Chapter 4

The statutory and administrative framework of the public health system



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Introduction

In this chapter, we set out the broad policy and legal framework governing health care in South Africa. This provides the context for understanding the health and health-related law that is described in other chapters of this book. We do not deal with every policy that has been developed or every piece of health legislation that has been passed or that is pending. This is because, since 1994, Parliament has passed many laws dealing with health-related issues. In addition, several provinces have also passed health laws.

Instead, this chapter focuses on those laws and policies that are intended to establish the overall statutory and administrative framework governing health care in South Africa. After looking at the legislative framework, we consider the political and administrative framework that is legally responsible for managing the health system and ensuring the delivery of health care. This includes:

- the structure of the Department of Health (DoH) at all spheres of government; and
- the allocation of roles and functions of officials and units within the DoH. Health law and policy is constantly changing and is one of the most challenging areas of transformation facing South Africa. It requires the ideas and experience of providers of health care and all of us as consumers of health care. Therefore, we also consider the policy- and law-making process, explaining how interested parties can get involved.

The chapter concludes by looking at the future legislative agenda of the DoH, as well as areas of reform that have been identified but not yet carried out.

4.2 The broad legal and policy framework for health

Section 27(1)(a) of the Constitution of the Republic of South Africa, 1996 ("the Constitution") provides that "[e]veryone has the right to have access to ... health care services, including reproductive health care". Section 27(2) requires the state to "take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of" the right. Finally, section 27(3) ensures that "[n]o one may be refused emergency medical treatment".

As we have seen in Chapter 2, because the Constitution is the highest law of the land, all other laws must be consistent with its provisions. Any law that is passed must ensure that the rights of everyone to have access to health care

services are respected, while laws that deal specifically with - or have a direct impact on - access to health care services must "protect, promote and fulfil" this right.

In 1998, for example, Parliament passed the Medical Schemes Act, 131 of 1998, which prohibits medical schemes from unfairly discriminating against people because of their "state of health" or preventing old or sick people from becoming scheme members or beneficiaries. In other words, medical schemes have to accept any person who can afford to pay the premiums, which cannot be higher just because someone is old or sick. This is an example of the state taking a reasonable legislative measure to prevent third parties – in this case private medical schemes - from limiting access to health services.

See Chapter 6 for more on the regulation of private medical schemes.

Health policy

Recognising the right to health care is different from realising it in a context where people have been deprived of health care for centuries. It is for this reason that, after the first democratic elections in 1994, the new government began to develop a new policy based on its vision of health care for all.

Although the African National Congress (ANC) had already set out a vision for health in the Reconstruction and Development Programme (RDP), the government needed to develop detailed proposals for health policy and law. This led to a number of committees being set up to advise the new Minister of Health on proposals for reform.

In the early years of South Africa's democracy, a complex process of research and consultation into policy culminated in the release in 1997 of the White Paper on the Transformation of the Health System in South Africa. A White Paper ordinarily sets out a government department's detailed policy principles and objectives.

The White Paper

The White Paper, which sets out a detailed framework for health care delivery, also identified how government intended to transform South Africa's health care system. It still remains one of the most important policy documents that guides health sector transformation today.

The White Paper built upon the ANC's 1994 Health Plan and the RDP. It states that government's overall objective is to develop a unified health system capable of delivering quality health care to all, guided by the strategic approach of providing comprehensive primary health care (PHC).

According to the White Paper, all health sector policy and legislation would be: "based on a common vision which reflects the principles of the RDP:

- a) The health sector must play its part in promoting equity by developing a single, unified health system.
- b) The health system will focus on districts as the major locus of implementation, and emphasise the PHC approach.
- c) The three spheres of government, NGOs and the private sector will unite in the promotion of common goals.
- d) The national, provincial and district levels will play distinct and complementary roles.
- e) An integrated package of essential PHC services will be available to the entire population at the first point of contact."

The White Paper speaks about decentralising the management of health services and sets out the position and objectives of government in areas such as human resources, health information, HIV/AIDS and sexually transmitted diseases (now ordinarily referred to as sexually transmitted infections, or STIs). It also contains a table of goals, objectives and indicators for 2000 - most of which were not achieved.

Other policy documents

Both before and after the White Paper was published, other important policy framework documents were issued, including:

- The *National Drug Policy* of 1996.
- The Health Sector Strategic Framework 1999-2004 of 2000.
- The Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa ("the Operational Plan") of 2003.
- The Strategic Priorities for the National Health System 2004-2009 of 2004.

It is this combination of policy documents – together with many other detailed policies dealing with specific health issues – that aims to provide the detailed framework for the state to discharge its constitutional duty to ensure that "everyone" in South Africa is able to access health care services.

Example: Patients' Rights Charter

An example of a policy that consciously aimed to give legitimacy to health rights is the Patients' Rights Charter of 1998 - which speaks about rights that were later given legislative effect in the National Health Act, 61 of 2003.

The Charter helps:

- health care workers to understand and respect the rights of patients; and
- patients to take responsibility for their health and respect the rights of health care workers.

Example: PEP for needlestick injuries

Government has a policy to provide antiretroviral (ARV) medicines - at its expense – to health care workers who sustain needlestick injuries. This policy, which is necessary to reduce the risk of HIV transmission in the public health sector workplace, is already in force, although its implementation varies across different parts of the country.

This post-exposure prophylaxis (PEP) is very different from policies on restructuring the public health care sector. These set out what are known as policy objectives - in other words, the aims of the policy. These policy objectives are linked to a process of law reform and usually give government's vision of providing services in the future.

For example, the DoH's Strategic Priorities for the National Health System 2004-2009 identify a 10-point plan, indicating laws that need to be passed or amended. In many respects, the passing of the National Health Act represents the culmination of much law reform regarding health. It establishes in law the authority for the implementation of new policies.

The relationship between health policy and law

As we have seen, government policy can have a variety of purposes, including setting out legislative intent. But not all policy is, or needs to be, reflected in specific laws. Thus, a policy document can explain your rights or be part of plans or programmes for service delivery. In addition, a special law to give effect to the right of health care workers to get free PEP, for example, is not necessary because we can use the policy to enforce their rights. Simply put, it is not necessary to legislate on every policy objective.

Because policies guide the conduct of government, they too must respect the constitutional right of access to health care. This point was highlighted in the dispute between the Treatment Action Campaign (TAC) and the Minister of Health over the use of nevirapine (or any other effective ARV medicine) to prevent mother-to-child transmission of HIV.

In its unanimous judgment in the TAC case, the Constitutional Court confirmed that the judiciary may make orders that affect policy as well as law:

"A factor that needs to be kept in mind is that policy is and should be flexible. It may be changed at any time and the Executive is always free to change policies when it considers it appropriate to do so. The only constraint is that policies must be consistent with the Constitution and the law." (paragraph 114)

The Court ordered that the policy be changed, advising that a reformulated policy "must meet the Constitutional requirement of providing reasonable measures within available resources for the progressive realisation of the rights of such women and children" (paragraph 122).

4.3 The National Health Act: the legal framework for health and healthrelated legislation

The first draft of a new National Health Bill was published in 1998. However, the delay in introducing the Bill to - and passing it in - Parliament led to a long period of confusion, particularly concerning the precise responsibility for providing health services at provincial and local level. Until it was passed, the legislative framework for South Africa's health system remained fragmented.

In many respects, the National Health Act (NHA) gives legislative effect to the 1997 White Paper. It is the most important law setting out the legislative framework for health care delivery in the country. It replaces - and goes well beyond – the previous Health Act of 1977, whose contents reflected the apartheid era in which it was passed.

Aims of the NHA

According to its preamble, the NHA aims to:

- unite the various elements of the national health system in a common goal to actively promote and improve the national health system";
- "provide for a system of cooperative 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 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"; and

• "promote a spirit of cooperation and shared responsibility among public and private professionals and providers and other relevant sectors within the context of national, provincial and district health plans".

Divided into 12 chapters, the NHA deals with a range of issues – including the structure of the national health department, the rights of users and providers of health care, the functions and duties of the district health system and health research. It is essential reading for health activists, who would do well to understand how it deals with people's health rights and the state's corresponding obligations. In addition, it sets out the systems and structures through which health users can ensure the delivery of proper health services. Importantly, it recognises that one of the main objectives of the national health system is to provide "the best possible health services that available resources can provide".

Three health system levels

The NHA gives legislative effect to a public health system that is designed to function through three tiers or levels: national, provincial and district. The functions and responsibilities of each tier are set out in chapters 3, 4 and 5 of the NHA:

- National functions include identifying national goals and priorities, and developing norms and standards for the provision of health services. The Minister of Health is given overall responsibility for discharging these duties.
- Provincial functions include taking care of public and private hospitals, providing specialised hospital care, ensuring that systems are in place to maintain quality control, and supporting districts in providing health services. The NHA also says that the head of health in a province must "consult with communities regarding health matters". The nine members of the provincial executive councils (MECs) responsible for health must ensure the implementation of all these responsibilities.
- District health structures are meant to be at the centre of health care service delivery, particularly primary health care services provided through clinics. The boundary of each health district is the same as district and metropolitan municipal boundaries. However, to improve services in big municipalities, provincial governments are allowed to set up health subdistricts. These districts (and sub-districts) are responsible for providing municipal health services, as well as water and sanitation services.

Free health care services

In 1995, then President Nelson Mandela announced a policy of free health care services for pregnant women and children under six. The NHA gives legislative effect to this policy, guaranteeing the provision of such services (including termination of pregnancy services) - at state expense - to all pregnant women and children who are not members or beneficiaries of private medical schemes.

Equally important, the NHA says that all people (other than those who have medical scheme coverage) are entitled to free primary health care services. But what does this include? The NHA, which empowers the Minister to prescribe (through regulations) what is included in the definition of primary health care, also states that she must "ensure the provision of such essential health services" to all people who live in South Africa.

For more on rights under the Choice on Termination of Pregnancy Act, see Chapter 11 dealing with gender and health.

Rights of users and duties of providers

A very important aspect of the NHA is its recognition of a range of rights belonging to users of health care. In particular, the NHA gives legal force to the contents of the 1999 Patients' Rights Charter by saying that every user must:

- be given information about their health and treatment options, as well as their right to refuse treatment;
- provide informed consent for treatment or care by a health service provider and participate in decisions about their care;
- be provided with a written report when they are discharged from a health establishment and have access to their own personal information;
- have their medical records kept confidential; and
- have their complaints investigated.

Particularly significant is the duty on all health authorities to disseminate information about local health services to the public, including:

- the types and availability of health services;
- the organisation of health services; and
- operating schedules and timetables for visits.

A successful health system depends on respect for the rights of both users and providers of health care. In recognition of this, the NHA requires patients to treat health workers with dignity and respect, and says that health workers are entitled to refuse to treat a patient who is abusive or who sexually harasses them.

For more on the rights of users of the health care system, see Chapter 8.

For more on the rights of health workers, see Chapter 10.

Realising these rights is critically dependent on the health system employing enough people to offer these services. This aspect of health care provision has been seriously overlooked, resulting in shortages of most categories of health care workers and a general failure to discharge the obligations of the NHA. After much delay, the DoH finally published its human resources for health plan in April 2006. While a welcome development, the plan has been criticised by civil society as lacking in appropriate detail and commitments.

Establishing advisory and consultative bodies

The NHA envisages a health system based on a "spirit of enquiry and advocacy which encourages participation". It requires the Minister and MECs to set up at each sphere of government – a number of bodies with functions that include policy-making, expert guidance and monitoring of health service delivery:

- The National Health Council (NHC) is made up solely of government officials. In discharging its primary function, which is to advise the Minister on policy, it may consult with or receive representations from civil society.
- In practice, the *National Health Consultative Forum* which "must include relevant stakeholders" – plays a role that is largely limited to information sharing (on an annual basis). This appears to be somewhat contrary to the intention of the NHA.
- Provincial Health Councils must be established in every province. Like the NHC, they are composed only of members of government, have a purely advisory role (to the Health MEC) and may consult with and receive representations from civil society.
- Again, mirroring the situation at a national level, *Provincial Health* Consultative Forums must be established and meet at least once a year.
- Provincial governments are required to pass legislation providing for the functioning of District Health Councils.
- Unlike the situation at the national and provincial sphere of government, there are no district consultative forums. Instead, the NHA says that the Minister and provincial governments must establish "representative" hospital boards and clinic committees that have to include representatives of the communities served by the clinic or hospital.

These structures may indeed provide the best opportunity for communities and structures of civil society to play a constructive role at the local level, by providing a formal space for engaging directly with those involved in service delivery.

Even though civil society is excluded from the national and provincial structures that advise the Minister and MECs, the mere existence of such bodies should benefit the promotion of access to quality health care. For example, communities can exercise their rights of access to information to obtain the minutes of these meetings and monitor these bodies to ensure that they discharge their obligations.

In addition to these bodies, the NHA establishes a number of other structures - their functions are fully explained in other chapters of this book:

- A Forum of Statutory Health Professional Councils made up of representatives from each professional council, officials from the DoH and community representatives.
- A National Health Research Committee, with the task of identifying and coordinating health research priorities.
- A National Health Research Ethics Council, tasked with setting norms and standards for health research.

For more details on these structures in assisting with health research, see Chapter 12.

Establishing monitoring bodies

One of the most important and novel aspects of the NHA is the way in which it establishes a range of special institutions and offices to monitor compliance with the NHA. This is an important reform. Statutory bodies such as the Health Professions Council of South Africa (HPCSA) – known as the South African Medical and Dental Council during the years of apartheid – are responsible for ensuring good practice by health professionals. But while complaints can be made against individuals, such bodies do not oversee or investigate health facilities themselves. This previous gap in the law is now addressed by the NHA:

- Each provincial health department must establish an Inspectorate for Health Establishments to monitor "compliance" and produce a quarterly report for the Health MEC.
- The Director-General (DG) has to establish a national Office of Standards Compliance and an Ombudsperson who can receive complaints about health care. This office is given major responsibilities to monitor public and private health care services, and must inspect each health establishment every three years.

■ Health Officers must be appointed by the Minister, MECs or mayors to "monitor and enforce compliance with the Act". These officials are given wide powers to carry out inspections and to request documents. Any attempt to obstruct health officers or to deny them information is a criminal offence.

In May 2005, all but two of the chapters of the NHA (chapters 6 and 8), and parts of some chapters that need new regulations, came into force. For example, the part of chapter 10 that deals with the Office of Standards Compliance is not yet in force, so that the appropriate infrastructure can be set up.

Key Point: Opportunity for advocacy and monitoring

The coming into effect of the NHA was an important milestone in the development and implementation of South Africa's health law. It expressly imposes new and much clearer duties on government to realise the right to health, and presents opportunities for human rights activists – advocacy, monitoring and perhaps even litigation – to ensure the provision of better health care services.

4.4 Other laws that have an impact on health

There are many other laws that directly affect the provision and quality of health care in South Africa. In addition, policy and legislation that is not directly about health care can have a positive or negative impact on health and the legal framework for health. The Constitution, for example, says that everyone has a right "to an environment that is not harmful to their health or well-being". While creating positive duties on all spheres of government to protect the environment, this right may have an impact on local government legislation in relation to refuse dumps and waste disposal.

For an explanation of laws dealing with the policy framework for private health care delivery, see Chapter 6; for laws that regulate traditional and alternative health care, see Chapter 7; and see Chapter 13 for laws that regulate the registration and sale of medicines.

Similarly, labour practices can be examined to ensure that they do not harm the health of employees. Legislation that specifically protects the health and safety of employees is already a part of our law, and is recommended by international bodies such as the International Labour Organisation (ILO).

Even laws that appear to have no relationship to health at all may affect people's rights of access to health care services, such as laws on intellectual property and trade that limit access to essential medicines.

For more on international law and intellectual property, see Chapters 5 and 14.

Laws that can promote the right to health

In addition to the NHA, there are a number of laws that promote rights that are directly relevant to health service delivery. These include:

- the Promotion of Equality and Prevention of Unfair Discrimination Act, 4 of 2000 ("the Equality Act"); and
- the Promotion of Access to Information Act, 2 of 2000 (PAIA).

The Equality Act

Amongst other things, the Equality Act provides for non-discriminatory access to health care in both public and private health sectors. It prohibits the denial of access to health services on a range of grounds, including race, gender, sexual orientation and disability. In particular, it can be used to prohibit limiting women's access to social services or benefits such as health care services.

The Equality Act makes it unlawful, for example, to deny a transgender person access to health services or a health facility because he is dressed in "women's clothing", or for a private facility to deny access to emergency medical treatment on the basis that someone is too poor to pay. Simply put, it can be used to guarantee equitable access to health care services.

Promotion of Access to Information Act

PAIA provides for access to information in an open, democratic and transparent society. It aims to give effect to the right of access to information in section 32 of the Constitution, and thereby contribute towards the establishment of a culture of human rights and social justice. To ensure that this happens, it is vital that people understand their rights as set out in PAIA. Organisations such as the Open Democracy Advice Centre (ODAC) play a crucial role in this regard.

PAIA attempts to promote transparency, accountability and effective governance in the public and private spheres. To achieve this, it:

- tries to balance the right of access to information with all the other rights in the Constitution;
- effectively empowers and educates people to understand better the function and operations of public bodies;

- provides mechanisms for accessing information necessary for monitoring and participating in decision-making by public bodies; and
- sets out limitations on the right of access to information to protect people's privacy and confidential commercial information.

There are concerns, however, about whether PAIA goes far enough in giving effect to the constitutional right to access information. Some argue that some of the limitations it places on accessing information are neither reasonable nor justifiable.

CASE STUDY 1: COMPELLING AN 'ORGAN OF STATE'

PAIA has already been used with some success by organisations such as ODAC. In Mittalsteel SA Ltd v Hlatshwayo [2006] SCA 94 (RSA), for example, the organisation acted on behalf of a graduate student to get access to minutes of certain meetings held by Mittalsteel's predecessor, Iscor. Holding that Iscor was, "at the relevant time, and when exercising the functions in respect of which the respondent requested records, a 'public body' for the purpose of s 11 of PAIA", the SCA upheld the High Court decision to compel Mittalsteel to hand over the requested documents.

CASE STUDY 2: USING PAIA TO FRUSTRATE ACCESS

In 2004, TAC tried to use PAIA to force the Minister of Health to make available the timetable for implementing the public sector ARV treatment programme. This timetable was referred to as "Annexure A" in the Operational Plan. But despite carefully following the provisions of the statute for months, nothing but silence was forthcoming. TAC had no option but to litigate.

Faced with this, the Minister indicated that the document requested was in fact a draft document that had never been adopted as policy, and that any reference to it in the Operational Plan was an "error". Reluctantly, TAC accepted this explanation. But because the Minister took so long to respond – only after the initiation of legal proceedings – TAC pursued a costs order in the High Court.

In Treatment Action Campaign v Minister of Health, a judgment of the Pretoria High Court that condemned the conduct of the DoH, Acting Justice Ranchod said that it was "trite that the Minister concerned of any department bears ultimate responsibility for the functioning of his or her department". Of concern, however, is the fact that no implementation timetable has ever been released. Despite lengthy litigation, TAC's initial concern remains.

In his decision, Ranchod AJ confirmed that government departments may not ignore requests for information:

"The failure of the respondent and her department to respond to the applicant's request in terms of the Act and to the applicant's subsequent appeal under the Act was in breach of their obligations under the Act. It was accordingly inconsistent with section 1(c) of the Constitution."

Section 1(c) of the Constitution refers to the founding value of "[s]upremacy of the Constitution and the rule of law".

4.5 The administrative framework for the delivery of health care

The DoH has the overall responsibility for ensuring that people living in South Africa have access to health care services in the public and private sector. Based in Pretoria, it is made up of a number of different units and clusters. As political head of the department, the Minister of Health oversees the department and has the constitutional responsibility for ensuring the provision of health care services.

The Minister is supported by a Deputy Minister and a DG. The President appoints the Minister and his or her deputy. While the Minister may select the DG, that appointment is nevertheless subject to Cabinet approval.

The NHA sets out the functions of the DG, who is responsible for:

- implementing national health policy;
- developing guidelines for health policy implementation; and
- drawing up national health and human resource plans annually.

The structure of the national Department of Health

The DoH is made up of various parts. The organogram on the opposite page - which reflects certain incorrect information regarding the names of people - shows the relationships between the parts.

As the organogram shows, there are four main clusters in the department, and within each cluster, there are different units sometimes called directorates. Thus within Strategic Health Programmes, for example, there are directorates for:

- Communicable Diseases;
- HIV and AIDS & STIs (formerly known as TB, HIV/AIDS and STDs);
- Pharmaceutical Policy and Planning;
- Medicines Regulatory Authority; and
- Maternal, Child & Women's Health and Nutrition.

Each unit is given the specific task of ensuring that services are provided according to the needs of the country.

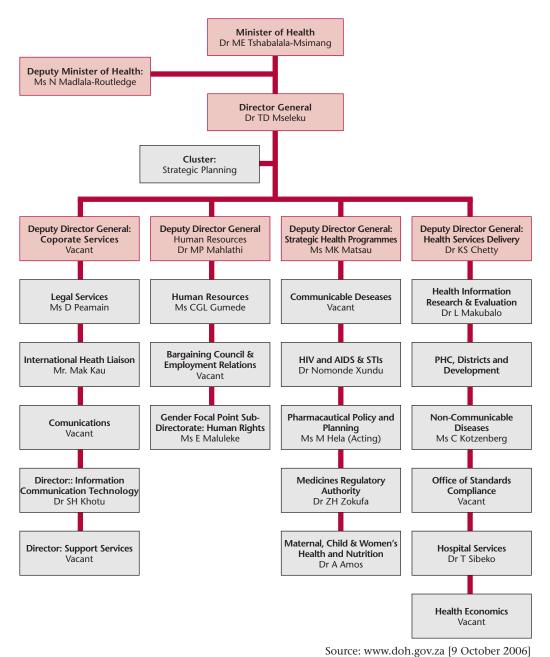


Figure 4.1: Organogram showing structure of DoH

The Constitution identifies health services as one of the "functional areas of concurrent national and provincial legislative competence". In other words, health is a shared responsibility. In addition, provincial governments also delegate much of this responsibility to districts. Each province also has a provincial department of health to ensure that each province is able to discharge its constitutional role. Nine MECs for health are the political heads of the provincial departments. A provincial head of department plays a role at the provincial sphere similar to that played by the DG at the national sphere. For more on government responsibilities under the Constitution, see Chapter 2.

Co-ordination between different provinces and ensuring uniformity of implementation is essential if health care services are to be delivered equitably - to allow people who live in the poorest provinces of South Africa to receive the same quality of care as people in richer provinces. This co-ordination was meant to happen through a committee known as the "Health MinMEC", an informal structure comprised of the Minister and all nine MECs. Today, such co-ordination falls under the reach of the National Health Council, which has already been discussed in this chapter.

The role of the district health system

Much of the ANC and government vision for health is supposed to be realised through effective and quality primary health care delivered through the district health system. In the first few years after 1994, however, there was some confusion - municipal boundaries had not been finalised, requiring health district boundaries to be readjusted in 1999 and thereby causing disruption and confusion. Although the provision of public health services has been based on the health districts since 1999, it was only when the NHA was brought into force in 2005 that health districts were given formal statutory recognition.

According to the NHA, provinces must pass legislation to govern the functioning of district health councils. These bodies are required to promote cooperative governance and to "ensure the co-ordination of planning, budgeting, provisioning and monitoring of all health services that affect residents of the health district". In addition, the NHA requires each health district to "ensure that appropriate municipal health services are effectively and equitably provided in their respective areas".

This is done by the relevant MEC for health assigning the administration of certain health services to the district health council. This must be done in agreement with the council and in accordance with section 156(4) of the Constitution, which allows for assignment if the service "would most effectively be administered locally" and the council "has the capacity to administer it". For assignment to take place, each District Health Council must enter into what is known as a service level agreement that must provide for:

- the services to be rendered by the municipality;
- the resources that the relevant MEC must make available for such services to be provided;
- performance standards to be used to monitor services rendered by the municipality; and
- conditions under which the agreement may be terminated. In addition, the NHA says that each district must develop and implement local health and human resource plans "in accordance with national guidelines".

Key Point: Monitoring district health

Service level agreements, district health plans and human resource plans should be made publicly available. They can then be used by health activists, health sector trade unions and medical associations to:

- monitor the provision and quality of health care; and
- ensure that there is no corruption and mismanagement of funds and contracts.

4.6 Processes for developing health policy and law

The Constitution provides for a democratic and open society where government is based on the will of the people within the rights-based framework provided by the Bill of Rights. It actively encourages public participation when it develops policies and laws. Thus in Doctors for Life International v The Speaker of the National Assembly (CCT 12/05, 17 August 2006), the Constitutional Court's Justice Ngcobo held as follows:

"Public participation in the law-making process is one of the means of ensuring that legislation is both informed and responsive. If legislation is infused with a degree of openness and participation, this will minimise dangers of arbitrariness and irrationality in the formulation of legislation. The objective in involving the public in the law-making process is to ensure that the legislators are aware of the concerns of the public. And if legislators are aware of those concerns, this will promote the legitimacy, and thus the acceptance, of the legislation. This not only improves the quality of the law-making process, but it also serves as an important principle that government should be open, accessible, accountable and responsive. And this enhances our democracy." (at paragraph 205, footnote omitted)

When laws and policies are developed, individuals, NGOs and other interested parties may lobby government through formal and informal means to ensure that their interests and the interests of the people they represent are promoted and protected. Interested parties may seek meetings with the relevant minister and/or advisers to find out more about the policy intentions of the department, or they may meet with the technical committee or policy task team appointed to develop the policy of the department.

With this in mind, this part of the chapter discusses how laws and policies come about, and how those outside of government can influence or contribute to these various processes.

The work of Parliament

Parliament and most provincial legislatures have public participation officers or departments. Their role is to promote public participation and assist people with the information and skills they need in order to participate. To facilitate this participation and involvement, all legislatures must conduct their business in a transparent manner. This means that South Africans have a right to attend:

- all the meetings of parliamentary committees; and
- all the sittings of the National Assembly (NA), the National Council of Provinces (NCOP) and the provincial legislatures.

Access can be denied only when there is reasonable and justifiable basis for excluding the public. Exclusion is the exception, not the rule.

When a bill is tabled in Parliament, it is published in the *Government Gazette*. The deadline for written submissions is usually indicated in the same notice. After the deadline has expired, the relevant portfolio

committee in the NA usually holds public hearings. At these hearings, any interested organisation or person who made a written submission may also make oral submissions. Once the public hearings are concluded, the bill may be amended to include some of the submissions made during these hearings.

Parliamentary committees

It is important to engage with parliamentary committees because they influence the drafting process and the processes leading to the adoption of laws and policies. There are four types of parliamentary committees:

- Portfolio committees.
- Select committees.
- Ad-hoc committees.
- Joint standing committees.

We will briefly examine each of these parliamentary committees.

PORTFOLIO COMMITTEES

Portfolio Committees, where most of the work of Parliament takes place, are made up of members of the NA. They convene regularly to oversee every ministry and government department. The Portfolio Committee on Health, for example, is responsible for monitoring, scrutinising and investigating the DoH.

Portfolio committees have the power to:

- make recommendations about any aspect of the relevant department's legislative programme;
- make enquiries and hear evidence; and
- summon any person to appear before it to supply information, including a minister or the President.

SELECT COMMITTEES

Because select committees are made up of members of the NCOP, they deal only with matters that affect the provinces. Unlike the NA, the NCOP does not have a committee for each ministry or government department. Instead, it joins different departments together using a cluster approach. Thus, for example, there is a select committee on social services - covering education, health and social development.

AD-HOC COMMITTEES

Ad-hoc committees are set up to deal with specific once-off issues – in other words, they are not permanent. For example, an ad-hoc committee for the "Task Group on the Sexual Abuse of Children", made up of members of the NA and NCOP, was established in 2003. Its mandate was to investigate sexual abuse. Once it had submitted its report to Parliament, it disbanded.

JOINT STANDING COMMITTEES

Joint standing committees are committees set up by members of the NA and NCOP. They work collectively on a particular issue. For example, the Joint Budget Committee includes members of the Finance Portfolio Committee and members of the NCOP Select Committee on Finance.

Bills and Acts

It is important for health activists to understand how legislation is developed and at which points in the process it is possible for civil society to intervene. The legislative process is set out in the Constitution, which sets out how laws must be introduced and passed at national and provincial levels. It also requires that Parliament and the provincial legislatures facilitate public participation in legislative processes.

Processes in the NA and NCOP

Before a policy becomes law, the NA and NCOP consider a draft version of the law. This draft version, which is called a bill, is usually introduced in the NA – only a limited category of bills may be introduced first in the NCOP. Only a member of Cabinet, a deputy minister, or a member or committee of the NA may introduce a bill in the NA. In the NCOP, only a member or committee of that body may introduce a bill. This means that an ordinary person cannot go to Parliament to try to pass a law.

Bills in the NA

The NA can pass four different types of bills, which are the following:

- **a** bill that does not affect provinces, called a section 75 bill;
- an ordinary bill that affects provinces, called a section 76 bill;
- amendments to the Constitution, dealt with in terms of section 74 of the Constitution; and
- money bills, dealt with in terms of section 77 of the Constitution according to the procedures set out in section 75.

The procedures for passing legislation are set out in the Constitution. In this chapter, we deal only with the first two types of bills. This is because health legislation usually falls within these two categories.

See Chapter 3 for more on how the health budget is developed and passed by Parliament, including a discussion of money bills.

From a bill to an Act

A bill becomes a law only after these steps are taken:

- A majority of the members of the NA must be present before a vote may be taken to decide whether they approve of the draft law or not.
- Even if the NA approves a bill that does not affect the provinces (a section 75 bill), they still have to refer the bill to the NCOP.
- The NCOP must then pass, reject or amend the bill.
- If the NCOP amends or rejects the bill, the NA must then reconsider the bill and take into account the amendments proposed by the NCOP.
- The NA may then pass the bill with or without amendments, or decide not to proceed with the bill.
- If the bill is passed, it must then be sent to the President for assent and signature. It is only after the President agrees to and signs the bill that it becomes an Act.

In some cases, the NCOP may reject a bill that has been passed by the NA, or the NA may refuse to amend a bill in accordance with the NCOP's recommendations. In such cases, the Constitution provides for a mediation committee to attempt to resolve the areas of dispute.

WHAT DOES THE PRESIDENT DO WHEN A BILL IS APPROVED?

When presented with a bill that has been approved by the NA and the NCOP, the President normally assents to and signs the bill. It then becomes an Act – even before it is proclaimed. But if the President has concerns about the constitutionality of the bill, he or she must refer it back to Parliament for reconsideration. Once reconsidered by Parliament, which may decide to leave the Bill untouched, the President has two options:

- to assent to and sign the bill; or
- to refer it to the Constitutional Court to decide on its constitutionality. If the Constitutional Court declares that it is constitutional, the President has no option but to agree to and sign the bill into law.

See an example of such a referral to the Constitutional Court in the case of *Ex parte President* of the Republic of South Africa: In re Constitutionality of the Liquor Bill, discussed in Chapter 2.

The Constitution also allows the Premier of a province to make similar referrals in respect of provincial bills. In addition, the Constitution also makes provision for the following groups of people to refer signed statutes to the Constitutional Court before they become law:

- a group comprising at least one third of the members of the NA may refer an Act of Parliament; and
- a group comprising at least one third of the members of provincial legislature may refer a provincial Act.

Example: Gauteng School Education Bill

In 1995, the Speaker of the Gauteng legislature referred a dispute over the constitutionality of the Gauteng School Education Bill to the Constitutional Court for adjudication. In the 1995 case of *In re Gauteng School Education Bill* 1996 (3) SA 165 (CC), the Court decided that the Bill complied with the Constitution.

When does an Act come into force?

Once the President assents to and signs a bill, it becomes an Act. The Act is then published in the *Government Gazette*. But there can still be a further period before it is brought into force – this is while government takes the necessary steps to be able to implement the law, such as the drafting of regulations. For example, although the NHA was passed in 2003 and signed by the President in 2004, the date of commencement was proclaimed only in April 2005 and it came into effect on 2 May 2005.

If the Act is silent on the date of its operation, it comes into effect when published in the *Government Gazette*. This is not what ordinarily happens. An Act of Parliament will usually say that it (or particular sections of it) comes into effect on a date:

- set out in the Act; or
- determined by an identified person ordinarily the President.

Although the date on which an Act comes into effect may be delayed, this delay cannot be unreasonable.

CASE STUDY: UNREASONABLE DELAY

S v Walters 2002 (4) SA 613 (CC) considered a 1998 amendment to the Criminal Procedure Act that had not been put into operation by 2001. The amended Act gave the President the power to fix the date of its implementation. In its decision, the Constitutional Court held that the power to determine when an Act comes into force cannot lawfully be used to veto or otherwise block legislation passed by Parliament. In other words, there should be no unreasonable delay in putting legislation or amendments into operation.

Challenging the validity of an Act

Once the President has signed a bill, it becomes an Act and is subject to legal challenge. In *Doctors for Life International*, the Constitutional Court's Justice Ngcobo held as follows:

"In terms of section 81, '[a] Bill assented to and signed by the President becomes an Act of Parliament'. The fact that the statute may not have been brought into operation cannot deprive this Court of its jurisdiction. There is nothing in the wording of section 80 that precludes this Court or any other court from considering the validity of an Act of Parliament at the instance of the public. Nor is there anything in the scheme for the exercise of jurisdiction by this Court that precludes it from considering the constitutional validity of a statute that has not yet been brought into operation. The legislative process is complete, and there can be no question of interference in such a process. Once a bill is enacted into law, this Court should consider its constitutionality." (paragraph 64)

It is not necessary to prove or show an actual violation of a constitutional right – even the possibility of a violation is sufficient to allow a challenge.

Example: Using a legal challenge to delay implementation

In February 1998, the Pharmaceutical Manufacturers Association of South Africa (PMA) filed papers in the Pretoria High Court challenging the Medicines and Related Substances Control Amendment Act, 90 of 1997 – on the basis that it was said to violate their property rights as well as South Africa's obligations under international trade law. This legal challenge – subsequently abandoned in April 2001 in the face of international pressure and a realisation that the case was weak – effectively prevented the President from promulgating the law for three years.

Regulations

Regulations give effect to an Act and provide details of how different parts of the law will be implemented. Most statutes provide that a Minister or a relevant public official responsible for implementing the legislation must prepare and pass regulations.

The NHA gives the Minister extensive powers to introduce regulations after consulting with the National Health Council on anything that "may or must be prescribed in terms of the Act", as well as "generally" on any issue on which it is "necessary or expedient to prescribe". Some of the areas listed in the NHA are:

- developing an Essential Drugs List;
- I human resource development; and
- determining communicable diseases and notifiable medical conditions.

Example: Regulations on prescribed minimum benefits

When the Medical Schemes Act was passed in 1998, the Minister issued regulations to give effect to certain provisions in the Act. One of these was the Prescribed Minimum Benefits (PMBs), a minimum set of benefits guaranteed to all medical scheme beneficiaries but not defined in the Act.

In some cases, an Act can come into force only once the regulations are ready – otherwise there will be no guidance on how its provisions must be implemented. This means that an Act, or part of an Act, could be delayed until regulations are in place. For example, although the NHA came into effect in May 2005, chapters 6 and 8 were delayed while waiting for regulations to be finalised.

Example: Regulations needed for act to be proclaimed

In 1999, the PMA successfully challenged the promulgation of the South African Medicines and Medical Devices Regulatory Authority Act, 132 of 1998. They successfully argued that the law could not come into effect until the regulations needed to give effect to the Act were in place. In that case, the Constitutional Court held that the President had acted irrationally – and therefore unconstitutionally – by bringing a statute into force too soon.

Challenging the validity of regulations

When a Minister intends to promulgate regulations, he or she ordinarily starts by publishing draft regulations for public comment. Interested organisations and individuals will have a period – sometimes as short as a few weeks but often up to three months – to make written submissions commenting on the draft. When the regulations are finalised and approved, they are published in the *Government Gazette*. Anyone who wishes to challenge the constitutionality of the regulations may do so at this point, even if they have not yet come into effect.

Section 90(4) of the NHA, for example, specifically says that regulations must be published "at least three months" before their commencement. However, possibly in recognition of the fact that health matters can sometimes create urgent situations, section 90(4) of the Act also empowers the Minister to act more speedily:

"The Minister may, if circumstances necessitate the immediate publication of a regulation, publish that regulation without ... consultation."

ON WHAT BASIS CAN REGULATIONS BE CHALLENGED?

Regulations may not unreasonably or unjustifiably limit the rights in the Bill of Rights. For example, a regulation that limits access to health care without good reason is invalid. In addition, there are numerous other ways of challenging regulations, for example where:

- the regulations were not drafted according to the correct procedure; or
- there was no authority given by the Act to the Minister to make the regulations.

CASE STUDY: MEDICINE PRICING REGULATIONS

In 2004, a case was brought in the Cape High Court by New Clicks, the Pharmaceutical Society of South Africa (PSSA) and others challenging regulations that were promulgated to give full and final effect to the transparent medicine pricing system described in the Medicines Act.

The applicants challenged the regulations in their entirety, but were most aggrieved by the regulations dealing with the appropriate dispensing fee to be charged by pharmacists and other dispensing health practitioners. They argued that the prescribed fee was so low that it would effectively put many pharmacists out of business.

In a controversial judgment, the Cape High Court dismissed this application. On appeal to the SCA, the regulations - as a whole - were declared invalid. A further appeal to the Constitutional Court had mixed results. In general, the regulations were held to be valid. A number of them were changed by the Court itself. Most importantly, the dispensing fee was found to be inappropriate. It was referred back to government for revision. At the time of writing, a year after the Constitutional Court's decision, the dispensing fee issue had just been finalised.

For more information on this case, see Chapter 14.

CASE STUDY: REGULATIONS ON MAKING AIDS NOTIFIABLE

In 1999, the DoH proposed draft regulations to make AIDS a notifiable medical condition. If passed, they would have required health care workers to disclose the HIV status of people living with AIDS to health authorities, as well as to immediate family members and caregivers.

The AIDS Law Project and other organisations made written submissions opposing the introduction of these regulations. They argued further that notification - in the manner proposed - would violate the right to privacy of people living with HIV/AIDS. They argued that the regulations would not succeed in providing government with accurate information on the numbers of people with AIDS – the alleged intended public health aim – and could therefore not be justified. Notification regulations were never introduced.

Provincial health legislation

Bills that affect individual provinces do not go through the same processes as national legislation, primarily because there is no upper chamber such as the NCOP. Instead, a provincial bill is simply discussed in the relevant provincial parliamentary committee and then introduced in the provincial legislature.

Once a bill is passed by a provincial legislature, the Premier must either sign it or refer it back to the legislature for consideration. Thereafter:

■ The Premier must sign the bill if all of his or her concerns regarding the Bill's constitutionality are addressed.

- If they are not, the Premier can either agree to and sign the bill, or refer it to the Constitutional Court for review.
- If the Constitutional Court finds that the bill is constitutional, then the Premier has to agree to and sign the bill.

Once a bill is agreed to and signed by the Premier of a province, it becomes a provincial Act. It is then published and comes into effect either on the date on which it is published, on a date as set out in the provincial Act or on a date decided by the person tasked by the provincial Act with promulgating the law.

Examples: Some provincial health laws

- Eastern Cape Provincial Health Act, 10 of 1999
- Free State School Health Services Act, 11 of 1998
- Gauteng District Health Services Act, 8 of 2000
- KwaZulu-Natal Health Act, 4 of 2000
- Limpopo: Northern Province Circumcision Schools Act, 6 of 1996
- Limpopo: Northern Province Health Services Act, 5 of 1998
- North West Health Development, Social Welfare and Hospital Governance Institutions Act, 2 of 1997
- Western Cape Health Facility Boards Act, 7 of 2001

Because of the delay in passing the NHA, many provinces were cautious about passing provincial health legislation that might later conflict with the NHA. This may have been a wise move, because now that the NHA has become law, it sets out a number of activities that provincial governments must carry out. For example it says that:

- provincial health councils must advise the MEC for health on provincial health legislation before it is introduced to the provincial legislature; and
- provincial legislation must provide for the functioning of district health councils, and for establishing and describing the functions of clinic and community health centre committees.

The South African Law Reform Commission

The role of the South African Law Commission, established in terms of the South African Law Commission Act, 19 of 1973, was to conduct research into all branches of law in order to make recommendations to develop, improve, modernise or reform the law. Since 1994, the Commission - now known as the South African Law Reform Commission (SALRC) - has been transformed and restructured into an independent research commission with the task of promoting law reform.

The President appoints the members of the SALRC. The Chairperson is usually a judge of the Constitutional Court – currently Justice Yvonne Mokgoro. Other members are appointed because of their legal skills and expertise, as well as their research abilities. They are usually judges, advocates, attorneys and university lecturers.

A government department, Minister, Member of Parliament or a parliamentary committee may ask the SALRC to conduct research on a particular topic. Ordinary citizens and NGOs can also suggest research. However, the Minister of Justice and Constitutional Development has the final say about whether research into the suggested area of law can be conducted by the SALRC.

The SALRC is not a body tasked with researching health law. However, given the many factors that have an impact on health, the SALRC's work often affects health law and policy. For example, in recent years the SALRC has investigated the Sexual Offences Act and the Child Care Act – both of which overlap with aspects of health.

Participating in SALRC research

The SALRC provides civil society with the opportunity to intervene at a very early stage in the law reform process. This can be done after the commission releases an issue paper on a particular topic, by making written and/or oral submissions to the relevant Project Committee. After considering all the submissions made, the committee does further research, releasing a discussion paper for further comment. The final stage of its work is a report containing its proposals for reform, which usually includes a draft bill (or bills). This report is presented to the Minister of Justice and Constitutional Development for his or her consideration.

Key Points: Commenting on SALRC discussion papers

- Any interested person or organisation can make written and oral submissions on a discussion paper.
- Submissions are taken into account in the proposals for law reform made in the final version of the SALRC report that is submitted to the Minister of Justice and Constitutional Development.
- The Minister then decides on whether or not to accept the proposals
 whether to initiate amendments to current laws, to introduce new laws or not to act at all.

Example: Research on legal issues related to HIV

The SALRC began its investigation into the reform of the law affecting HIV/AIDS in 1993. Its discussion document (Working Paper 58), which was published for general information and comment during 1995, was heavily criticised. A reconstituted Project Committee – now chaired by Justice Edwin Cameron – was thereafter set up to take the process forward.

The committee's first interim report, dealing with matters such as condom standards, universal infection control measures in occupational safety regulations, implementing a national policy on HIV testing and amendments to regulations governing communicable diseases, was adopted by the SALRC and tabled in Parliament on 28 August 1997.

Thereafter, the committee investigated various other aspects of the law relating to HIV and issued four further interim reports with recommendations on:

- pre-employment HIV testing;
- discrimination in schools;
- compulsory HIV testing of people accused of sexual offences; and
- the criminalisation of "harmful HIV-related behaviour".

All of these reports were published and endorsed by the SALRC. However, it is up to the government to decide whether or not to implement the recommendations. For example, the SALRC's recommendation regarding the need for a law to ban pre-employment HIV testing was largely responsible for the inclusion – in the Employment Equity Act, 55 of 1998 – of a section that prohibits such testing unless permission has first been obtained from the Labour Court.

4.7 The future legislative agenda

In South Africa, there are huge differences in the provision of health services. While the private sector spends large amounts of money on relatively few people, the public sector has to do with less for the majority of the population.

Government has passed laws to regulate the conduct of providers in the private sector. Some of these laws aim to reduce the differences between the private and public sectors, and to encourage the private sector to take up more of the health burden. This is important because for a long time the private sector was largely unregulated, leading to many cases of unfair discrimination against old and sick people.

At present, the most important piece of legislation that regulates the private health sector is the Medical Schemes Act, 131 of 1998. Chapter 6 deals with

this legislation and other means of regulating the private sector in order to achieve equitable access to health care services. In addition, government is planning to introduce several more laws and policies to try and make the private sector respond more equitably to the health problems in our country.

National Health Insurance

The future vision for the South African health care system was outlined in the *Report of the Social Security Committee of Inquiry* (the *Taylor Report*), which was released in May 2002. This was followed in July 2004 by the DoH's document entitled *Strategic Priorities for the National Health System*, 2004-2009. In many respects, the latter document appears ignorant of the *Taylor Report*.

Key Point: Recommended NHI system

The *Taylor Report* recommended that South Africa move ultimately towards a National Health Insurance (NHI) system that integrates the public sector and private medical schemes into a universal contributory system. In other words, all people who earn pay money into a national fund so that anyone who needs health services can get them either in the public or private sector.

The first phase of developing a NHI system is to introduce a Social Health Insurance (SHI) system. This means that, as part of the longer-term process of health care reform in South Africa, SHI will be introduced first.

These are some of the aspects of a proposed SHI system:

- SHI deals with the formal employment sector only, aiming to ensure that every person who is formally employed in South Africa pays a certain amount of money to a national SHI fund. This will be calculated according to how much they earn.
- Every worker will then be able to get health care in the private and public sector the costs will be paid by the SHI fund.
- SHI will be compulsory for all workers in other words, all formal sector employees and their employers will have to contribute to SHI. What this means is that those workers who earn more money will cross-subsidise workers who earn very little money.

- Workers will not be paying anything more than existing medical scheme contributions. Rather, SHI will re-organise the payments to medical schemes.
- Direct payments to medical schemes will probably be reduced, and mainly lower-income earners will benefit substantially.

To date, however, SHI has yet to be implemented. At this stage, it is unclear if and when NHI will be implemented.