of antiretroviral treatment and whilst on treatment.

http://www.section27.org.za/nha/

Code of Good Practice on HIV and AIDS and the World of Work, 2012

The Minister of Labour published this Code on the advice of the Commission for Employment Equity in terms of the Employment Equity Act 55 of 1998. The focus of the code is broad and includes HCT, disclosure, and management of HIV and AIDS in the workplace. It also includes measures to address discrimination on the basis of HIV status in the workplace.

http://www.info.gov.za/view/DownloadFileAction?id=167203

The Draft National Infection Prevention and Control Policy for TB, MDR-TB & XDR-TB, 2007

The goal of this policy is to help health care facility management and staff minimise the risk of TB transmission in their facilities and other facilities where the risk of transmission of TB may be high due to high prevalence of both diagnosed and undiagnosed TB, such as prisons.

http://www.section27.org.za/nha/

Management of Drug-Resistant Tuberculosis – Policy Guidelines, 2012

These policy guidelines are for use by health care professionals involved in the task of managing mono- and poly-resistant TB, MDR- and XDR-TB patients. They focus on the clinical management; referral mechanisms; models of care; psychosocial support to ensure comprehensive management of the patients; strategies for infection prevention and control and occupational health services for health care workers.

http://www.doh.gov.za/docs/policy/2012/TBpolicy.pdf

Multi-Drug Resistant Tuberculosis: A Policy Framework on Decentralised and Deinstitutionalised Management for South Africa, 2011

Decentralised DR-TB treatment offers more effective treatment for the patient by taking social and family pressures into consideration. It also avoids the need for a person to spend an extremely lengthy period in hospital. The policy explains the rationale and protocols for such an approach.

http://www.doh.gov.za/docs/policy/2011/policy_TB.pdf

Appendix C
Contact information for important regulatory councils, oversight bodies, and other health organisations

NATIONAL STRUCTURES

National Department of Health (NDoH)

National Department of Health Switchboard

Mail: Private Bag X828, Pretoria, 0001
Tel: (012) 395 8000
Fax: (012) 395 9165
Website: www.doh.gov.za

Office of the Director-General

Mail: Private Bag X828, PRETORIA, 0001
Tel: (012) 395 9150
E-mail: ngobet@health.gov.za (appointments)
E-mail: khanyv@health.gov.za (enquiries and correspondence)

SECTION27 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.

Allied Health Professions Council of South Africa (AHPCSA)

Tel: (012) 329 4001
Fax: (012) 329 2279
E-mail: info@ahpcsa.co.za (account and general enquiries)
E-mail: registrar@ahpcsa.co.za (complaints)
Website: http://www.ahpcsa.co.za

Council for Medical Schemes (CMS)

Mail: Private Bag X34, Hatfield, 0028
Tel: (012) 431 0500
Fax: (012) 430 7644
E-mail: support@medicalschemes.com
Website: www.medicalschemes.com

Health Professions Council of South Africa (HPCSA)

Client Care Centre

Mail: P O Box 205, Pretoria, 0001
Tel: (012) 338 9300/9301
Fax: (012) 328 5120
E-mail: info@hpcsa.co.za
Website: http://www.hpcsa.co.za

Medical Research Council (MRC)

Mail: PO Box 19070, Tygerberg, 7505
Tel: (021) 938 0911
Fax: (021) 938 0200
E-mail: info@mrc.ac.za
Website: http://www.mrc.ac.za

Medicines Control Council (MCC)

Mail: Private Bag X828, Pretoria, 0001
Tel: (012) 395 8000
Fax: (012) 395 9201
Website: http://www.mccza.com

National Health Research Committee (NHRC)

Tel: (012) 395 9029
Fax: (012) 632 5479
E-mail: KgasiM@health.gov.za
Website: http://www.nhrc.org.za

National Health Research Ethics Council (NHREC)

Secretariat:

Ms Khanyisa Nevhutalu
Tel: (012) 395 8125
Fax: (086) 632 7341
E-mail: nhrec@health.gov.za
Website: http://www.uhrec.org.za

South African National AIDS Council (SANAC)

Tel: (012) 395 9100
E-mail: communications@sanac.org.za
Website: http://www.sanac.org.za

South African Nursing Council (SANC)

Mail: P O Box 1123, Pretoria, 0001
Tel: (012) 420 1000
Fax: (012) 343 5400
E-mail: registrar@sanc.co.za
Website: http://www.sanc.co.za

South African Pharmacy Council

Tel: (086) 172 7200
Fax: (012) 321 1492/79
E-mail: customercare@sapc.za.org
Website: http://www.sapc.za.org

EASTERN CAPE

Eastern Cape Department of Health

Mail: Private Bag X0038, Bisho, 5605
Tel: (040) 608 1000
Fax: (040) 609 3892

Alfred Nzo Health District

Tel: (039) 727 4462
Fax: (039) 727 1044

Amathole Health District

Tel: (043) 722 2194
Fax: (043) 743 0032

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

(NHI Pilot 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, Bloemfontein, 9300
Tel: (051) 408 1103
Fax: (051) 408 1566
Website: http://www.fshealth.gov.za

Fezile Dabi Health District

Tel: (016) 970 9371
Fax: (016) 970 9333
E-mail: modikoso@fshealth.gov.za

Lejweleputswa Health District

Tel: (057) 910 3326/27
Fax: (086) 545 1598

Motheo Health District

Tel: (051) 447 2194
Fax: (051) 430 0238
E-mail: kgasanen@fshealth.gov.za

Thabo Mofutsanyane Health District

(NHI Pilot District)

Tel: (058) 713 2154
Fax: (058) 713 2154
E-mail: dlaminmg@fshealth.gov.za

Xhariep Health District

Tel: (051) 447 2777
Fax: (051) 447 1036 / (086) 723 4877
E-mail: moatlhodil@fshealth.gov.za

GAUTENG

Gauteng Department of Health

Mail: Private Bag X35, Johannesburg, 2000
Tel: (011) 355 3000 / 2222 / 7633 / 7650 / 7636 / 7633
Fax: (011) 355 3811 / 7633
Website: http://www.health.gpg.gov.za

Ekurhuleni Health District

Tel: (011) 876 1700 / 1800
Fax: (011) 876 1818

Johannesburg Metro Health District

Tel: (011) 407 7513
Fax: (011) 339 2866
Website: http://www.joburg.org.za

Sedibeng Health District

Tel: (016) 950 6000
Fax: (016) 950 6016

Tshwane-Metsweding Health District

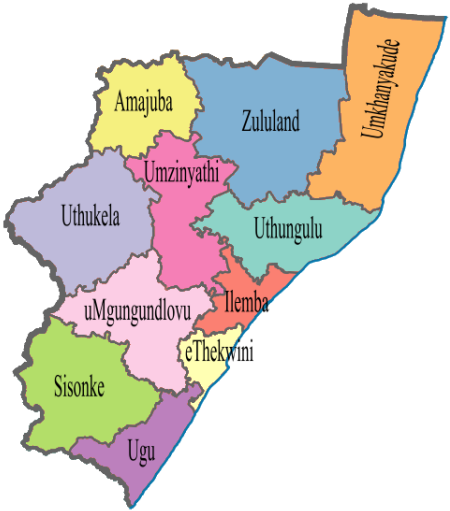
(NHI Pilot District)

Tel: (012) 303 9012 / 393 9600
Fax: (012) 323 2259

West Rand Health District

Tel: (011) 953 2152 / 1090
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
Website: http://www.kznhealth.gov.za

Amajuba Health District

Tel: (034) 328 7000
Fax: (034) 315 1092
E-mail: nonhlanhla.khyzwayo2@kznhealth.gov.za

eThekwini (Durban) Health District

Tel: (031) 240 5300
Fax: (031) 240 5504
E-mail: mtsheutshela.mbuso@kznhealth.gov.za

Ilembe Health District

Tel: (032) 437 3500
Fax: (032) 551 1590
E-mail: bonie.ndlele@kznhealth.gov.za

Sisonke Health District

Tel: (039) 834 8200 / 8300
Fax: (039) 834 1301 / 1305
E-mail: zwide.ndwandwe@kznhealth.gov.za

Ugu Health District

Tel: (039) 688 3000
Fax: (039) 682 6296
E-mail: khulekani.msomi@kznhealth.gov.za

uMgungundlovu Health District

(NHI Pilot District)

Tel: (033) 897 1000
Fax: (033) 897 1078
E-mail: musawenkosi.mncwabe@kznhealth.gov.za

Umkhanyakude Health District

Tel: (035) 572 1327
Fax: (035) 572 1251
E-mail: makho.themba@kznhealth.gov.za

Umzinyathi Health District

(NHI Pilot District)

Tel: (034) 299 9100
Fax: (034) 212 4800
E-mail: jabulani.mndebele2@kznhealth.gov.za

Uthukela Health District

Tel: (036) 631 2202
Fax: (036) 631 2217
E-mail: bonga.hlomuka@kznhealth.gov.za

Uthungulu Health District

Tel: (035) 787 0633
Fax: (035) 787 0646
E-mail: sibongisemi.mangele@kznhealth.gov.za

Zululand Health District

Tel: (035) 874 2381
Fax: (035) 874 2457
E-mail: thabisile.ngcobo@kznhealth.gov.za

LIMPOPO

Limpopo Department of Health and Social Development

Mail: Private Bag X9302, Polokwane, 0700
Tel: (015) 293 6000
Fax: (015) 293 6211
Website: http://www.dhsd.limpopo.gov.za

Capricorn District

Tel: (015) 290 9000
Fax: (015) 291 1568

Greater Sekhukhune District

Tel: (015) 633 2300
Fax: (015) 633 7927

Mopani District

Tel: (015) 811 6500
Fax: (015) 812 1529

Vhembe District

(NHI Pilot District)

Tel: (015) 962 1000
Fax: (015) 962 2373

Waterberg District

Tel: (015) 718 1483
Fax: (014) 717 1429

MPUMALANGA

Mpumalanga Department of Health and Social Development

Mail: Private Bag X11285, Nelspruit, 1200
Tel: (013) 766 3428 / 29 / 30
Fax: (013) 766 3458
Website: http://www.mpumalanga.gov.za/dept/health_social_developmen
htm

Ehlanzeni District

Tel: (013) 752 3585 / 759 8500
Fax: (013) 752 7498

Gert Sibande District

(NHI Pilot 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: Private Bag x2068, Mmabatho, 2735
Tel: (018) 388 3805 / 3774
Fax: (018) 387 5794
Website: http://www.dohsoc.nwpg.gov.za/NWDoH/

Bojanala Health District

Tel: (014) 592 3472 / 8426 / 8427
Fax: (014) 592 7319 / 9224

Dr Ruth Sekgomotsi Mompati Health District

Tel: (053) 927 0456
Fax: (053) 927 0009

Ngaka Modiri Molema Health District

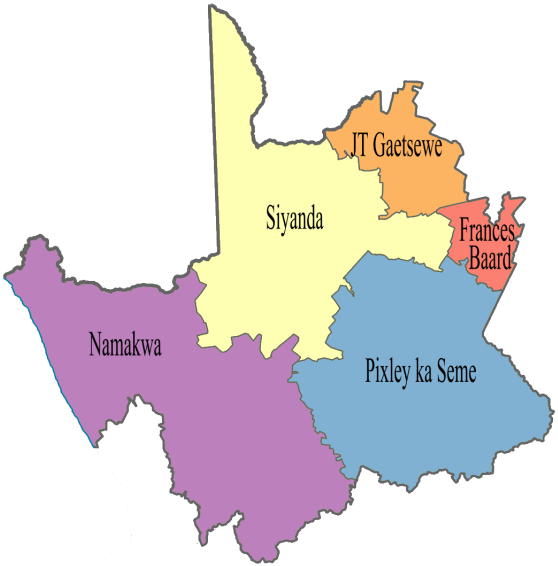
Tel: (018) 384 0240
Fax: (018) 392 1655

Dr Kenneth Kaunda Health District

(NHI Pilot 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

JT Gaetsewe 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

(NHI Pilot 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 3235
Fax: (021) 483 6169
Website: http://www.westerncape.gov.za/eng/your_gov/305

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

(NHI Pilot District)

Tel: (044) 803 2707
Fax: (044) 873 5929

West Coast Winelands Health District

Tel: (022) 487 9210
Fax: (022) 487 1775






Making local government work

an activist's guide

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SECOND EDITION

THE NATIONAL HEALTH ACT A GUIDE

In 2003 the National Health Act (NHA) was 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, which places express obligations on the state to progressively realise rights of access to health care services within its available resources. This book provides the latest information on laws, policies and court judgments that affect the right to health services and will be useful to users of health care services, health care providers, students, lawyers and others. It aims to make the NHA more accessible to people who use health care services and to empower them to demand the full implementation of their rights under the NHA and under the Constitution.

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