THIRD EDITION

THE NATIONAL HEALTH ACT GUIDE

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THE National Health Act GUIDE

THIRD EDITION

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National Health Act Guide

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Foreword

The National Health Act Guide, now in its third edition, is an invaluable resource for government, health care workers, health service users, academics, students and civil society. The *Guide* contains not only the Act itself but also detailed analysis and commentary, including links to and explanations of related legislation, regulations and policy. The *Guide* also contains an up-to-date list of contact details for all health departments in the country.

The National Health Act Guide focuses on what all of us can do to improve health in South Africa: from participation in clinic committees and hospital boards, to becoming organ donors, to taking part in the budget- and policy-making process.

Government has a huge responsibility to provide health care services and to regulate the private sector, but it cannot operate alone. Civil society and individuals must speak up and government must listen, to ensure that we have a health care system that serves all the people of South Africa.

At a time of great policy shifts and a struggling health care system, which is both public and private, I welcome the publication of the third edition of *The National Health Act Guide*. I encourage everyone with an interest in health to use the *Guide* and to become an activist for positive change in our health care system. This publication must be on every policy maker's table, on every manager's desk, in every health worker's pocket, and in every student's bag.

Malebona Precious Matsoso
Director-General of the National Department of Health
March 2019

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Contents

List of Acronyms

AGYW	Adolescent Girls and Young Women
AIDS	Acquired Immune Deficiency Syndrome
AHPCSA	Allied Health Professions Council of South Africa
ANC	Antenatal care
ART	Antiretroviral Therapy
CEO	Chief Executive Officer
CMS	Council for Medical Schemes
DHB	District Health Barometer
DHMIS	District Health Management Information System
DR-TB	Drug Resistant Tuberculosis
GBV	Gender-based violence
HCT	HIV Counselling and Testing
HIV	Human Immunodeficiency Virus
HPCSA	Health Professions Council of South Africa
HPV	Human Papilloma Virus
HRH	Human Resources for Health
KP	Key population
LGBTQIA+	Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual and Others
MCC	Medicines Control Council (now South African Health Products Regulatory Authority)
MDR-TB	Multi-Drug-Resistant Tuberculosis
MEC	Member of the Executive Committee
MRC	Medical Research Council
MSM	Men who have sex with men
NAPHISA	National Public Health Institute of South Africa
NHREC	National Health Research Ethics Council
NHA	National Health Act

NHI	National Health Insurance
NHLS	National Health Laboratory Service
NHRC	National Health Research Committee
OHSC	Office of Health Standards Compliance
PEP	Post-exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PFMA	Public Finance Management Act 1 of 1999
PMB	Prescribed Minimum Benefit
PMTCT	Prevention of Mother to Child Transmission
PrEP	Pre-exposure Prophylaxis
SAMA	South African Medical Association
SANC	South African Nursing Council
SRHR	Sexual and Reproductive Health and Rights
STI	Sexually Transmitted Infections
TAC	Treatment Action Campaign
TB	Tuberculosis
ToP	Termination of Pregnancy
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organisation
XDR-TB	Extensively Drug-Resistant Tuberculosis

Introduction

This third edition of *The National Health Act Guide* comes at a time of great flux in the health care system and the health policy landscape. Since the first edition (2008) and second edition (2013) of this *Guide*, new strategies, legislation and regulations have been produced to govern matters of health care in South Africa. Some important examples include the National Development Plan: Vision 2030, with its chapter on health;[1] the Ward-Based Primary Health Care Outreach Team Policy 2018/19 to 2023/24,[2] which standardises the employment of and conditions relating to community health workers; and the promulgation of the National Health Amendment Act in 2013, which brought the Office of Health Standards and the Health Ombud into existence. Perhaps even more significantly, the draft National Health Insurance Bill and the Medical Schemes Amendment Bill have both been approved by the South African Cabinet, and the Provisional Report of the Competition Commission Market Inquiry into the Private Health Sector has been published, paving the way for fundamental change to the structure and funding of health care in South Africa.

This health legislation and policy change is located in the context of the continued and deepening weakness of a divided health care system. The public health sector is overburdened by patients with a limited choice of health care options, and crippled by severe mismanagement fault lines, deep-seated corruption, historic underdevelopment, and instances of poor policy choices, including the poor implementation of sound policies.

[1] https://www.nationalplanningcommission.org.za/Documents/devplan_ch10_0.pdf

[2] https://rhap.org.za/wp-content/uploads/2018/04/Policy-WBPHCOT-4-April-2018-1.pdf

The private health sector is increasingly expensive, unaffordable for most, insufficiently regulated, and is not measured to ensure that its services are of a high quality and also meet other standards.

This edition of the *Guide* comes at an appropriate time, allowing us to reflect on the legal landscape in health care provision, and the overall health care system in South Africa.

Users of health facilities, health care providers and health activists must have a clear understanding of the legal framework that guides South Africa's health care system. This knowledge empowers us to take advantage of opportunities for input, activism and change.

We hope that this third edition of *The National Health Act Guide* not only serves as an update, but also makes the National Health Act (NHA) more accessible to a wide range of actors, including activists, health care users and providers, government and the private sector.

Big changes on the health care system horizon

2019, the year of publication of the third edition of this *Guide*, could be a year of significant change for the South African health system.

National Health Insurance (NHI) has been discussed and debated for a long time but, in late 2018, a draft Bill was approved by Cabinet and was the subject of a public consultation process. The National Health Insurance Bill envisages wide-ranging changes to the health care system, including the development of an NHI Fund that will pay for the health care services of all South Africans (excluding most non-nationals). In terms of the Bill, health care users will access services from accredited providers, either in the public sector or the private sector, and will be entitled to receive services from a package of services that is yet

to be defined. The Bill envisages the establishment of a number of institutional structures, including District Health Management Offices and Contracting Units for Primary Care, both of which are responsible for the organisation of services.

Unfortunately, there are some serious problems with the Bill as it is currently drafted, and with the health care system that it seeks to establish. Insufficient attention is paid to governance, particularly of the NHI Fund and the various structures established. The Minister of Health has governance, management and decision-making functions in respect of too many of the structures and institutions, and this leads to over-centralisation. Quality control is not given sufficient consideration, and the majority of non-nationals are excluded from any coverage, which constitutes an unacceptable regression in access to health care services. We await further developments with regard to the Bill and the changes that it may effect.

The Medical Schemes Amendment Bill was approved by Cabinet at the same time as the NHI Bill was approved. This Bill seeks to make changes to medical schemes and the regulation thereof. This Bill is however no longer a priority as the findings of the Competition Commission's Health Market Inquiry are still awaited. The Commission has been investigating the private health sector since January 2014. The Preliminary Report of the Health Market Inquiry made a series of far-reaching recommendations for quality monitoring and improved regulation of the private health care sector, among other recommendations. On 23 January 2019, the Competition Commission announced that the work of the Inquiry would be postponed until April 2019, due to budgetary constraints. This apparent deficit of political will is of great concern as a failure to implement the recommendations, which are the result of years of evidence assessment and data analysis, will disadvantage health services users.

Finally, the National Public Health Institute of South Africa (NAPHISA) is a public entity that will be created by the National Public Health Institute of South Africa Bill, first published in 2017. NAPHISA will perform health surveillance functions and strengthen the epidemiology of communicable diseases, non-communicable diseases, occupational health and safety, cancer, injury and violence prevention, and environmental health, among other functions. At the time of publication, the Bill is being considered by the National Council of Provinces, which is the final step before signature by the President. If the Bill is passed, NAPHISA should strengthen South Africa's surveillance of and ability to mitigate the effects of a range of public health risks.

The 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 provides as follows:

Health care, food, water, and social security

(1) Everyone has the right to have access to—
  (*a*) health care services, including reproductive health care;
  (*b*) sufficient food and water; and
  (*c*) social security, including, if they are unable to support themselves and their dependents, appropriate social assistance.

(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights; and

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

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

- An inability to access nutritious food affects health and access to health care services: children whose growth is stunted due to undernutrition and people who are obese due to over- or poor nutrition will experience health problems and this places a strain on the health care system.
- If patients who access health services are examined or physically exposed in front of others in a health facility or have their personal medical information shared improperly, then their rights to privacy and to dignity are infringed.
- The right to equality requires equal access to health care services, which means that all individuals, including people who are not citizens of South Africa, should be provided with health care services.
- Enjoying the right to health, and the right to exercise autonomy in decisions related to one's own health (in line with the rights to bodily integrity and security of the person), may mean that one requires access to one's own medical records from a health facility or elsewhere in order to lodge a complaint or to give consent for medical treatment.

In short, the right to health is not fully realisable without other constitutional rights being realised.

Section 27 is also not the only section of the Constitution that deals with health. Section 28 provides that every child has the right to 'basic nutrition, shelter, basic health care services and social services'. This right is not subject to progressive realisation or available resources, which means that the right is immediately realisable. The health needs of people who are arrested or detained are specifically provided for in section 35(2), which

provides for medical treatment at state expense and the detainee's right to be visited by his or her chosen medical practitioner.

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.

The National Health Act as the foundational law on health

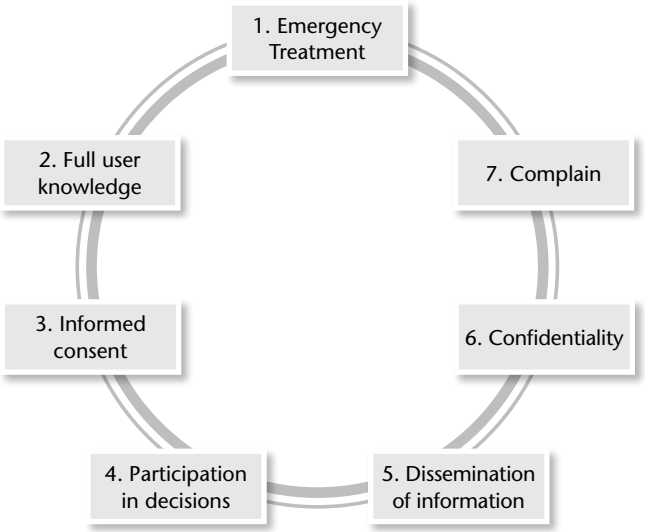
The National Health Act (NHA) sets out the structure of the health care system, delineating power and responsibility at national level, provincial level and district level, and providing for public and private components to the system. The Act is designed to create the framework for delivering health care services, including the duty on the Minister under section 3 to 'promote the inclusion of health services in the socio-economic development plan of the Republic', and providing for the rights and duties of health care personnel, the governance of health facilities, the quality of health care services, and human resources planning, among others.

As with every piece of legislation, the NHA cannot contain everything. Section 90 of the NHA provides for the Minister to make regulations on a long list of issues. Other Acts and policies deal with specific aspects of health law and the health system, including health care workers, medicine registration, mental health, traditional health practitioners, and abortion, among others. Health-related legislation is listed in Appendix B.

The full promulgation of the NHA has taken a long time with, for example, the provisions relating to the Office of Health Standards Compliance being promulgated only in 2015. With the intended reorganisation of the health care system under the National Health Insurance Act, it is unclear what the future is for the NHA.

Rights within the health care system

The NHA includes a large set of patient rights. We highlight and explain some of these rights in the diagram and commentary below:



Emergency medical treatment

In line with section 27(3) of the Constitution, section 5 of the NHA provides that no one may be refused emergency medical treatment by a health care provider, health worker or health establishment.

People may need emergency medical treatment for many different reasons, for example, when they sustain injuries due to

motor accidents, are victims of violence, or sustain burns in fires. In such situations ,they will require urgent attention from the nearest health facility, public or private. The right not to be refused emergency medical treatment means that there is an obligation on all health facilities, including private facilities or providers, to stabilise a person in need of emergency medical treatment *before* requiring them to pay. This is important to note, because it means that in an emergency you cannot be turned away from a private health facility simply because you are unable to pay.

On 1 December 2017, the Regulations relating to Emergency Medical Services (http://section27.org.za/wp-content/uploads/2018/02/EMS-Regulations-2017.pdf) were published by the National Department of Health (NDoH). Emergency medical services providers (including ambulances) in the public and private sectors are required to be licensed from December 2018, which entails compliance with certain standards. This is a welcome development in policy but will not address all the problems in accessing emergency medical services, such as provinces having insufficient vehicles and insufficient human resources to run the service. Such problems require better planning and budgeting from provincial departments of health, in line with the obligation not to refuse emergency medical treatment.

Full user knowledge, informed consent and participation in decisions

The right to full user knowledge includes knowledge about your health status, the range of procedures available to you, the risks, costs and benefits of those procedures, and the right to refuse treatment. This right recognises the autonomy of the patient and the power imbalances between patients and health providers. The patient must be able to choose what is best for him or her, having been provided with the information needed to make such

a choice, rather than the doctor making choices for an unwitting or uninformed patient.

The right to informed consent is linked to the right to full user knowledge, and is important to prevent medical procedures being performed on people without their knowledge and considered agreement.

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 state that you have the right to participate in making any decisions regarding what treatment you want, and that you must consent before you are treated, unless it is an emergency and you are unable 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 these cases there is an obligation on the provincial department of health to monitor the person's treatment to ensure that his or her rights are respected.

A person can be forcibly admitted to a health establishment or forced to receive treatment only 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 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 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 contained in the Sexual Offences Act and its regulations, not in the NHA.

Dissemination of information

Appropriate, adequate and comprehensive information must be distributed by provincial departments, districts and municipalities about all aspects of health services that would be useful to the public. This includes information about your rights and duties, timetables for access to services, types of services available at facilities, and complaints procedures. Such information should be available at health facilities and more generally. Further information can be found in section 12 of the NHA. The kind of information described in this section is frequently unavailable, making use of the health care system difficult.

Laying of complaints

The right to complain and to have a complaints procedure through which to do so is at the very core of our legal system, as is the right to advocate for rights generally. Effective complaints mechanisms are central to the functioning of health care facilities and are therefore part of everyone's right to access health care services.

Section 18 of the NHA gives people the right to complain about how they have been treated by a health facility. The procedures to follow in laying a formal complaint should 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.

Since 2013, an additional avenue for complaints about health facilities has been available in the Office of Health Standards Compliance (OHSC) and the Health Ombud, provided for in Chapter 10 of the NHA. The work of the OHSC focuses specifically on resolving matters related to health establishments, and not matters relating to individual health professionals. The procedures for the referral of complaints to the OHSC or the Health Ombud can be found at http://healthombud.org.za/submit-complaint/.

Where a complaint concerns the conduct of or treatment by a particular health professional, a patient can lay a complaint with the Health Professions Council of South Africa (HPCSA), using the procedure that can be found here: http://www.hpcsa.co.za/Complaints. The HPCSA is required to investigate the complaint and may hold a hearing about the complaint, at which the complainant will have to testify.

In addition to health-specific complaints channels, there are other opportunities to complain, either to institutions supporting democracy or to independent human rights organisations.

Chapter 9 of the Constitution establishes the Public Protector (section 182) and the South African Human Rights Commission (section 184). These bodies have a number of functions, which include receiving and investigating complaints about the functionality of and conduct of public servants at state institutions. The details about laying a complaint can be found here: http://www.pprotect.org/?q=content/complaint-process and here: https://www.sahrc.org.za/index.php/what-we-do/lodge-complaints.

Organisations such as SECTION27, the Treatment Action Campaign and the Rural Health Advocacy Project, among others, are independent human rights-based organisations that work on

realising the right of access to health care services and can be contacted for assistance or advice. Further information and contact details can be found here:

- SECTION27 — 011 356 4100; www.section27.org.za
- Treatment Action Campaign — 011 100 4721; www.tac.org.za
- Rural Health Advocacy Project — 010 601 7427; www.rhap.org.za

Community involvement in the health care system

The Constitution requires that government proactively attempts to involve us all in not only voting for the government, but in the daily running of the government. The Constitutional Court has described our country as a 'participatory democracy', that is, one in which we do not simply hand over control of our country and the use of public resources to our elected representatives between elections. Instead, we can participate in processes, which include making public services work efficiently every day. Section 195 of the Constitution requires that all public servants, including health care professionals, must ensure that 'people's needs must be responded to, and the public must be encouraged to participate in policy-making.' The importance of community participation in the running of health care facilities should be understood in this context. The NHA sets up several bodies that allow for the public to be involved in the governance of health care facilities and the system as a whole.

Clinic and community health centre committees

Section 42 of the NHA provides that clinic and community health centre committees should be created and must include members of the community. The powers and responsibilities of these committees are unclear in the NHA. However, the Act requires that provincial legislation should outline the functions of a committee. Many provinces still do not have provincial health laws dealing

with clinic and community health centre committees. Only four provinces (Kwa-Zulu Natal, the Eastern Cape, the Western Cape and the Free State) have passed provincial legislation or have adopted policies on the regulation of these committees, but not all these documents deal with the powers and responsibilities of the structures. Clinic and community health centre committees therefore remain insufficiently governed and have various weaknesses, including political interference, lack of knowledge of roles (among committee members, community members and health facility management), lack of empowerment and lack of funding. The much-needed user participation in health facilities will not occur without the development of proper processes for the election and functioning of these committees.

The provincial legislation that currently exists and the provisions relating to health committees are set out below.

Eastern Cape Provincial Health Act 10 of 1999

The Act was promulgated before the NHA but deals briefly with health committees. Section 35 states that the MEC shall appoint a community health committee for each community health facility within the Province.

The Act does not set out the duties and powers of clinic committees. However, it states that the MEC must set out the terms of reference for the committees. The terms of reference must be published in a gazette.

Free State Provincial Health Act 3 of 2009

Section 39(1) states that the MEC must consult with the district health council to establish a clinic committee for a ward in which the clinic is located.

The duties of a clinic committee are set out in section 39(3), and include:

- advising the management of a health facility;

- investigating administrative complaints in respect of a health facility and making recommendations regarding the resolving of complaints;
- assisting users in following the complaints procedures; and
- investigating health service delivery problems at the facility and making recommendations to the district health council.

Gauteng District Health Services Act 8 of 2000

The Act is not yet in effect and, in any case, does not provide for the establishment of clinic and/or community health centre committees.

KwaZulu Natal Health Act 1 of 2009

Section 42(1) states that the MEC must establish committees within 12 months of the Act coming into effect.

The powers and functions of the committees are set out in section 43(1), and include:

- overseeing the administration of human resources, financial resources, assets, facilities and the general affairs of a facility;
- reporting any maladministration of a facility to the MEC;
- providing the MEC with biannual reports on the performance of a facility; and
- acting as a link to ensure collaboration with stakeholders in all provincial and national health-related initiatives.

Limpopo Province Health Services Act 5 of 1998

The Act was promulgated before the NHA and does not provide for the establishment of clinic and/or community health centre committees.

Western Cape Health Facility Boards and Committees Act 4 of 2016

Section 4(4) states that the MEC must establish a committee for each primary health care facility or for a group of primary health care facilities.

The duties of a clinic committee are set out in section 12, and include:

- requesting feedback on measures taken by the management of the facility to improve the quality of service at the facility;
- assisting the community to effectively communicate its needs, concerns and complaints to the management of the facility;
- conducting scheduled visits to the facility, without impeding its functioning, and providing constructive written feedback on such visits to the management; and
- providing constructive feedback to the management of the primary health care facility in order to enhance service delivery.

In terms of section 13, the committee has the power to:

- conduct surveys, meetings and consultative workshops in the community or communities concerned;
- disseminate information to the community on various issues, including the performance standards and policies of the facility;
- advise and make recommendations to the MEC, the management of the primary health care facility, the head of department or the municipality concerned, on any matter relating to the performance of the committee's functions; and
- obtain information from the facility if the information does not violate the rights of a patient or staff member to privacy and confidentiality.

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. Membership of hospital boards provides community members with the opportunity to provide input into the governing of the hospitals that serve them.

National, provincial and district health councils

The National Health Council is established by section 23 of the NHA and includes the Minister, the Deputy Minister, the Director-General and Deputy Directors-General at national level, and all MECs and heads of department at provincial level, among others. Its role is to advise the Minister of Health on policy, legislation, proposed norms and standards for the establishment of health establishments, guidelines for the management of health districts, the implementation of national health policy, the national and provincial integrated health plans contemplated in section 21(5), and an integrated national strategy for health research, and to perform any other function determined by the Minister.

Section 26 of the NHA establishes similar structures at the provincial level. Like the National Health Council, provincial health councils are responsible for advising the provincial department on health policy, among other functions.

Section 31 of the NHA instructs the MEC for Health in each province to create a district health council in each health district.

Although there is no official role for members of the community in national, provincial or district health councils, the councils may consider representations from any person, organisation, institution or authority. Therefore, health activists must monitor these bodies since they help to establish national, provincial and district health policy, and may be a useful target for advocacy.

Consultative health forums

Sections 24 and 28 of the NHA establish consultative health forums at the national and provincial levels respectively. The main function of these bodies is to promote and facilitate the sharing of information on health issues. Provincial consultative health forums must include relevant stakeholders, such as community-based organisations, and must meet at least every 12

months. The consultative health forums are important targets for mobilisation and advocacy. Health care advocates should enquire about the meetings of consultative health forums and make sure that they attend, to ensure that the agendas include issues that are important to users of the health care system, and to ensure that critical voices are heard when necessary.

National, provincial and district health plans

Section 33 of the NHA requires each district health manager to create annual district health and human resource plans and to present them to the MEC and the district health council. Section 25 of the NHA contains the same obligation in respect of provinces and requires that provincial plans be submitted to the Director-General. The district and provincial health plans must be developed according to guidelines published by the NDoH. At a national level, section 21(3) to (5) of the NHA requires 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, as this knowledge gives advocates the ability to monitor what those responsible for health at the national, provincial and district levels are meant to accomplish, and to hold them accountable for any 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 needs-based health assessment of a community or district.

Budgeting for health

While the NHA establishes the structure of the health system, it does not state how that system will be funded. Instead, the public

health system is funded and financially managed in terms of national and provincial legislation, which is framed by the rights, duties and principles of governance and financial management established by the Constitution. Key legislation includes the Public Finance Management Act 1 of 1999, the Intergovernmental Fiscal Relations Act 97 of 1997, the Money Bills Amendment Procedure and Related Matters Act 9 of 2009, the Division of Revenue Act (enacted annually) and the Appropriations Act (enacted annually).

How public health services are funded

National government raises revenue (money) through a variety of means, including taxes. Section 213 of the Constitution states that all revenue raised nationally must be deposited into a National Revenue Fund. In addition, government borrows money to close the gap between planned expenditure and expected revenue. The total government budget is 'vertically' divided between the three spheres of government: national, provincial and local. The national share of revenue goes to national departments and agencies, the provincial share goes to provincial governments and agencies, and the local share goes to local municipalities.

Schedule 4 of the Constitution and the NHA establish that health services are a concurrent function of national government and provincial government. This means that there are national and provincial departments of health, which have distinctive but interdependent and interrelated responsibilities.

The National Department of Health is responsible for overall priority setting and the development of national laws and policies, which provincial governments must implement. Provincial departments of health are responsible for the day-to-day management and functioning of health care facilities and programmes,

including the management of hospitals and clinics. The bulk of the health care budget is therefore spent at the provincial level.

In the 2019/20 financial year, the NDoH received R51.5 billion out of a total health budget of R208.8 billion. However, R45 billion of this allocation was transferred directly to provincial health departments in the form of conditional grants. Conditional grants must be spent on specific national priorities by the provinces. For the past decade, the largest conditional grant has been the comprehensive HIV, AIDS and TB grant, which received R20 billion in 2019/20, reflecting the high priority status given to combating these epidemics. The other direct grants are given for national tertiary services (R13.2 billion), health facility revitalisation (R6.0 billion) and health professions training and development (R2.9 billion).

However, provinces' main source of funding is their equitable share allocation. This is a share of revenue raised nationally that is allocated ('horizontally') to each province, based on a formula that takes account of a number of factors, including the demand for health services.

Provinces have the discretion to decide how to allocate their equitable share allocation. On average, provincial governments allocate 32% of their total budget (including conditional grants) to health care, with Gauteng and the Western Cape allocating the highest proportion at 36%, and Mpumalanga and the North West allocating the lowest proportion, at 26% and 27% respectively in 2017/18.

User fees (such as those fees charged at hospitals) make up a very small proportion of provincial health funding, at only 1% on average.

With conditional grants, equitable share and provincial own revenue (user fees) included, provinces have approximately R202.3 billion of the R208.8 billion health budget available to

spend on delivering quality health services to all. This is equal to 97% of the total spend on public health.

The programmes funded and implemented by the NDoH in 2018/19 were: Administration; National Health Insurance, Health Planning and Systems Enablement; HIV/AIDS, Tuberculosis, and Maternal and Child Health; Primary Health Services; Hospitals, Tertiary Health Services and Human Resource Development; and Health Regulation and Compliance Management.

At the provincial level, programmes can vary, but in 2018/19 they generally included: Administration, District Health Services, Emergency Medical Services, Provincial Hospital Services, Central Hospital Services, Health Sciences and Training, Health Care Support Services, and Health Facilities Management.

Participating in the budgeting process

The budgeting process refers to the process of raising, allocating and evaluating the expenditure of public money. Overall, this process is managed by the National Treasury, but it involves all government departme nts and agencies at the national and provincial level, as well as the 278 local municipalities. The process results in budget proposals that are tabled in the national and provincial legislatures. When voted for and adopted by the legislatures, these proposals are captured in legislation (the Appropriations Act and the Division of Revenue Act), in which the budgets of every government department and agency are contained.

The budgeting process, as well as the use and accounting of public funds, is governed by the Public Finance Management Act 1 of 1999 (PFMA). The object of the PFMA is 'to secure transparency, accountability, and sound management of the revenue, assets and liabilities of [public/state] institutions.' The Constitution and the PFMA require that public participation in

the budgeting process is encouraged and facilitated. As a result of a number of transparency reforms intended to give effect to these principles, South Africa has one of the most transparent budgeting processes in the world.

Any member of the public can access a comprehensive range of national and provincial budget information by visiting vulekamali.gov.za. In relation to health, one can access the main and adjusted budgets of all national and provincial health departments, as well as additional information, such as information about health infrastructure projects. Users of the portal can compare what was budgeted to what was actually spent and see whether budgets are increasing in real terms or whether cuts have been applied. The performance and audit information contained in annual reports and Auditor-General reports is also accessible.

Unfortunately, despite the availability of budget information, public participation in the budgeting process remains low. It is especially poor at the planning and prioritising stages of the budgeting process, compared to the budget review and evaluation stages. Opportunities for public participation do exist, however, especially in the national and provincial legislatures.

Opportunities for public participation in the budgeting process

Any member of the public can:

- Make written or oral submissions or petitions in any of the official languages of South Africa to the parliamentary committees of the National Assembly, the National Council of Provinces and the provincial legislatures.
  - The key committees involved in the health budgeting process are Finance, Appropriations, Public Accounts and Health.
  - You can find more information about these committees, including when they meet, at www.pmg.org.za.

- Request MPs to ask questions on your behalf in the parliamentary committees and in monthly sessions with the executive.
- Participate in public hearings on the budget organised by the national and provincial treasuries.
- Lobby national and provincial health departments on their budget submissions as well as on their performance and spending of their budgets.
- Keep up with key national budget events by visiting https://vulekamali.gov.za/events
- Submit 'Budget Tips' to the Minister of Finance by visiting www.treasury.gov.za.
- Tweet the National Treasury @TreasuryRSA or the National Department of Health @HealthZA

Trends in health funding

After about a decade of positive growth in the public health care budget between 2000 and 2010, health care funding has recently slowed to a crawl as a result of austerity[3] and sluggish economic growth. This has put severe strain on health services and delayed the implementation of NHI, which requires a doubling of spending on public health. Other policies delayed as a result of a lack of funds in recent years include palliative care, health infrastructure improvements and the formalisation (and remuneration) of community health workers. Perhaps the biggest impact, however, has been on posts in provincial health departments, which have been frozen at times in order to meet austere expenditure ceilings. Vacant doctor, nursing and other posts—estimated by the National Director-General of Health at more than 40 000 nationally in 2017—have undoubtedly affected the quality of care available at public health facilities and have contributed to

[3] The policy of government since 2012 to cut public expenditure in order to reduce the budget deficit.

an exponential rise in medico-legal claims[4] in recent years. These posts urgenly need to be filled.

NHI proposals for health funding revolve around the introduction of an NHI Fund that will pay for all health care services. How the fund will be funded (ie whether through existing or new taxation measures) and how it will be managed and governed are still to be decided. The evolution of public health funding in South Africa over the next decade will largely depend on how these two questions are resolved.

Sexual and reproductive health and rights

The Constitution specifically includes the right to reproductive health care services in section 27. The Constitution thus appropriately prioritises this fundamental component of the right to health, and its intersection with the rights to dignity, bodily integrity, freedom and security of the person, privacy and equality.

What are sexual and reproductive health rights? It is helpful to start with the definition of sexual and reproductive health. In May 2018, a report published by the Guttmacher-*Lancet* Commission[5] provided a helpful combined definition of sexual and reproductive health: 'sexual and reproductive health is a state of physical, mental and social wellbeing in relation to all aspects of sexuality and reproduction, not merely the absence of disease, dysfunction, or infirmity.'

[4] Medico-legal claims against provincial health departments have grown from R28.6 billion in March 2015 to R804 billion in March 2018 (National Treasury, 2019 Budget Review).

[5] Guttmacher-*Lancet* Commission *Accelerate Progress: Sexual and Reproductive Health and Rights for All* (May 2018). Available at https://www.thelancet.com/commissions/sexual-and-reproductive-health-and-rights.

The attainment of sexual and reproductive health requires the realisation of sexual and reproductive health rights, which include everyone's right to:

- have their bodily integrity, privacy and personal autonomy respected;
- freely define their own sexuality, including sexual orientation and gender identity and expression;
- decide whether and when to be sexually active;
- choose their sexual partners;
- have safe and pleasurable sexual experiences;
- decide whether and when, and whom to marry;
- decide whether, when, and by what means to have a child or children, and how many.

The realisation of sexual and reproductive health rights therefore goes far beyond a health care system, requiring societal and attitudinal change, as well as cooperation between many different stakeholders, including those in government (the health sector, the education sector and the police service) and civil society.

Included in the requirements for the realisation of sexual and reproductive health rights are the health services required for the realisation of these rights. The Guttmacher-*Lancet* Commission report notes the following services are needed for the realisation of the rights:

- Counselling and care related to sexuality, sexual identity and sexual relationships;
- Services for the prevention and management of sexually transmitted infections, including HIV;
- Prevention and management of cancers of the reproductive system;
- Access to all forms of affordable, safe, effective and acceptable methods of contraception of one's choice;

- Access to appropriate health care services to ensure safe and healthy pregnancies and childbirth, and healthy infants;
- Access to safe abortion services, including post-abortion care.

Many of the services listed in the Guttmacher-*Lancet* report form part of the service package that is meant to be available within the public health sector in South Africa. The reproductive health services offered by the state include access to contraception, ante-natal care, abortion, ante-retroviral treatment (ART) for the management of HIV, HIV prevention, screening and management of reproductive cancers, screening and treatment of sexually transmitted infections (STIs), and psycho-social support. These services should be accessed at public clinics, hospitals, schools and community health centres. Services at public health facilities should be free for pregnant and lactating women.

However, access to such services is still limited for many people. A number of issues hinder access to such critical services, including:

- Stock-outs of vital medicines and supplies such as ART, contraceptives, abortion pills and female condoms. As a result of these stock-outs, we see continuing high levels of unwanted pregnancies, HIV and STIs.
- While the Choice on Termination of Pregnancy Act 92 of 1996 (CToP Act) has existed for over two decades, access to safe abortion services remains a problem. According to the CTOP Act, a woman or girl can terminate a pregnancy upon request during the first 12 weeks of gestation. Termination of pregnancy can still be offered to women and girls after 12 weeks under certain conditions. However, women still find it difficult to access abortions due to the insufficiency of designated facilities that offer abortion, conscientious objection by health providers, staffing shortages, abortion medication stock-outs and others. This has led to an increase in complicated and incomplete

abortions occurring outside of the designated facilities at illegal centres, sometimes affecting the life and health of the woman concerned.

- The public health system is faced with a huge and increasing shortage of skilled health personnel. As health care workers leave the public sector, the system is weakened and access to services, including sexual and reproductive health services, decreases.
- The problems in access to emergency medical services, particularly in rural areas, have a real impact on the realisation of sexual and reproductive health rights. Pregnant women sometimes give birth at home when the ambulance they called fails to arrive, posing risks to the mother and the baby.
- The public health sector offers multiple options for HIV prevention. However, access to most options is limited, and focus has mostly been on the expansion of the male condoms roll-out programme. There is lack of social marketing of other methods, such as the female condom, post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP). The use of PrEP as an HIV prevention tool started in 2016, when it was provided to sex workers in a number of demonstration sites. The programme of PrEP roll-out has been gradually increasing to include men who have sex with men (MSM) and young people. At the time of publication, there are only 72 sites that provide PrEP, however, and so the majority of people at substantial risk of acquiring HIV are unaware of the option or lack access to PrEP.
- South Africa has a large family planning programme, but in many instances women are not informed about the different forms of contraception available and are given whatever the nurse decides to give them. The right to participate in decisions is therefore denied.

- In trying to ensure that everyone's sexual and reproductive health and rights are accommodated, the South African National LGBTI HIV Plan 2017 to 2022 offers a guide to health care providers and communities on how to provide services to LGBTQIA+ people. The plan notes the importance of sensitisation of health care providers to providing population-specific services. It provides for a core package of health services. The plan also entails the provision of dental dams, finger cots and rectal swab examinations to test for rectal cancer. However, these services are not currently being offered to LGBTQIA+ people, and many still face discrimination and prejudice when seeking sexual and reproductive health care services.
- The Department of Basic Education National HIV, STI and TB Policy specifies the services that should be provide to adolescents of school-going age in order to prevent, treat and manage the three epidemics. These services include access to modern methods of contraception, referral to abortion services, condoms, HPV vaccinations and comprehensive sexuality education. Progress has been made by the state in providing HPV vaccinations, which are critical for the prevention of cervical cancer, to nine-year-old girls in schools. Between 2014 and 2016, 1 093 880 Grade 4 learners (nine-year-old girls) received vaccinations. More recent numbers are not available at the time of publication. However the continued lack of access to other required services has hindered progress in trying to curb the rates of teenage pregnancy and untreated STIs among learners in schools.

Selected SRHR policy documents and guidelines

A very brief summary of various SRHR-related policy documents and guidelines follows, together with links to allow the reader to access the relevant documents. Policy documents and guidelines

related to the health system in general and to HIV and TB can be found in Appendix C.

National Condoms Policy and Management Guidelines (2011)

The policy aims to ensure that condoms are readily available and easily accessible to all communities and individuals in South Africa. It provides a plan for the procurement and distribution of male condoms to every sexually active individual to protect against unwanted pregnancies, STIs and HIV.

https://www.medbox.org/za-policies-others/
south-africa-national-condoms-policy-and-management-guidelines/preview?

National Contraception and Fertility Planning Policy and Service Delivery Guidelines and National Contraception Clinical Guidelines (2012)

These documents seek to promote (to health care providers and health service users) the use of the different types of contraceptives available in the public health sector, and to integrate HIV and sexual and reproductive health services.

https://www.health-e.org.za/wp-content/uploads/2014/05/National-contraception-clinical-guidelines.pdf
www.health-e.org.za/2014/05/06/guidelines-national-contraception-fertility-planning-policy/

South African National Guidelines for Medical Male Circumcision (2016)

This document provides comprehensive guidance for organising and ensuring the quality of voluntary male medical circumcision service delivery, both in the public sector and the private sector.

https://www.usaidassist.org/toolkits/vmmc-cqi-and-eqa-toolkit/
south-african-national-guidelines- medical-male-circumcision

PrEP Implementation Pack (2017)

This document comprises the PrEP draft policy, guidelines and roll-out plans. It is a guide for the provision of PrEP to individuals who are identified as being at substantial risk of contracting HIV.
https://www.prepwatch.org/wp-content/uploads/2017/07/SA_ImplementationPack.pdf

National Cancer Strategic Framework 2017–2022

The National Cancer Strategic Framework is the basis of the other policies on cancer, described below. It is important to read the *Strategic Framework* in conjunction with the following policies on cancers of the reproductive health system:

1. Cervical cancer prevention and control policy (2017)
   http://www.health.gov.za/index.php/2014-08-15-12-53-24?download=1393:cervical-cancer-policy-pdf
2. Breast cancer prevention and control policy (2017)
   http://www.health.gov.za/index.php/2014-08-15-12-53-24?download=2533:breast-cancer-policy
3. Prostate cancer diagnostic and treatment guidelines (2013)
   http://prostate.acitravel.co.za/cake/app/webroot/uploads/files/Prostate_Cancer_Guidelines_2013.pdf

Department of Basic Education National Policy on HIV, STIs and TB (2017)

This policy is intended to assist the Department of Basic Education in the management of HIV, STIs and TB in schools, by mainstreaming a response to HIV, STIs and TB, improving sex and sexuality education, improving access to services, and increasing the retention of learners, educators, school support staff and officials.
https://serve.mg.co.za/content/documents/2017/06/14/dbehivtbpolicyfinaljune2017-cabinetapproved.pdf

Guidelines for Maternity Care in South Africa: A manual for clinics, community health centres and district hospitals (2015)

These guidelines include the basic information that all professional nurses and doctors need to have in relation to maternity care. These guidelines seek to decrease high maternal and perinatal morbidity and mortality rates and improve the quality of care of mothers and their babies.

https://www.health-e.org.za/wp-content/uploads/2015/11/Maternal-Care-Guidelines-2015_FINAL-21.7.15.pdf

The Tshwane Declaration of Support for Breastfeeding in South Africa, 2012

The NDoH convened the National Breastfeeding Consultative Meeting in 2012, which adopted a policy 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

Draft Department of Basic Education National Policy on the Prevention and Management of Learner Pregnancy (2018)

The draft policy seeks to ensure the provision of accessible information on prevention, choice of termination of pregnancy, care, counselling and support, frameworks for impact mitigation, and guidelines for systemic management and implementation in schools.

http://www.governmentpublications.lib.uct.ac.za/news/draft-dbe-national-policy-prevention-and-management-learner-pregnancy

Conclusion

Since the last edition of this *Guide*, significant progress has been made in promulgating sections of the NHA and in

legislative interventions to improve access to health care services. Unfortunately, the legislative interventions have not translated into substantial improvements in access to high quality health care services. It is hoped 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 the Constitution.

National Health Act 61 of 2003[1]

(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;

[1] Most provisions of the NHA were brought into effect on 2 May 2005. In subsequent years, provisions that had not been initially promulgated (meaning brought into effect) were promulgated and should, therefore, be implemented. Notably, the National Health Amendment Act 12 of 2013 brought into effect (and amended) the provisions relating to the Office of Health Standards Compliance and the Health Ombud as of 2 September 2013. Sections 36, 37, 38, 39 and 40 relating to the requirement for certificates of need were promulgated on 21 March 2014, but the promulgation was subsequently set aside by the Constitutional Court on 27 January 2015, in case CCT 201/14. These sections of the NHA are therefore not currently in effect. The only other provision that is not yet in effect is section 47(2) of the NHA.

BEARING IN MIND THAT—

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

Sections

1. Definitions

In this Act, unless the context indicates otherwise—

"authorised institution" means any institution designated as an authorized 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 Standard Compliance Board established in terms of section 79A;

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

"certificate of need" means a certificate contemplated in section 36;

"Chief Executive Officer" means the person appointed as Chief Executive Officer in terms of section 79H(1);

"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 No. 108 of 1996);

"death" means brain death;

"Director-General" means the head of the national department;

"district health council" means a council established in terms of section 31;

"essential health services" means those health services prescribed by the Minister to be essential health services after consultation with the National Health Council;[2]

[2] As of April 2019, the Minister had not yet promulgated regulations defining 'essential health services'. For more information on the significance of a definition of 'essential health service' see note 25 on page 54 below.

"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 No. 75 of 1997), involving health workers or health care providers;[3]

"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 No. 63 of 1982);

(b) Health Professions Act, 1974 (Act No. 56 of 1974);

[3] 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, other persons—
(*a*) who render services to, or perform work for, the client and
(*b*) who are remunerated by the temporary employment service.

(c) Nursing Act, 1978 (Act No. 50 of 1978);[4]
(d) Pharmacy Act, 1974 (Act No. 53 of 1974); and
(e) Dental Technicians Act, 1979 (Act No. 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);

"**health research**" includes any research which contributes to knowledge of—

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

"**health research ethics committee**" means any committee registered in terms of section 73;

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

"health services" means—

(a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution;[5]

(b) basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution;[6]

[5] 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; and
(*c*) 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.

[6] 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. There is no definition of 'basic health care services'. Importantly, however, there is no provision in section 28(1)*(c)* for these rights of children to be realised progressively. This means that a child's right to basic health care services is immediately realisable. In *Governing Body of the Juma Musjid Primary School and others v Essay NO and others (Centre for Child Law and another, amici curiae)* 2011 (8) BCLR 761 (CC) at para 37 the Constitutional Court referred to the immediately realisable nature of the right to basic education—another right that is not limited by the internal limitation of 'progressive realisation'. What 'immediately realisable' means in practice has not yet been defined by the courts. Dr Faranaaz Veriava has written that 'where there is a violation of the right to basic education, government will be required to provide a particular educational input immediately, unless and to the extent that it is impossible under the circumstances.' F Veriava 'The Contribution of the Courts and of Civil Society to the Development of a Transformative Constitutionalist Narrative for the Right to Basic Education' LLD thesis, University of Pretoria, 2018.

(c) medical treatment contemplated in section 35(2)(e) of the Constitution;[7] and

(d) municipal health services;[8]

"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 No. 101 of 1965);[9]

[7] 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 their dignity and provides them 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; 2009 (2) SA 248 (C) (*Goliath*) the Western Cape High Court accepted the argument made by the respondents that persons detained in terms of the NHA (in order to be treated for drug-resistant TB against their will) are also entitled to the protections contained in section 35(2) of the Constitution. However, the court did not consider this point from a legal perspective and another court may make a different decision. In addition, in *Dudley Lee v Minister for Correctional Services* (CCT 20/12) [2012] ZACC 30; 2013 (2) BCLR 129 (CC); 2013 (2) SA 144 (CC); 2013 (1) SACR 213 (CC), 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 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.

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

[9] According to section 1 of the Medicines and Related Substances 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

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

"hospital" means a health establishment which is classified as a hospital by the Minister in terms of section 35;[10]

"inspector" means any person appointed as an inspector in terms of section 80(2);

"military health establishment" means a health establishment which is, in terms of the Constitution and the Defence Act, 2002 (Act No. 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;[11]

"municipal health services", for the purposes of this Act, includes—

(a) water quality monitoring;

(b) food control;

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pace maker does help prevent heart attacks, it would not be considered a medicine, while a tablet that reduces the risk of heart disease would be a medicine. A pace maker would be a 'health technology', according to the NHA's definition.

[10] The Minister, in consultation with the National Health Council, promulgated regulations on 2 March 2012 that classify categories of hospital and list all public hospitals. The regulations specify which services different categories of hospital must provide.

[11] 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 municipal councils.

(c) waste management;
(d) health surveillance of premises;
(e) surveillance and prevention of communicable diseases, excluding immunisations;
(f) vector control;
(g) environmental pollution control;
(h) disposal of the dead; and
(i) chemical safety, but excludes port health, malaria control and control of hazardous substances;

"municipality" means a municipality as defined in section 1 of the Local Government: Municipal Systems Act, 2000 (Act No. 32 of 2000);[12]

"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;

[12] According to section 1 of the Local Government: Municipal Systems Act, the definition of 'municipality' depends on how the word is used. Municipality refers either to the municipal government (ie 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 the NHA 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);

"**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;[13]

"**pollution**" means pollution as defined in section 1 of the National Environmental Management Act, 1998 (Act No. 107 of 1998);[14]

"**premises**" means any building, structure or tent together with the land on which it is situated and the adjoining land used in connection with it and includes any land without any building, structure or tent and any vehicle, conveyance or ship;

[13] According to section 239 of the Constitution, an organ of state includes all government departments at the national, provincial or local levels. 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 regarded as organs of state. Administrators of public facilities, such as public hospitals, are also organs of state.

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

"prescribed" means prescribed by regulation made under section 90;[15]

"primary health care services" means such health services as may be prescribed by the Minister to be primary health care services;[16]

"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;[17]

[15] See Appendix A for a list of regulations prescribed under the NHA.

[16] The Minister has not prescribed which services constitute primary health care services. See note 25 on page 54 below for more on the significance of a definition for 'primary health care services'. A number of policies that relate to primary health care services have, however, been developed. See Appendix C for a list of a selection of the policies.

[17] 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 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.

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

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

"statutory health professional council" means—

(a) the Health Professions Council of South Africa established by section 2 of the Health Professions Act, 1974 (Act No. 56 of 1974);[18]

(*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; and

(*c*) 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.

[18] 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

(b) the South African Nursing Council established by section 2 of the Nursing Act, 1978 (Act No. 50 of 1978);[19]

(c) the South African Pharmacy Council established by section 2 of the Pharmacy Act, 1974 (Act No. 53 of 1974);

(d) the Allied Health Professions Council of South Africa established by section 2 of the Allied Health Professions Act, 1982 (Act No. 63 of 1982);

(e) the South African Dental Technicians Council contemplated in section 2 of the Dental Technicians Act, 1979 (Act No. 19 of 1979); and

(f) such other statutory health professional council as the Minister may prescribe;

"**this Act**" includes any regulation made thereunder;

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

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

"**user**" means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a 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 No. 74 of 1983), "user" includes the person's parent or guardian or another person authorised by law to act on the first mentioned person's behalf;[20] or

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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.

[19] See note 4 on page 43 above.

[20] The Child Care Act was repealed by the Children's Act 38 of 2005. Section 129 of the 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 they are over 12 years and have the ability to

(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 first mentioned person's behalf;

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

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

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understand the benefits, risks, and consequences of the treatment. Consent for surgical treatment is the same, except the child must also be assisted by a parent or guardian when making a decision. The Act also governs the HIV testing of children (see 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, and section 134 governs children's access to contraceptives. Consent for the termination of pregnancy is different. Section 5 of the Choice of Termination of Pregnancy Act 92 of 1996 says that a minor must be 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, a child 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 series of helpful guides to the Children's Act for health professionals and others in the health sector. The guides can be found here: http://www.ci.uct.ac.za/ci/law-reform/childrens-act/guides.

(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;[21] and

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

3. Responsibility for health[22]

(1) The Minister must, within the limits of available resources—

(a) endeavour to protect, promote, improve and maintain the health of the population;[23]

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

[22] The Minister has promulgated the Policy Guidelines for the Licensing of Residential and/or Day Care Facilities for Persons with Mental Illness and/or severe or Profound Intellectual Disabilities in terms of this section of the NHA. A link to the Policy Guidelines can be found in Appendix A.

[23] In *Treatment Action Campaign and Another v Rath and Others* (12156/05) [2008] ZAWCHC [2008]; 4 All SA 360 (C) (13 June 2008), the Western Cape High Court 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

(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;[24]
(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;[25] and
(e) equitably prioritise the health services that the State can provide.[26]

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

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and Related Substances Act (Medicines Act). For more information, see Appendix B relating to the Medicines Act.

[24] The Minister promulgated the Policy on the Management of Public Hospitals in terms of this section. A link to the Policy can be found in Appendix C.

[25] 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 April 2019, the Minister had not yet promulgated a definition for either.

[26] The use of the concept of equity here is important. As opposed to 'equality', which requires equal treatment, 'equity' requires just treatment according to the circumstances of different people. This means that different interventions will be required for different people or communities. In a rural area, for example, access to health services may require the provision of staff accommodation or transport for health service users coming from far away, which may not be required in urban areas.

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.[27]

(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;[28]

[27] As of April 2019, the Minister had not yet determined any conditions regarding eligibility for free health services. That means 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, regardless of nationality or any other characteristics. The Minister could expand 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.

[28] It is important to note here that there is nothing limiting the care available to pregnant and lactating women and children under the age of six years to primary health care services. The right is to *all* health care services. It is also important that the right of the pregnant and lactating

(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 No. 92 of 1996), free termination of pregnancy services.

CHAPTER 2
RIGHTS AND DUTIES OF USERS AND HEALTH CARE PERSONNEL

5. Emergency treatment[29]

A health care provider, health worker or health establishment may not refuse a person emergency medical treatment.[30]

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woman is not limited to her health needs as they relate to her pregnancy or lactation.

[29] See pages 7–8 in the Introduction to this *Guide* for further information on access to emergency treatment.

[30] There is no definition of 'emergency medical treatment' but provision of such treatment has been dealt with in two Constitutional Court cases. 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*) the Constitutional Court helped to 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 ongoing 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' that 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 that access to health care services is progressively realised. The Constitutional

6. User to have full knowledge[31]

(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.

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.

In *Oppelt v Head: Health, Department of Health Provincial Administration: Western Cape* (CCT185/14) [2015] ZACC 33; 2016 (1) SA 325 (CC); 2015 (12) BCLR 1471 (CC), the majority found that an unreasonable delay in transferring a young man with a spinal cord injury to specialised care that could have prevented his permanent paralysis constituted a 'constructive' refusal of emergency medical treatment in violation of section 27(3) of the Constitution.

Two regulations relating to emergency medical treatment have been promulgated: the Regulations Relating to Emergency Care at Mass Gathering Events, and the Emergency Medical Services Regulations. Links to both sets of regulations can be found in Appendix A.

[31] See pages 8–10 in the Introduction to this *Guide* for further information on full user knowledge.

7. Consent of user[32]

(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 consent 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;[33]

(d) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or

(e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his

[32] See pages 8–10 in the Introduction to this *Guide* for further information on user consent.

[33] After many years of development, the Regulations Relating to the Surveillance and the Control of Notifiable Medical Conditions were promulgated on 15 December 2017. A link to the regulations can be found in Appendix A. Regulation 15 deals with mandatory medical examination, prophylaxis, treatment, isolation and quarantine, and provides that the head of a provincial department of health must apply to a High Court for a court order if a person who is a clinical or laboratory confirmed case, carrier or contact of a notifiable medical condition refuses consent for medical examination, prophylaxis, treatment, isolation and quarantine. Various protections are put in place to prevent court orders under this section being sought unnecessarily.

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.[34]

(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[35]

(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

[34] For a patient in a hospital or clinic to give informed consent, he or she must know about and understand which health service is going to be given to him or her. They 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 (SCA). However, even though patients must know about and understand the risks before giving consent, their doctor does not have to warn them of every possible risk (such as the risk of minor harm that is unlikely to occur).

[35] See pages 8–10 in the Introduction to this *Guide* for further information on user participation in decisions.

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

9. Health service without consent[36]

(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.

[36] See pages 8–10 in the Introduction to this *Guide* for further information on the provision of health services without consent.

(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.[37]

(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[38]

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

(a) the types and availability of health services;

(b) the organisation of health services;

(c) operating schedules and timetables of visits;

[37] The Regulations relating to Research on Human Participants prescribes in regulation 5 how users must be informed of the nature of the service. The regulations were promulgated on 19 September 2014. A link to the regulation can be found in Appendix A.

[38] See page 10 in the Introduction to this *Guide* for further information on the duty to disseminate information.

(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 No. 43 of 1996), and the Promotion of Access to Information Act, 2000 (Act No. 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[39]

(1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.

[39] 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), then Minister of Health Dr Tshabalala-Msimang 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 promulgate 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

(2) Subject to section 15, no person may disclose any information contemplated in subsection (1) unless—
  (a) the user consents to that disclosure in writing;
  (b) a court order or any law requires that disclosure; or
  (c) non-disclosure of the information represents a serious threat to public health.

15. Access to health records

(1) A health worker or any health care provider that has access to the health records of a user may disclose such personal information to any other person, health care provider or health establishment as is necessary for any legitimate purpose within 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 No. 2 of 2000).[40]

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stigmatised when they go to a health facility for a medical assessment or treatment for a cause of illness such as infection with HIV.

[40] 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;

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—[41]

(a) fails to perform a duty imposed on them in terms of subsection (1);

(*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 awarder 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.

[41] See note 39 on page 62 above.

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

commits an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding one year or to both a fine and such imprisonment.

18. Laying of complaints[42]

(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—

[42] See the relevant section in the Introduction to this *Guide* for further information on the laying of complaints.

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

20. Rights of health care personnel

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

Chapter 3
NATIONAL HEALTH

21. General functions of national department

(1) The Director-General must—

(a) ensure the implementation of national health policy in so far as it relates to the national department; and
(b) issue guidelines for the implementation of national health policy.

(2) The Director-General must, in accordance with national health policy—
(a) liaise with national health departments in other countries and with international agencies;
(b) issue, and promote adherence to, norms and standards on health matters, including—
(i) nutritional intervention;
(ii) environmental conditions that constitute a health hazard;[43]
(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;

[43] The National Environmental Health Norms and Standards for Premises and Acceptable Monitoring Standards for Environmental Health Practitioners have been promulgated in terms of this section. A link to the Norms and Standards can be found in Appendix A.

(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;
(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.[44]

(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.[45]

[44] This is an important section but co-ordination is a weakness in the health system. The NDoH complains of a failure by provincial departments to implement policies, while provincial departments complain that 'unfunded mandates' (orders to do certain things or implement certain policies without being given the necessary funding to do so) are handed down by the NDoH. This section places a clear obligation on the NDoH, and its accounting officer, the Director-General, to provide services not provided by provincial departments to ensure the establishment of a comprehensive national health system.

[45] The National Department of Health: Strategic Plan 2015–2020 is available at http://www.health.gov.za/index.php/2014-03-17-09-09-38/strategic-documents/

(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.[46]

22. Establishment and composition of National Health Council[47]

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

(2) The National Health Council consists of—
  (a) the Minister, or his or her nominee, who acts as chairperson;
  (b) the Deputy Minister of Health, if there is one;
  (c) the relevant members of the Executive Councils;

category/229-2015str?download=1057:strategic-plan-2015. The National Department of Health Annual Performance Plan 2018/19–2020/21 can be found here: http://www.health.gov.za/index.php/2014-03-17-09-09-38/strategic-documents/category/442-2018-strategic-documents?download=2680:annual-performance-plan-2018. There is no publicly available strategic, medium-term human resources plan.

[46] It is unclear whether the integrated health plans required by this section have been produced. They are not publicly available.

[47] The most recent meeting of the National Health Council at the time of publishing was reported to have been in December 2018, but the details of the meetings are not publicly available. See the relevant section in the Introduction to this *Guide* for further information on the importance of monitoring proceedings in the National Health Council.

(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;[48] and
(h) the head of the South African Military Health Service.

23. Functions of National Health Council

(1) The National Health Council must advise the Minister on—
(a) policy concerning any matter that will protect, promote, improve and maintain the health of the population, including—
(i) responsibilities for health by individuals and the public and private sector;
(ii) targets, priorities, norms and standards relating to the equitable provision and financing of health services;
(iii) efficient co-ordination of health services;
(iv) human resources planning, production, management and development;
(v) development, procurement and use of health technology;
(vi) equitable financial mechanisms for the funding of health services;

[48] Section 163 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.

(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[49]

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

[49] The Presidency held a National Health Consultative meeting on 24 August 2018 on National Health Insurance. It is unclear whether this was a National Consultative Health Forum meeting.

Chapter 4
PROVINCIAL HEALTH[50]

[50] Health services is a functional area in which national government and provincial government share legislative competence, while the only health-related functional area that is the exclusive domain of provincial government is ambulance services. Concurrent legislative competence means that both provincial government 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. The department was returned to the control of the provincial administration in 2015. The financial position of the department improved during the time of intervention, although there has been subsequent deterioration, leading to calls for the Limpopo Department of Health to be placed under administration again, because of its failure to pay the salaries of medical personnel. On 26 April 2018 the North West Department of Health was placed under the administration of the national government under section 100(1)*(b)* of the Constitution.

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, by intervening in terms of section 100(1)*(b)*,

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—[51]

(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;

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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 published a position paper on the provincialisation of personal primary health care services in 2009. This document includes useful information on health care services at a provincial level. It is available at https://www.salga.org.za/Documents/Knowledge%20Hub/SALGA%20Position%20Papers/SALGA-Position-Paper-on-Provincialisation-of-Primary-Health-Care.pdf.

[51] The extensive powers and responsibilities of the head of department in a provincial department of health are laid out here. While MECs for Health hold political power, the HoDs bear significant legal responsibility for the provision of health care services in the province. Political interference in health can, therefore, put HoDs in the position of having to decide whether to comply with political instructions from a superior or with their obligations under the NHA. On paper, this may seem an easy decision to make but, in reality, many HoDs have found it difficult.

(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;
(m) provide and co-ordinate emergency medical services and forensic pathology, forensic clinical medicines and related services, including the provision of medico-legal mortuaries and medico-legal services;
(n) control the quality of all health services and facilities;
(o) provide health services contemplated by specific provincial health service programmes;
(p) provide and maintain equipment, vehicles and health care facilities in the public sector;
(q) consult with communities regarding health matters;
(r) provide occupational health services;
(s) promote health and healthy lifestyles;
(t) promote community participation in the planning, provision and evaluation of health services;
(u) provide environmental pollution control services;
(v) ensure health systems research; and
(w) provide services for the management, prevention and control of communicable and non communicable diseases.

(3) The head of a provincial department must—

(a) prepare strategic, medium term health and human resources plans annually for the exercise of the powers of, the performance of the duties of and the provision of health services in the province by the provincial department; and

(b) submit such plans to the Director-General within the time frames and in accordance with the guidelines determined by the National Health Council.

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

26. Establishment and composition of Provincial Health Council[52]

(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;

[52] KwaZulu-Natal Health Department inaugurated a provincial health council in 2011. On 9 November 2012, the regulation for the council was drafted (http://www.kznhealth.gov.za/mediarelease/2011/phc11.8.2011.htmf). However, it is unclear whether the council is still functioning. Chapter 4 of the Free State Health Act 2009 established a provincial health council (http://www.fshealth.gov.za/portal/pls/portal/PORTAL.wwsbr_imt_services.GenericView?p_docname=3136978.PDF&p_type=DOC&p_viewservice=VAH&p_searchstring). However, it is unclear whether the council is still functioning. It is also unclear whether other provinces have established and maintained the functioning of provincial health councils. See the Introduction to this *Guide* for further information on participation in provincial health councils.

(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.[53]

27. Functions of Provincial Health Council

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

(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

[53] For more on section 163 of the Constitution, see note 48 on page 71 above.

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.[54]

28. Provincial consultative bodies[55]

(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.

[54] Given the apparent failure to establish provincial health councils in 7 out of 9 provinces, section 27(7) of the NHA appears not to have been complied with.

[55] The KwaZulu-Natal Health Department established a provincial health consultative forum in Chapter 5 of the KwaZulu-Natal Health Act 2009 (http://www.rhap.org.za/wp-content/uploads/2014/05/KZN-Health-Act-1-20091.pdf).
The Act refers to section 28 of the NHA, stating that it applies to the forum's establishment and composition. The most recent meeting of the forum appears to have taken place on 21 November 2017 (http://www.kznhealth.gov.za/mediarelease/2017/Media-invite-Health-matters-to-fall-under-spotlight.htm).
The Free State Health Department established a provincial health consultative forum in Chapter 4 of the Free State Health Act 2009 (http://www.fshealth.gov.za/portal/pls/portal/PORTAL.wwsbr_imt_services.GenericView?p_docname=3136978.PDF&p_type=DOC&p_viewservice=VAH&p_searchstring=).
The forum's most recent meeting appears to have been held in 2015 (https://www.ofm.co.za/article/local-news/161747/beleaguered-free-state-health-mec-holds-health-forum). See the Introduction to this *Guide* for further information on participation in provincial health consultative forums.

(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[56]

29. Establishment of district health system

(1) A district health system is hereby established.

(2) The system consists of various health districts, and the boundaries of health districts coincide with district and metropolitan municipal boundaries.

30. Division of health districts into subdistricts

(1) (a) The relevant member of the Executive Council may, with the concurrence of the member of the Executive Council responsible for local government in the province in question and subject to subsection (2), divide any health district in the province into subdistricts and may determine and change the boundaries of such subdistricts.

(b) Where a health district falls within more than one province, the members of the Executive Council of all the relevant provinces must agree to any division, determination or change contemplated in paragraph (a).

(c) Details of any division, determination or change must be published in the *Gazette*.

[56] 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: www.hst.org.za/publications/Pages/HSTDistrictHealthBarometer.aspx

(2) The members contemplated in subsection (1) must have due regard to the principles laid down in sections 27[57] and 195[58] of the Constitution and the criteria laid down in section 25 of the Local Government: Municipal Demarcation Act, 1998 (Act No. 27 of 1998),[59] particularly in so far as they relate to—
(a) equity;
(b) access to services;
(c) quality;
(d) overcoming fragmentation;
(e) comprehensive services;
(f) effectiveness;
(g) efficiency;
(h) local accountability;
(i) community participation;
(j) developmental and intersectoral approach; and
(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,

[57] 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 5 on page 44 above.

[58] Section 195 of the Constitution sets out the basic principles governing public administration. The entire text of section 195 is set out in note 17 on page 49 above.

[59] Section 25 of the Local Government: Municipal Demarcation 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 affect 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.

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—[60]

(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

[60] Most provinces have not complied with the obligation to promulgate provincial legislation on health that covers the various matters referred to in the NHA, including the functioning of district health councils under section 31, the establishment and functioning of clinic and community health centre committees under section 42, and the provision of health services at public health establishments other than hospitals under section 43. Provincial health legislation dealing with these matters exists in the Free State, KwaZulu-Natal and the Western Cape in the form of the Free State Provincial Health Act 3 of 2009 (came into effect on 30 March 2009), the KwaZulu-Natal Health Act 1 of 2009 (came into effect on 6 September 2012), the Western Cape District Health Councils of Act 5 of 2010 (came into effect on 24 August 2011) and the Western Cape Health Facility Boards and Committees Act 4 of 2016 (came into effect on 7 December 2017). Provincial health legislation promulgated before the NHA, which is therefore not in line with the Act, exists in Limpopo, the Eastern Cape and Gauteng in the form of the Limpopo Province Health Services Act 5 of 1998 (came into effect on 30 September 1999), the Eastern Cape Provincial Health Act 10 of 1999 (came into effect on 1 March 2000) and the Gauteng District Health Services Act 8 of 2000 (not in effect). Mpumalanga, the Northern Cape and the North West have no relevant provincial legislation on health at the time of publication.

(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 as are contemplated in section 156(4) of the Constitution.[61]

(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.

[61] Section 156(4) of the Constitution provides that both the national government and the provincial government 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 government or the national government.

33. Preparation of district health plans[62]

(1) Each district and metropolitan health manager must within the national budget cycle develop and present to the district health council in question and the relevant member of the Executive Council a district health plan drawn up in accordance with national guidelines issued by the Director-General with due regard to national and provincial health policies and the requirements of the relevant integrated development plan prepared in terms of section 25 of the Local Government: Municipal Systems Act, 2000 (Act No. 32 of 2000).[63]

(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.

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[62] 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 D. Additionally, the NDoH has issued Guidelines for District Health Planning and Reporting, which is included within the 2018/2019 District Health Planning and Monitoring Framework.

See http://www.health.gov.za/DHP/docs/DHP_and_M_Framework_and_Guidelines_25Aug_DG.pdf.

[63] Section 25 of the Local Government: Municipal Systems 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 must 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

35. Classification of health establishments[64]

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

(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[65]

(1) A person may not—
  (a) establish, construct, modify or acquire a health establishment or health agency;

[64] Through the Regulations: Categories of Public Hospitals, promulgated in 2012, 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. A link to the regulations can be found in Appendix A.

[65] Sections 36, 37, 38, 39 and 40 of the NHA relating to certificates of need are not in effect. For more detail, see note 1 on page 33 above.

(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 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 No. 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[66]

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

[66] Sections 36, 37, 38, 39 and 40 of the NHA relating to certificates of need are not in effect. For more detail, see note 1 on page 33 above.

38. Appeal to Minister against Director-General's decision[67]

(1) Any person aggrieved by a decision of the Director-General in terms of section 36 may appeal in writing to the Minister against such decision.

(2) Such appeal must—

(a) be lodged within 60 days from the date on which written reasons for the decision were given by the Director-General or such later date as the Minister permits; and

(b) set out the grounds of appeal.

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

(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[68]

(1) The Minister may, after consultation with the National Health Council, make regulations relating to—

(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

[67] Sections 36, 37, 38, 39 and 40 of the NHA relating to certificates of need are not in effect. For more detail, see note 1 on page 33 above.

[68] Sections 36, 37, 38, 39 and 40 of the NHA relating to certificates of need are not in effect. For more detail, see note 1 on page 33 above.

(d) any other matter relating to the granting of a certificate of need and the inspection and administration of health establishments and health agencies.

(2) Regulations made under subsection (1)—

(a) must ensure the equitable distribution and rationalisation of health, with special regard to vulnerable groups such as woman, older persons, children and people with disabilities;

(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[69]

(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 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.

[69] Sections 36, 37, 38, 39 and 40 of the NHA relating to certificates of need are not in effect. For more detail, see note 1 on page 33 above.

(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.[70]

(5) The functions of a central hospital board must be prescribed by the Minister.[71]

(6) (a) The relevant member of the Executive Council must—[72]

(i) appoint a representative board for each public health establishment classified as a hospital or for each group of such public health establishments within the relevant province;

(ii) prescribe the functions of such boards; and

(iii) prescribe procedures for meetings of the board.

(b) A hospital contemplated in paragraph (a) does not include a central hospital.

[70] 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 D for contact information for each local health district.

[71] In March 2012 the NDoH promulgated its Policy on the Management of Public Hospitals, which deals in part with the functions of hospital boards. The core function of hospital boards is to advise on policy and processes. The policy states that the hospital boards are largely advisory governance structures that have a mandate to act honestly in the best interests of the public and the users. In addition, hospital boards must develop a working knowledge of the hospital and must be cognisant of the economic, social, and political milieu in which the hospital operates. A link to the policy can be found in Appendix C.

[72] See page 16 in the Introduction to this *Guide* for further information on hospital boards.

(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[73]

(1) Provincial legislation must at least provide for the establishment in the province in question of a committee for—[74]

[73] See the Introduction to this *Guide* for further information on clinic and community health centre committees.

[74] For further information on provincial legislation, see note 60 on page 84 above. Unfortunately, because many provinces have not finalised legislation, these committees—which are meant to include community

(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—[75]
(a) minimum standards and requirements for the provision of health services in locations other than health establishments, including schools and other public places; and
(b) penalties for any contravention of or failure to comply with any such standards or requirements.

(2) Provincial legislation must provide for the provision of health services at health establishments in the province in question other than hospitals.

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representatives—have not yet been established in the manner intended. There are, however, some clinic committees operating in facilities across the country.

[75] The Minister has prescribed regulations relating to the provision of emergency medical services—in general and at mass gatherings—in terms of this section. Links to the regulations can be found in Appendix A. In addition, while the Integrated School Health Programme is not published in terms of this section, it provides for health service provision at schools. A link to the policy can be found in Appendix C.

(3) (a) The Minister may, in the interests of the health and well-being 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.[76]

(2) The national department, any provincial department or any municipality may enter into an agreement with any private practitioner, private health establishment or non-governmental 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 No. 1 of 1999), or any municipal finance management legislation, as the case may be.

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[77]

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

[76] The coordination of public and private health establishments is weak. One of the aims of National Health Insurance is to improve this coordination by integrating licensed and accredited health establishments (be they public or private) into a single health care system and by allowing health services to be purchased from any health establishment within that system.

[77] The Office of Health Standards Compliance is responsible for the evaluation of health facilities in terms of the promulgated norms and standards. However, the quality of the services provided in the public sector or private sector is not evaluated in accordance with set standards. This weakness should be addressed as part of reforms in line with National

(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).

Chapter 7
HUMAN RESOURCES PLANNING AND ACADEMIC HEALTH COMPLEXES

48. Development and provision of human resources in national health system[78]

(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

Health Insurance. Section 47(2) of the Act is one of the few provisions of the NHA whose commencement date has not been proclaimed.

[78] The NDoH published a Human Resources for Health South Africa: HRH Strategy for the Health Sector 2012/13–2016/17. The strategy was not accompanied by a plan and was largely unimplemented. There has been no publicly available strategy or plan since 2016/17, and insufficient human resources for health remains a significant impediment to access to health care services.

(c) the effective and efficient utilisation, functioning, management and support of human resources within the national health system.

49. Maximising services of health care providers

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

50. Forum of Statutory Health Professional Councils[79]

(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

[79] We understand that this forum exists and is functioning, but there is no information available online about the forum.

the time of his or her appointment, and may be reappointed at the expiry of his or her term of office.

(c) Any member of the Forum of Statutory Health Professional Councils, including the chairperson, must vacate his or her office if—

(i) his or her estate is sequestrated;

(ii) he or she becomes disqualified from practising his or her profession in terms of any law;

(iii) he or she becomes mentally ill to such a degree that it is necessary that he or she be detained, supervised or controlled;

(iv) he or she is convicted in the Republic or elsewhere of an offence involving dishonesty or an offence in respect whereof he or she is sentenced to imprisonment without the option of a fine;

(v) he or she ceases to be a South African citizen;

(vi) he or she has been absent from more than two consecutive ordinary meetings of the Forum without leave from the Forum;

(vii) he or she tenders his or her resignation in writing and the Minister accepts the resignation;

(viii) he or she ceases to hold any qualification necessary for his or her appointment; or

(ix) the Minister, in the public interest, terminates his or her membership.

(4) The Forum of Statutory Health Professional Councils must—

(a) protect the interests of the public and users;

(b) ensure communication and liaison between the statutory health professional councils upon matters affecting more than one of the registered professions;

(c) in the interests of the public, promote inter-professional 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) inter-professional 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

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;[80] and

(b) any co-ordinating committees that may be necessary in order to perform such functions as may be prescribed.

[80] As of April 2019 the academic health complexes that exist do so only at the ten central hospitals and do not, as intended in this section, consist of facilities throughout the health care system, providing a training platform at the various levels of health service provision.

52. Regulations relating to human resources[81]

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

(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 No. 101 of 1997), for the—

(i) recruitment of health care personnel from other countries; and

(ii) education and training of health care providers or health workers in the Republic, to make up the deficit in respect of scarce skills, expertise and competencies;

(e) prescribe strategies for the recruitment and retention of health care personnel within the national health system;

(f) ensure the existence of adequate human resources planning, development and management structures at national, provincial and district levels of the national health system;

(g) ensure the availability of institutional capacity at national, provincial and district levels of the national health system to plan for, develop and manage human resources;

(h) ensure the definition and clarification of the roles and functions of the national department, provincial departments and

[81] As of April 2019, no regulations under this section have been released for public comment or passed.

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[82]

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

[82] The majority of sections in Chapter 8 came into effect on 1 March 2012. In conjunction with this, the Minister promulgated a number of regulations regulating the control of the use of human blood, blood products, tissue and gametes, primarily in terms of section 68. These regulations can be found in Appendix A.

or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.[83]

54. Designation of authorised institution

(1) The Minister may, by notice in the Gazette, designate any institution other than an institution contemplated in section 63 as an authorised institution.[84]

(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—

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

[84] Although section 54 came into effect on 1 March 2012, as of April 2019, the Minister has not designated any institutions in terms of this section.

(a) with the written consent of the person from whom the tissue, blood, blood product or gametes are removed granted in the prescribed manner; and
(b) 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 No. 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.

(6) For the purpose of this section—

(a) "reproductive cloning of a human being" means the manipulation of genetic material in order to achieve the 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[85]

(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.

[85] In 2016, Peter Frederiksen was tried in the High Court, Free State Division in *S v Frederiksen* 2018 (1) SACR 29 (FB) on 58 counts, including rape, child pornography, and transgressions of the NHA. The transgressions of the NHA that he was alleged to have committed concerned the surgical removal of the clitorises of various women in his bedroom, which he used as a surgical theatre, in Bloemfontein. Mr Frederiksen was charged with having committed offences under sections 55 and 58 of the NHA. While non-compliance with the provisions of equivalent sections under the Human Tissues Act 65 of 1983 had been offences, no offences are listed under section 55 and 58 of the NHA, which repealed the Human Tissues Act. In the circumstances, Mr Frederiksen was acquitted on these counts. He was put to his defence on the other counts. The judgment can be found here: https://juta.co.za/media/filestore/2017/12/S_v_Frederiksen.pdf.

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 No. 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[86]

(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 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 done.

(c) If no done 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

[86] Donations of the body, tissue, blood or blood products of a deceased person is governed by Regulations: General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes, which came into effect on 2 March 2012. A link to the regulations can be found in Appendix A.

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

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

(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;[87] or

[87] One of the purposes of donation of organs and tissue is for transplantation. The Southern African Transplantation Society provides useful information regarding transplantation. Its website is https://www.sats.org.za. There are not enough people registered as organ donors in South Africa. If you would like to be an organ donor, register at the Organ Donor Foundation and tell your family about your wishes. The Organ Donor Foundation website is https://www.odf.org.za/.

(e) the production of a therapeutic, diagnostic or prophylactic substance.

(2) This Act does not apply to the preparation of the body of a deceased person for the purposes of embalming it, whether or not such preparation involves the—

(a) making of incisions in the body for the withdrawal of blood and the replacement thereof by a preservative; or

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

65. Revocation of donation[88]

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[89]

(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

[88] The Regulations: General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes of 2012 also provides the process to be followed if a person has made conflicting donations. In these circumstances, the donation that was last made is the one that will be given effect to. If a person first donated her entire body to one donee and afterwards donated specific tissue to another donee, the donation of her entire body will take precedence.

[89] Although not made in terms of this section, the Regulations Regarding the Rendering of Forensic Pathology Service of 2018 are relevant to this section as they lay out clearly the requirements for the rendering of such service and the conducting of post-mortem examinations. A link to the regulations can be found in Appendix A.

(c) such an examination is necessary for determining the cause of death.

(2) A post mortem examination may not take place unless—

(a) the medical practitioner in charge of clinical services in the hospital or authorised institution or of the mortuary in question, or any other medical practitioner authorised by such practitioner, has authorised the post mortem examination in writing and in the prescribed manner; or

(b) in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorised by the person in charge of such hospital or authorised institution, has authorised the post mortem examination in writing and in the prescribed manner.

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 No. 25 of 1999), for the purposes of that Act.[90]

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

(2) The medical practitioner in charge of clinical services in the hospital or authorised institution or of the mortuary in question, or any other medical practitioner authorised by such practitioner, or, in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorised by the person in charge of such hospital or authorised institution, may, in writing and in the prescribed manner, authorise—

(a) a prescribed institution or person contemplated in section 63; or

(b) an authorised institution making application therefor in writing, to remove any specified tissue from the body concerned before burial thereof.

(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 No. 58 of 1959);[91] 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

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

(b) the body or tissue in question has been donated or if the removal would be contrary to a direction given by the deceased before his or her death.

68. Regulations relating to tissue, cells, organs, blood, blood products and gametes[92]

(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;

[92] There are 11 sets of regulations made in terms of this section, made in 2012 and 2013. Links to the regulations can be found in Appendix A.

(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.[93]

(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

[93] In terms of the Regulations: Tissue Banks, promulgated in 2012, an authorised tissue bank, organisation or person may receive payment only for the activities listed in section 60 of the NHA, and any payment must be recorded, including the amount paid, to whom the payment was made, the reason for the payment and who made the payment. A link to the regulations can be found in Appendix A.

notice in the Gazette exempt any person or category of persons from any or all of the regulations made under this section.[94]

Chapter 9
NATIONAL HEALTH RESEARCH AND INFORMATION

69. National Health Research Committee[95]

(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;

[94] As of April 2019, no exceptions have been published.

[95] The Regulations Governing the Establishment and Constitution of the National Health Research Committee (NHRC) were passed in 2010. A link to the regulations can be found in Appendix A. Other than the regulations and the advertisement for the appointment of members of the committee, there is little evidence of the functioning of the committee and we understand that as at April 2019 it is not functional.

(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[96]

(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.

[96] The Regulations Relating to Research with Human Participants were promulgated in 2014 in terms of this section. A link to the regulations can be found in Appendix A.

(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 well-being of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk.

72. National Health Research Ethics Council[97]

(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 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.

[97] The National Health Research Ethics Council (NHREC) is governed by regulations that were gazetted on 23 September 2010. A link to the Regulations Relating to the National Health Research Ethics Council can be found in Appendix A. The Council's website is at: http://www.nhrec.org.za/.

(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[98]

(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.

[98] 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://policyresearch.limpopo.gov.za/bitstream/handle/123456789/903/District%20Health%20management%20Information%20System%20Policy.pdf?sequence=1.
Information management remains a huge problem within the health system.

(2) The Minister may, for the purpose of creating, maintaining or adapting databases within the national health information system contemplated in subsection (1), prescribe categories or kinds of data for submission and collection and the manner and format in which and by whom the data must be compiled or collated and must be submitted to the national department.

75. Provincial duties in relation to health information

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

76. Duties of district health councils and municipalities

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

Chapter 10
OFFICE OF HEALTH STANDARDS COMPLIANCE, BOARD, INSPECTIONS AND ENVIRONMENTAL HEALTH INVESTIGATIONS, HEALTH OFFICERS AND INSPECTORS, COMPLAINTS AND APPEAL PROCEDURE[99]

77. Establishment of Office of Health Standards Compliance

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

[99] Chapter 10 was amended and brought into effect in September 2013 through the National Health Amendment Act 12 of 2013. The Office of Health Standards Compliance (OHSC) is a separate juristic entity and is funded by money appropriated by Parliament directly. The OHSC is subject to the Public Finance Management Act 1 of 1999. The main object of the OHSC is to protect and promote the health and safety of people using health services. The OHSC does this by monitoring compliance

(2) The Office is funded by—
(a) money appropriated by Parliament; and

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by health establishments with the norms and standards prescribed by the Minister in relation to the national health care system. In addition, the OHSC acts as a mechanism for complaints to be investigated and handled. The OHSC advises the Minister, as well as inspecting and certifying health establishments. The OHSC is run by a CEO appointed by the Minister. The chapter sets out in a fair amount of detail the way in which the health officers from the OHSC 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 their constitutional obligations, such as respecting the right to privacy and dignity.

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, investigate that complaint. The Ombud can also initiate an investigation itself. 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 Ombud has conducted a number of important and high profile investigations, including an investigation into the deaths of mental health care users who were moved out of Life Esidimeni and into Tower Hospital in the Eastern Cape. The recommendations in the Life Esidimeni investigation report formed the basis for mental health system reform efforts and led to the initiation of the Life Esidimeni arbitration, which culminated in an arbitration award providing for apologies, counselling, the development of a monument, and financial compensation, including constitutional damages. The Life Esidimeni investigation report can be found here: http://ohsc.org.za/wp-content/uploads/2017/09/FINALREPORT.pdf and the arbitration award can be found here: http://www.saflii.org/images/LifeEsidimeniArbitrationAward.pdf. The Tower Hospital Report can be found here: http://ohsc.org.za/wp-content/uploads/OHO-Report-Final.pdf

Regulations relating to the Office of Health Standards and Compliance procedures and the Norms and Standards, according to which the OHSC monitors health facilities, were promulgated in 2016 and 2018 respectively, although they were not promulgated explicitly in terms of this chapter. Links to the regulations can be found in Appendix A.

(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.

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 or investigation; and
(d) negotiate 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 Board

(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, paediatrics, 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 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 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[100]

(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;

[100] See note 99 on page 126 above for further information on the work of the Ombud.

(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 states 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.

(2) If the investigation reveals that a condition contemplated in subsection (1) exists, the health officer must endeavour to determine the identity of the person responsible for such condition.

(3) The health officer must issue a compliance notice to the person determined to be responsible for any condition contemplated in subsection (1) to take appropriate corrective action in order to minimise, remove or rectify such condition.

(4) Any person aggrieved by a determination or instruction in terms of subsection (2) or (3) may, within a period of 14 days from the date on which he or she became aware of the determination or instruction, lodge an appeal with the person who appointed a health officer in terms of section 80(1).

(5) 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).

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—

(a) the owner and occupier of any premises or health establishment that the national or provincial department or the municipality occupies or uses; and
(b) the employer of persons in the service of that national or provincial department or municipality if, as an employer, the national or provincial department or municipality—
  (i) performs any duty imposed upon an employer by or under this Act; or
  (ii) exercises any power conferred upon an employer by or under this Act.

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[102]

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

(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;

(d) the performance of the functions of the Board and the Office;

(e) the development of an essential drugs list and medical and other assistive devices list;

(f) human resource development;

(g) 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;

(h) 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;

[102] For a list of all regulations that have been promulgated as of April 2019, see Appendix A.

(h) the functions of persons who render voluntary, charitable or similar services in connection with a public health establishment;
(i) the rendering of forensic pathology, forensic medicine and related laboratory services, including the provision of medico-legal mortuaries and medico-legal services;[103]
(j) communicable diseases;[104]
(k) notifiable medical conditions;
(l) rehabilitation;
(m) emergency medical services and emergency medical treatment, both within and outside of health establishments;[105]
(n) environmental health, including health nuisances and medical waste;
(o) the import and export of pathogenic micro-organisms;
(p) health laboratory services, including—
(i) the classification, accreditation and licensing of health laboratories; and
(ii) setting, monitoring and enforcing quality control standards applicable to health laboratories;
(q) non-communicable diseases;[106]

[103] The Regulations Regarding the Rendering of Forensic Pathology Service were promulgated in 2018 in terms of this section. A link to the regulations can be found in Appendix A.
[104] The Regulations Relating to the Surveillance and the Control of Notifiable Medical Conditions were finally promulgated in 2017 in line with this section and with section 90(1)*(k)* below. See note 33 on page 58 above for more information.
[105] The Regulations Relating to Emergency Care at Mass Gathering Events and the Emergency Medical Services Regulations were both promulgated in 2017 in terms of this section. Links to the regulations can be found in Appendix A.
[106] The Regulations Relating to Cancer Registration were promulgated in 2011 in terms of this section. A link to the regulations can be found in Appendix A.

(r) health technology;
(s) health research;[107]
(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;[108]
(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

[107] The Regulations Relating to the National Health Research Ethics Council and the Regulations Relating to the Establishment of the National Health Research Committee were both promulgated in 2010 in terms of this section. Links to the regulations can be found in Appendix A.

[108] The Regulations Relating to the Obtainment of Information and the Processes of Determination and Publication of Reference Price List were promulgated in 2007 in terms of this section. A link to the regulations can be found in Appendix A. The regulations were promulgated in terms of section 90(1)*(u)* and *(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.

(2) The Minister, subject to the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), and after consultation with the National Health Research Ethics Council, may make regulations regarding research on human subjects.

(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.

(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).[109]

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.[110]

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

(a) its composition, functions and working procedure;

(b) in consultation with the Minister of Finance, the terms, conditions, remuneration and allowances applicable to its members; and

(c) any incidental matters relating to that advisory or technical committee.

92. Assignment of duties and delegation of powers

Subject to the Public Finance Management Act (Act No. 1 of 1999)—

[109] The Regulations Relating to the Management of Human Remains were promulgated in 2013 in terms of this section. A link to the regulations can be found in Appendix A.

[110] Seven committees have been established under this section: the National Committee on Confidential Enquiries into Maternal Deaths, the NHI Advisory Committee, the Advisory Committee on the Prevention and Control of Cancer, the National Forensic Pathology Services Committee, the Ministerial Committee on e-Health, the Advisory Committee on Health Technology Assessment, and the Advisory Committee on Organ Transplants. Links to the notices to this effect, other than in relation to the National Committee on Confidential Enquiries into Maternal Deaths and and the Advisory Committee on Organ Transplant, about which we were unable to trace the relevant notices, can be found in Appendix A.

(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[111]
(Section 93)

No. and year of Act	Short title	Extent of repeal
Act No. 63 of 1977	Health Act, 1977	The whole
Act No. 18 of 1979	Health Amendment Act, 1979	The whole
Act No. 33 of 1981	Health Amendment Act, 1981	The whole
Act No. 37 of 1982	Health Amendment Act, 1982	The whole
Act No. 21 of 1983	Health Amendment Act, 1983	The whole
Act No. 65 of 1983	Human Tissue Act, 1983	The whole
Act No. 2 of 1984	Health Amendment Act, 1984	The whole
Act No. 106 of 1984	Human Tissue Amendment Act, 1984	The whole
Act No. 70 of 1985	Health Amendment Act, 1985	The whole
Act No. 51 of 1989	Human Tissue Amendment Act, 1989	The whole
Act No. 116 of 1990	National Policy for Health Act, 1990	The whole
Act No. 86 of 1993	Academic Health Centres Act, 1993	The whole
Act No. 118 of 1993	Health and Welfare Matters Amendment Act, 1993	Sections 1, 2, 4, 5, 6, 7, 8, 9 and 10

[111] 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 under the National Health Act

- 18 January 201—Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud: Code of Conduct for Inspectors (*Gazette* 42162, Notice 11)
  - https://www.gov.za/sites/default/files/gcis_document/201901/42162gon11.pdf
- 23 March 2018—Regulations Regarding the Rendering of Forensic Pathology Services *(Gazette 41524, Notice 359)*
  - http://www.gpwonline.co.za/Gazettes/Gazettes/41524_23-3_Health.pdf
- 16 March 2018—Policy Guidelines for the Licensing of Residential Authority and/or Day Care Facilities for Persons with Mental Illness and/or Severe or Profound Intellectual Disability *(Gazette 41498, Notice 218)*
  - https://www.gov.za/sites/default/files/41498_gon218b.pdf
- 2 February 2018—Norms and Standards Regulations Applicable to Different Categories of Health Establishments *(Gazette 41419, Notice 267)*
  - http://us-cdn.creamermedia.co.za/assets/articles/attachments/72969_41419_gon67.pdf
- 15 December 2017—Regulations Relating to the Surveillance and Control of Notifiable Medical Conditions *(Gazette 41330, Notice 1434)*
  - http://www.gpwonline.co.za/Gazettes/Gazettes/41330_15-12_Health.pdf
- 1 December 2017—Emergency Medical Services Regulation, 2017 *(Gazette 41287, Notice 1320)*
  - http://section27.org.za/wp-content/uploads/2018/02/EMS-Regulations-2017.pdf
- July 2017—National Health Insurance White Paper (which establishes the Advisory Committee on Health Technology

Assessment, although it is not clear if the committee has in fact been established) *(Gazette 40969, Notice 625)*
  – http://www.health.gov.za/index.php/nhi?download=2257:white-paper-nhi-2017
- 15 June 2017—Regulations Relating to Emergency Care at Mass Gatherings *(Gazette 4019, Notice 566)*
  – https://www.gov.za/sites/default/files/40919_gon566s.pdf
- 2 November 2016—Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud *(Gazette 40396, Notice 1365)*
  – http://www.polity.org.za/attachment.php?aa_id=65754
- 24 December 2015—National Environmental Health Norms and Standards for Premises and Acceptable Monitoring Standards for Environmental Health Practitioners *(Gazette 39561, Notice 1229)*
  – http://www.polity.org.za/attachment.php?aa_id=58287
- 10 July 2015—Establishment of the National Advisory Committee on e-Health *(Gazette 38981, Notice 595)*
  – http://www.polity.org.za/attachment.php?aa_id=55946
- 19 September 2014—Regulations Relating to Research with Human Participants *(Gazette 38000, Notice 719)*
  – https://www.gov.za/sites/www.gov.za/files/38000_rg10268_gon719.pdf
- 11 March 2014—Establishment of the National Forensic Pathology Services Committee *(Gazette 37430, Notice 178)*
  – http://www.polity.org.za/attachment.php?aa_id=48875
- 4 December 2013—National Environmental Health Policy (*Gazette 37112, Notice 951)*
  – http://www.polity.org.za/attachment.php?aa_id=47911
- 22 May 2013—Regulations Relating to the Management of Human Remains *(Gazette 36473, Notice 363)*
  – http://www.polity.org.za/attachment.php?aa_id=44726

- 15 June 2012 — Call for Establishment of a National Advisory Committee on the Prevention and Control of Cancer *(Gazette 35447, Notice 462)*
  - Link not available without subscription to a database
- 2 March 2012 — Regulations Relating to Categories of Hospitals *(Gazette 35101, Notice 185)*
  - http://www.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/84-2012r?download=138:regulations-relating-to-categories-of-hospitals-r185-2012
- 2 March 2012 — Regulations Relating to Stem Cell Banks *(Gazette 35099, Notice 183)*
  - http://www.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/84-2012r?download=134
- 2 March 2012 — Regulations Relating to Tissue Banks *(Gazette 35099, Notice 182)*
  - http://www.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/84-2012r?download=139:regulations-relating-to-tissue-banks-r182-2012
- 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.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/84-2012r?download=243:regulations-relating-to-the-import-and-export-of-human-tissue-blood-blood-products-cultured-cells-stem-cells-embryos-foetal-tissue-zygotes-and-gametes-r181-2012&usg=AFQjCNFWfP_1DhhKVIFoo-FxVY-ssJCKMQ&sig2=rk4pPsvACg1ujADyIg9c9g
- 2 March 2012 — Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes *(Gazette 40816, Notice 392)*
  - https://www.gov.za/documents/national-health-act-regulations-general-control-human-bodies-tissue-blood-blood-products-0

- 2 March 2012—Regulations Relating to Blood and Blood Products *(Gazette 35099, Notice 179)*
  - http://www.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/84-2012r?download=241:regulations-relating-to-blood-and-blood-products-r179-2012
- 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.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/84-2012r?download=137:regulations-relating-to-the-registration-of-microbiological-laboratories-and-the-acquisition-importation-handling-maintenance-and-supply-of-human-pathogens-r178-2012
- 2 March 2012—Regulations Relating to the Use of Human Biological Material *(Gazette 35099, Notice 177)*
  - https://www.gov.za/sites/www.gov.za/files/35099_rg9699_gon177.pdf
- 2 March 2012—Regulations Regarding the Rendering of Clinical Forensic Medicine Services *(Gazette 35099, Notice 176)*
  - https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon176.pdf
- 2 March 2012—Regulations Relating to Artifical Fertilisation of Persons *(Gazette 35099, Notice 175)*
  - http://www.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/84-2012r?download=135:regulations-relating-to-artificial-fertilisation-of-persons-r175-2012
- 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.polity.org.za/attachment.php?aa_id=36525
- 26 April 2011—Regulations Relating to Cancer Registration *(Gazette 34248, Notice 380)*

  - https://www.gov.za/sites/default/files/gcis_document/201409/34248rg9527gon380.pdf
- 23 September 2010—Regulations Relating to the Establishment of the National Health Research Committee *(Gazette 33575, Notice 840)*
  - https://www.gov.za/sites/default/files/gcis_document/201409/33575840.pdf
- 23 September 2010—Regulations Relating to the National Health Research Ethics Council *(Gazette 33574, Notice 839)*
  - http://us-cdn.creamermedia.co.za/assets/articles/attachments/30051_r_839.pdf
- 11 September 2009—Establishment of the National Health Insurance Advisory Committee *(Gazette 32564, Notice 903)*
  - http://us-cdn.creamermedia.co.za/assets/articles/attachments/23668_not_903.pdf
- 23 July 2007—Regulations Relating to the Obtainment of Information and the Processes of Determination and Publication of Reference Price List *(Gazette 30110, Notice 681)*
  - http://www.health.gov.za/index.php/2014-03-17-09-09-38/legislation/joomla-split-menu/category/119-reg2007?download=246:regulations-relating-to-the-obtainment-of-information-and-the-processes-of-determination-and-publication-of-reference-price-list-part-1

Appendix B

Other Health 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.

As in the Health Professions Act, professional boards may be established to regulate the conduct of the various 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 of the Act, a pregnancy may be terminated:

(*a*) upon the request of a woman during the first 12 weeks of … 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 foetus 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 foetus; or
(iii) would pose a risk of injury to the foetus.

For information on access to and consent for a termination of pregnancy for a minor, see note 20 on page 51 above.

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) if a person has been the victim of a sexual offence and 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 the HIV testing of alleged sex offenders.

Provisions of the Amendment Act that criminalised consensual sex and sexual acts between teenagers were declared unconstitutional by the High Court on 15 January 2013,

and the declaration of unconstitutionality was confirmed by the Constitutional Court on 3 October 2013.

The provisions required any health care worker or other person who became 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.

Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972

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

In late 2017 and early 2018, there was an outbreak of listeriosis in South Africa, which was traced back to the consumption of processed meats produced at a plant in Polokwane. The outbreak resulted in the deaths of 200 people and exposed the lack of adequate regulation of cold meat production. Attempts to regulate hygiene standards for processed meat products had been stalled, partly due to industry pressure.

It is important to note that the Foodstuffs Act and the Medicines Act do not cover the same products. Anything that 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.

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. The Health Professions Act establishes the Health Professions Council of South Africa, which oversees the conduct of different categories of professionals through its professional boards. Each professional board represents and regulates a different field of health practitioners. The professional boards are responsible for receiving complaints and investigating those practising in their field. Practising in any of these fields without a licence is a criminal offence under the Act. The professional boards that have been established in terms of the Act are:

- Professional Board for Medical and Dental (and Medical Science)
- Professional Board for Dental Assisting, Dental Therapy and Oral Hygiene
- Professional Board for Dietetics and Nutrition
- Professional Board for Emergency Care
- Professional Board for Environmental Health
- Professional Board for Medical Technology
- Professional Board for Occupational Therapy, 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

Medical Schemes Act 131 of 1998

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. The Medical Schemes Act is likely to be substantially amended as the Department of Health seeks to move towards a NHI system. In June 2018 a draft Bill to this effect was published for public comment. At the time of publishing the Department of Health is reported to be awaiting the final report of the Competition Commissions Market Inquiry into the Private Healthcare Sector so that the findings can inform the final Bill and the subsequent Act.

The Medical Schemes Act currently provides that 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.[1]

[1] 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 of the health care provider and that patients should not have to pay. However, the case was not decided on the merits and so there was no pronouncement on this issue. In *Council for Medical Schemes v Genesis Medical Scheme* (CCT139/16) [2017]

Medicines and Related Substances Act 101 of 1965

The Medicines and Related Substances Act (Medicines Act) creates the regulatory structure that oversees all registration of medicines and medical devices in the country. Under the Medicines Act, anything that falls within the definition of a medicine[2] may not be sold or advertised in South Africa unless it has been proven to be

ZACC 16; 2017 (9) BCLR 1164 (CC); 2017 (6) SA 1 (CC), the dependent daughter of a member of a registered medical scheme ('Genesis'), who was entitled to coverage under her mother's plan, suffered a compound fracture to her leg and was surgically fitted with an external fixator, which was subsequently twice replaced. All three procedures were performed at private hospitals. In terms of the Medical Schemes Act, Genesis was obliged to pay in for the treatment of any 'prescribed minimum benefit condition', one of which was listed as an 'open fracture/dislocation of bones or joints'. Genesis disputed its liability to pay for the fixators, claiming they were fitted at a private hospital. It argued that since its rules provided that it would pay '100% of actual cost in respect of [PMBs] . . . when obtained from a Public or State Hospital or designated service provider [DSP]', and it had not appointed any DSPs, it was only obliged to pay for the costs of treating a PMB condition if it were 'obtained from a Public or State Hospital'. The Supreme Court of Appeal held that Genesis was liable to pay for all three prostheses even though they had been fitted at a private hospital. The Supreme Court of Appeal held that the rules of a medical scheme cannot be viewed in isolation and that, as the provisions of the Act have as their goal the obligation of a medical scheme to provide a prescribed level of treatment to all its members suffering from certain conditions, whether obtained from the private sector or public sector, Genesis could not be permitted to contract out of those provisions. Consequently, as the member's dependant suffered from a prescribed medical benefit condition, Genesis was obliged to pay for the treatment administered in respect thereof, including all three prostheses. Genesis had had the opportunity under the Act of ameliorating this by appointing designated service providers with whom it could have agreed beneficial rates, but it had failed to do so.

[2] '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—

safe for use in humans and 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 Association (SAMA) successfully sued Mathias Rath in *Treatment Action Campaign and Another v Rath and Others* (12156/05) [2008] ZAWCHC 34; [2008] 4 All SA 360 (C); 2007 (4) SA 563 (C) (13 June 2008). The court 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 of the Act. The court clearly held that the Minister of Health and the Director-General have a duty to take reasonable measures to prevent unauthorised clinical trials and the distribution of such unauthorised products.

The Medicines Act has been amended to replace the Medicines Control Council (MCC)—the body that was responsible for regulating the performance of clinical trials and the registration of medicines—with the South African Health Products Regulatory Authority (SAHPRA).[3] SAHPRA has a broader authority to regulate medical products—such as medical devices—than the MCC. The first Board and an Acting CEO of SAHPRA have been appointed and SAHPRA has commenced its work.

(*a*) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or

(*b*) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine.

[3] SAHPRA's website is https://www.sahpra.org.za/

The Regulations Relating to Transparent Pricing System for Medicines and Scheduled Substances are promulgated under the Medicines Act and set the dispensing fees that pharmacists may charge.[4] These regulations are intended to make medicines more affordable for everyone.

The most recent case involving the Medicines Act is *Minister of Justice and Constitutional Development and Others v Prince (Clarke and Others Intervening); National Director of Public Prosecutions and Others v Rubin; National Director of Public Prosecutions and Others v Acton* (CCT108/17) [2018] ZACC 30; 2018 (10) BCLR 1220 (CC); 2018 (6) SA 393 (CC) (18 September 2018), a case concerning the cultivation and use of cannabis. The case was the most recent in a series of cases involving Mr Garreth Prince, who first approached the Constitutional Court in relation to the use of cannabis for religious purposes in 2002. In the 2018 matter, the Constitutional Court found that section 22A(9)*(a)*(i) read with Schedule 7 of the Medicines Act was inconsistent with the Constitution in so far as it prohibits the possession, cultivation and use of cannabis by an adult in private or for his or her personal consumption. This, the court found, is a limitation on the right to privacy, which limitation is not reasonable and justifiable. The court suspended the declaration of unconstitutionality for a period of 24 months to allow the legislature to make the required changes to the Act, but in the interim read the following into the Act: an adult may use or be in possession of cannabis in private for their own personal consumption in private, the use of cannabis in public or in the presence of children or non-consenting adults is not permitted, and the cultivation of cannabis by an adult in a private place for their personal consumption in private is no longer a criminal offence.[5]

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

[5] The full decision can be found here: http://www.saflii.org/za/cases/ZACC/2018/30.html.

Mental Health Care Act 17 of 2002

The Mental Health Care Act provides for the care, treatment and rehabilitation of persons who are mentally ill. The Act sets out procedures for admission to mental health facilities and establishes Mental Health Review Boards to review admissions and to which complaints can be directed.

The Life Esidimeni disaster highlighted the severe problems in the mental health care system in South Africa. Following the move of mental health care users from chronic mental health facilities to ill-equipped NGOs, 144 people died. The ensuing Health Ombud's investigation and the Life Esidimeni arbitration has led to efforts at mental health system reform.

National Health Laboratory Service Act 37 of 2000

The National Health Laboratory Services Act establishes the National Health Laboratory Service (NHLS),[6] which is the consolidation of a number of previous institutes and centres. The NHLS is the backbone of 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 continuous severe funding shortfalls, partly due to non-payment by provincial health departments for NHLS services, affecting its ability to perform its functions and resulting in frequent crises.

Nursing Act 33 of 20057

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

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

[7] The Nursing Act 33 of 2005 repealed and replaced the Nursing Act 50 of 1978 that is referenced in the NHA.

Council (SANC). Practising without a licence is a criminal offence under the Act.[8] Draft Regulations Relating to the Keeping, Supply, Administering, Prescribing or Dispensing of Medicine by Registered Nurses were published on 14 December 2011. The regulations were intended to make it easier for nurses to dispense ARVs in line with the policy allowing nurses to initiate and managed antiretroviral treatment (Nurse-Initiated Management of Antiretroviral Treatment). The regulations have not yet been passed.

Pharmacy Act 53 of 1974

The Pharmacy Act regulates the registration, training, and practice 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[9] which, much like the South African Nursing Council and the professional boards established in the Health Professions Act, is responsible for registering and investigating complaints regarding pharmacists, and, if necessary, taking 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.

Prevention of and Treatment for Substance Abuse Act 70 of 2008

The Prevention of and Treatment for Substance Abuse Act provides for mechanisms aimed at reducing demand and harm in relation to substance abuse through prevention, early intervention, treatment and reintegration programmes. The Act provides for the registration and establishment of treatment centres and

[8] The SANC's website is available at: http://www.sanc.co.za.
[9] The Council's website is available at: http://www.pharmcouncil.co.za.

halfway houses. Finally, it provides for the committal of persons to and from treatment centres and for their treatment, rehabilitation and skills development in such treatment centres.

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, including the rights set out in Chapter 2 of the Constitution—including the right to access to health care—apart from those rights that apply only 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 at April 2019. Therefore the earlier version of the Act applies, providing that refugees are entitled to 'basic health services'. This term remains undefined.

A National Directive was issued by the NDoH in 2007, which clarified that refugees and asylum seekers—with or without identity documents—are able to access certain public health services, including ARVs, without payment.[10] This is subject to the person not being a member of a medical aid scheme. Despite this directive and section 4 of the NHA, refugees and asylum seekers still struggle to access health care services at public health facilities.

Sterilisation Act 44 of 1998

The Sterilisation Act provides for the right to access sterilisation services in a health facility. The Act sets out the circumstances in which sterilisation may be performed, either with or without consent. The age of consent for sterilisation is 18 years. Sterilisation may be performed on a person younger than 18 years only if a

[10] A copy of this directive can be found here:https://sahivsoc.org/Files/2008-Circular-Access-to-ART-for-Pts-without-SA-Identity-Documents.pdf.

failure to do so would jeopardise that person's life or seriously impair his or her health. The Act also covers the sterilisation of people who are incapable of consenting or are incompetent to consent due to mental disability. There is no provision for sterilisation if a person is HIV-positive. In reported cases, outside South Africa, health care workers either forced or coerced HIV-positive mothers to undergo sterilisation, based on a moral judgment about their lack of suitability as parents. No similar cases have occurred 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 his or her 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, and regulates the sale and advertising of tobacco products. This includes regulating what information must appear on the packaging of tobacco products. The most recent amendment to the Act occurred in 2008, when designated indoor smoking areas were introduced. In *British American Tobacco South Africa (Pty) Ltd v Minister of Health (National Council Against Smoking as amicus curiae)* [2012] JOL 29239 (SCA), British American Tobacco (BAT) alleged 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, because the hazards of smoking far outweigh the interests of smokers as a group. The 2018 Draft Control of Tobacco Products and Electronic Delivery Systems Bill introduces a number of changes to the existing legislation, including 100% smoke-free indoor and outdoor public places, the regulation of e-cigarettes, plain packaging of all tobacco products, a ban on the

sale of tobacco products in vending machines, and the removal of all advertising at point-of-sale. The Bill is subject to significant push back from tobacco companies, among others.

Traditional Health Practitioners Act 22 of 2007

The Traditional Health Practitioners Act creates a regulatory framework similar to that of the Health Professions Act. The Act seeks 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 without being registered with the Interim Traditional Health Practitioners Council. To do so—even as a student—is criminally punishable. The Council has the authority and responsibility to register and investigate the practices of traditional healers and to receive and investigate complaints of misconduct by a traditional healer.[11]

[11] Regulations Relating to the Appointment by the Minister as Members of the Interim Traditional Health Practitioners Council of South Africa were promulgated on 22 August 2011. A copy of the 2011 regulations is available at: http://www.lawsofsouthafrica.up.ac.za/index.php/browse/medical-and-health/traditional-health-practitioners-act-22-of-2007/regulations-and-notices/22-of-2007-traditional-health-practitioners-act-regs-gnr-685-2011-08-22-to-date-pdf/download. The Interim Traditional Health Practitioners Council was inaugurated in February 2013, and in May 2014 the sections of the Traditional Health Practitioners Act that give it full powers came into effect. However, the Council is reported to be having difficulties performing its functions. For more information, see B Tshela 'Traditional health practitioners and the authority to issue medical certificates' (April 2015) 105(4) *SAMJ*.

Appendix C

Policy Documents and Guidelines

The Department of Health has developed policies and guidelines covering many aspects of health care and disease management. There is no complete list of policies and guidelines but the list on the Department of Health's website can be found here: http://www.health.gov.za/index.php/2014-03-17-09-09-38/policies-and-guidelines. Below we provide links to some of the most important policies and guidelines. Links to and descriptions of policies and guidelines relating specifically to sexual and reproductive health rights can be found in the Introduction to this *Guide*.

Health system planning

National Development Plan, 2030: Promoting Health

'Promoting Health' is a chapter in the National Planning Commission Department's National Development Plan. 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 identified reducing the disease burden to a manageable level as a major goal. Furthermore, the Commission noted that human capacity is key and that appropriate training and management are needed, and that health care professionals need to be produced in adequate numbers and deployed where most needed. Importantly, the Commission noted that governance must be improved and infrastructure backlogs must be eliminated in order to strengthen the national health care system as a whole. Lastly, the Commission was of the view that a NHI 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.

https://www.gov.za/sites/www.gov.za/files/ndp2030_chap10.pdf

National Department of Health: Strategic Plan 2015–2020

The National Department of Health Strategic Plan 2015–2020 outlines the strategic goals of the Department over the medium term.

http://www.health.gov.za/index.php/2014-03-17-09-09-38/strategic-documents/category/229-2015str?download=1057:strategic-plan-2015

District Health Management Information System (DHMIS) Policy, 2012

This policy was developed to meet the requirement in the NHA for the NDoH to facilitate and coordinate the establishment, implementation and maintenance of 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 to develop 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.

https://www.idealhealthfacility.org.za/docs/policies/District%20Health%20Management%20Information%20System%20Policy_2011.pdf

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 Ten-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.

https://www.gov.za/sites/default/files/35101_rg9701_gon186.pdf

The National Infection Prevention and Control Policy and Strategy, 2007

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

https://www.idealclinic.org.za/docs/policies/IPC%20Policy.pdf

National Health Promotion Policy and Strategy, 2015

The National Health Promotion Policy and Strategy acknowledges health promotion as a strategy to reduce disease by addressing the social, behavioural and structural determinants of health. For example, the policy commits the NDoH to supporting health workers within ward-based outreach teams implementing community mobilisation efforts and to creating health promotion norms and standards. It also proposes the creation of a national obesity strategy and the development of a health promotion curriculum.

https://www.health-e.org.za/wp-content/uploads/2015/09/The-National-Health-Promotion-Policy-and-Strategy.pdf

Strategy for the Prevention and Control of Obesity in South Africa 2015–2020

This strategy focuses on six broad goals, including preventing childhood obesity, enabling access to healthy food and promoting physical activity.

https://www.health-e.org.za/wp-content/uploads/2015/12/National-Strategy-for-prevention-and-Control-of-Obesity-4-August-latest.pdf

Youth and child health

National Adolescent and Youth Health Policy, 2017

The National Adolescent and Youth Health Policy aims to promote the health and wellbeing of young people, aged from 10 to 24 years, by providing guidance to departments and organisations working with the Department of Health on how to respond to the health needs of young people. The approach of the policy is to focus on the promotion of healthy lifestyles, the mitigation of risk factors, and the development of 'safety nets' for prevention, early detection and intervention.

https://www.idealhealthfacility.org.za/docs/policies/National%20Adolescent%20and%20Youth%20Health%20Policy%202017.pdf

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. This policy envisages each district establishing a team that will be responsible for overseeing school health services.

https://www.health-e.org.za/wp-content/uploads/2013/10/Integrated_School_Health_Policy.pdf

HIV, STIs and TB

There are many policies and guidelines related to HIV, STIs and TB. We have provided descriptions of and links to a selection of these documents. For a complete list see https://sahivsoc.org/SubHeader?slug=ndoh-and-who-guidelines. There are also useful apps available in the App Store or Google Play, entitled 'HIV Clinical Guidelines', 'TB Clinical Guidelines' and 'EML Clinical Guidelines'.

National Strategic Plan on HIV, STIs and TB, 2017–2022

NSP 2017–2022 is the latest of four national strategic plans, developed as part of a comprehensive response to HIV and expanded to include TB. This iteration has the theme 'focus for impact', providing that '[w]hile comprehensive prevention and care will be provided countrywide, intensified, concentrated efforts will be made in the 27 districts that account for 82% of all people living with HIV and for the majority of new infections and in the 19 districts with the highest TB burden.' Each province should have a provincial implementation plan although the level of implementation of these plans is questionable.

http://sanac.org.za/wp-content/uploads/2017/05/NSP_FullDocument_FINAL.pdf

National HIV Testing Services Policy, 2016

The National HIV Testing Services Policy provides a guideline for the different types of HIV Testing Services that should be provided in the country to accelerate universal access to HIV prevention, treatment, care and support services for people living with HIV and AIDS. The goal of the policy is to identify people living with HIV timeously, by providing quality testing services for all and effectively linking them to appropriate prevention, care, treatment and support services.

https://sahivsoc.org/Files/HTS%20Policy%2028%20July%20final%20copy.pdf

National Consolidated Guidelines for the Prevention of Mother-to-Child Transmission of HIV (PMTCT) and the Management of HIV in Children, Adolescents and Adults, 2015

The consolidated guidelines provide standardised drug combinations for managing Prevention of Mother to Child Transmission (PMTCT), and for managing children, adolescents and adults with HIV/AIDS, TB and other common opportunistic infections. The guidelines are used to provide guidance for clinicians,

managers and trainers on the use of available regimens within the context of the continuum of HIV comprehensive care for prevention, treatment and support.

https://sahivsoc.org/Files/ART%20Guidelines%2015052015.pdf

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 counselling and testing, 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.labour.gov.za/DOL/downloads/legislation/acts/employment-equity/hivaidstechnicalguide.pdf

Interim Clinical Guidance for the Implementation of Injectable-free Regimens for Rifampicin-resistant Tuberculosis in Adults, Adolescents and Children, 2018

This document provides interim clinical guidance on the implementation of the modified short- and long-treatment regimens for people with Rifampicin Resistant Tuberculosis (RR-TB) in South Africa. National guidelines are scheduled to be revised in 2019 following the publication of the updated WHO policy guidelines on MDR-TB treatment.

http://www.tbonline.info/media/uploads/documents/dr_tb_clinical_guidelines_for_rsa_september_2018.pdf

The National Infection Prevention and Control Guidelines for TB, MDR-TB and XDR-TB, 2015

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 the high prevalence of both diagnosed and undiagnosed TB, such as prisons.

https://www.idealclinic.org.za/docs/National-Priority-Health-Conditions/Nationl%20IPC%20Guideline%20for%20TB%20MDR%20and%20XDR%202015.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.

https://www.tbfacts.org/wp-content/uploads/2015/08/SA-MDR-TB-Policy.pdf

Health policies passed by other departments

Other government departments have also developed policies that impact on access to health care services. For example, in 2018, the Department of Trade and Industry finalised the Intellectual Property Policy of the Republic of South Africa. The policy will be implemented in phases, and aims to strike a balance between intellectual property rights and the state's duty to promote the realisation of fundamental rights. Phase I of the policy covers issues relating to intellectual property and public health. It proposes several interventions that will improve access to medicines.

http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf

Appendix D

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THIRD EDITION

THE NATIONAL HEALTH ACT GUIDE

The National Health Act (NHA) is arguably the most important Act passed by Parliament to give effect to the right of everyone to have access to health care services.

This right is guaranteed by section 27 of the Constitution of the Republic of South Africa, 1996, which places express obligations on the state to progressively realise socio-economic rights, including access to health care. This booklet aims to make the NHA easily available and accessible to the public generally. It is hoped that by putting the text of the NHA into the hands of people in communities and organizations, they can start to mobilise to demand full implementation of their rights under the NHA and under the Constitution.

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