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2 health

Authors

Abstract

Health legislation can encompass almost any legal instrument that has a bearing on the health of the individual or community. To comprehensively cover all possible aspects is thus beyond the scope of a publication of this nature. This chapter focuses on the most important event of the last year, the promulgation of most of the National Health Act (Act 61 of 2003) ('Health Act'). This is ***the*** *fundamental piece of health legislation that will shape the future of the South African health system. While the past year has not seen a large number of new Acts, some have been amended or brought into effect. The Minister of Health has also announced a very ambitious legislative programme for 2005. A feature of the past year has been the number of very important legal challenges to aspects of new health legislation, notably relating to termination of pregnancy and both traditional / complementary and orthodox medicines legislation.*

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legislation

Introduction

Previous chapters of the South African Health Review (SAHR) have repeatedly called for progress in enacting a new fundamental Health Act for this country, to replace the 1977 Health Act. The 2003/04 SAHR, which reviewed a decade of post-apartheid health legislation noted that "the absence of this foundational legislative instrument, and of a Social Health Insurance Act, represents a significant gap in the government's legislative achievements".[1] The chapter did, however, note that although the National Health Bill had not been assented to by the President nor brought into effect, it had at last been passed by Parliament. This chapter will focus predominantly on the content of the Health Act and the process of bringing it into effect. It will also focus on the ongoing contestation of various legislative instruments, notably those associated with the Medicines and Related Substances Act (Act 101 of 1965), the Choice on Termination of Pregnancy Act (Act 92 of 1996), as well as other significant health-related legislation dealt with during the past year.

The National Health Act 2003

Despite being passed by Parliament in late 2003, the Health Act was only assented to by the President in July 2004.[2] A promulgation notice was issued in April 2005, bringing most sections of the Act into effect as from 2 May 2005. While this move is significant, the impression has been created that some real challenges still lie ahead and that much still needs to be clarified.[3] Draft regulations, covering the necessary detail that would allow those sections as yet not promulgated to come into effect, were reported to be almost ready to be published for public comment. The chapters of the Health Act are described below in some detail. Unless indicated, each of the provisions described was brought into effect on 2 May 2005.

The Health Act includes a lengthy preamble that reaffirms many of the principles included in the 1997 White Paper for the Transformation of the Health System in South Africa.[4] It makes very specific mention of the constitutional demands on the health system, and then states that the Health Act is intended 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". Among the principles echoed are commitments to "cooperative governance and management", "national guidelines, norms and standards", "decentralised management" and "a spirit of cooperation and shared responsibility among private and public health professionals and providers".

Chapter 1 of the Act restates the constitutional allocation of responsibility for health, which lies with "the national department, every provincial department and every municipality". Significantly, the Act provides finality on the vexed question of the meaning of the term "municipal health services". Municipal health services have now been defined as including water quality monitoring, food control, waste management, health surveillance of premises, surveillance and prevention of communicable diseases (excluding immunisations), vector control, environmental pollution control, disposal of the dead and chemical safety. Port health, malaria control and the control of hazardous substances have been excluded from the definition. In essence, this restricts municipalities to responsibility for the provision of environmental health services, as opposed to personal health services or comprehensive primary health care services. Lastly, this chapter provides a legislative

backing for a transformatory step previously accomplished by means of a policy directive only – it reaffirms the right of access of pregnant women and children under 6 years of age to free health services, and of all persons to free primary health care services, unless, in each case, they are members or beneficiaries of a medical aid scheme.

A number of definitions are integral to understanding the Health Act, including:

- Health care personnel – a catch-all phrase, incorporating both "health care providers" (professionals providing services in terms of any law, including the Allied Health Professions Act, Health Professions Act, Nursing Act, Pharmacy Act and Dental Technicians Act) and "health workers" (all other personnel "involved in the provision of health services to a user").
- Health establishments – a broad definition encompassing any public or private "institution, facility, building or place", whether for profit or not, that is "operated or designed to provide" any sort of health service.

Chapter 2 deals with the rights and duties of users and health care personnel. It begins, however, with the very important section 5, which states "A health care provider, health worker or health establishment may not refuse a person emergency medical treatment". This section has direct implications for the private sector, where the ability to pay is an important barrier to access. It has been noted that the Act does not define "emergency medical treatment", but that the Regulations to the Medical Schemes Act state that " 'emergency medical condition' means the sudden and, at the time, unexpected onset of a health condition that requires immediate medical or surgical treatment, where failure to provide medical or surgical treatment would result in serious impairment to bodily functions or serious dysfunction of a bodily organ or part, or would place the person's life in serious jeopardy".[5] The meaning of the term has also been tested in court.[6] In the Soobramoney case, the appellant based his claim on section 27(3) of the 1996 Constitution, which provides that "No one may be refused emergency medical treatment". The treatment in question – access to dialysis services – was judged not to constitute emergency treatment. In his concurring remarks, Sachs J stated:

> *"The special attention given by section 27(3) to non-refusal of emergency medical treatment relates to the particular sense of shock to our notions of human solidarity occasioned by the turning away from hospital of people battered and bleeding or of those who fall victim to sudden and unexpected collapse. It provides reassurance to all members of society that accident and emergency departments will be available to deal with the unforeseeable catastrophes which could befall any person, anywhere and at any time. The values protected by section 27(3) would, accordingly, be undermined rather than reinforced by any unwarranted conflation of emergency and non-emergency treatment such as that argued for by the appellant" (paragraph 51).*

This chapter has been brought into effect with the exception of section 11, which deals with health services rendered for the purposes of research. The Department has indicated that regulations are contemplated that will "set parameters and criteria for conducting experimental and research work in health establishments".[7] The "rights" outlined have been summarised by the Department as "the right to emergency medical treatment, the right to have full knowledge of one's condition, the right to exercise informed consent, the right to participate in decisions regarding one's health, the right to be informed when one is participating in research, the right to confidentiality and access to health records, and the right of health workers to be treated with respect". Although in effect, some sections still require regulations to provide the necessary detail, for example, section 13 calls for the information to be recorded in a health record to be "prescribed". Some of the provisions of this chapter provide a statutory basis for patient-friendly services. For example, section 12 requires that every provincial department, district and municipality make available a wide list of information on the services for which they are responsible.

Chapters 3, **4** and **5** complete the statutory enactment of many of the design features of the national health system. The first of these deals with the general functions of the national department and its organisation. It replaces the Health MinMEC with a statutory body, the National Health Council, representing national, provincial and local government. The first meeting of the newly constituted Council was held on 6 May 2005. The remit of the Council is generally that of policy making – it is to advise the Minister, who serves as chairperson, on "policy concerning any matter that will protect, improve and maintain the health of the population". Chapter 3 also creates the National Consultative Health Forum. The composition of this consultative body, which will meet at least once a year, has yet to be determined by the Minister.

Chapter 4 makes provision for similar structures at a provincial level. These include Provincial Health Councils and consultative bodies. Both chapters envisage integrated national and provincial 'health plans'. A clear hierarchy

is established – provincial health plans must 'comply with national health policy' and their format may be determined by the National Health Council.

Chapter 5 opens with the rather bland statement that "[a] district health system is hereby established". While the necessary building blocks may be provided, there remain many challenges to the full realisation of this policy goal. Some elements have already been implemented, for example, that "the boundaries of health districts coincide with district and metropolitan municipal boundaries." Further division into 'sub-districts' is provided for, but not mandatory. Together with the member of the Executive Council (MEC) responsible for local government, each MEC responsible for health must then establish district health councils, which will be responsible for the development of district health plans in line with provincial health policies. Much of this system is made dependent on provincial legislation. Critically, the Act prescribes that the provincial MEC responsible for health must assign certain health services to municipalities in terms of 'service level agreements.' In order to preserve existing services that fall outside of the narrow definition of 'municipal health services,' a transitional arrangement has been inserted into the Act. Section 34 states that "Until a service level agreement .... 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". Chapter four on the District Health System, in this Review, provides a more in-depth discussion of these issues.

Chapter 6 is, in all likelihood, the most controversial. This chapter has not been brought into effect yet, pending the development of suitable regulations. The basis of the chapter is the classification of health establishments into categories and then the introduction of a 'certificate of need' (CoN) for all such establishments. This will allow for all health establishments, whether public or private, to be registered by the Department of Health. The controversial element is that the CoN is intended to ensure that such establishments are distributed equitably. Not only will all new or enlarged facilities have to obtain a CoN, but all established facilities would need to obtain a CoN within 24 months of this chapter coming into effect. Such certificates will be valid for a prescribed period, not exceeding 20 years. Section 36(3) prescribes the factors that the Director-General must take into account when deciding whether or not to issue or renew a CoN. A recent Constitutional Court challenge has resulted in similar 'need' provisions being declared ultra vires.[8] General Regulation 18 to the Medicines and Related Substances Act was intended to assist the Director-General in deciding whether an applicant for a dispensing licence had shown the 'need' for such a service in a particular setting.[9] J. Ngcobo noted that government's intended purpose for these provisions was to "enhance the scope for efficient utilisation of resources ... [and] allow the government to plan and implement its health programme more effectively" (paragraph 113). Noting also that the provisions of Regulation 18 that related to the demonstration of 'need' were consistent with the National Drug Policy, the Constitutional Court nonetheless found them ultra vires, as the policy was "not discernable from the Medicines Act" (paragraph 119). The parallels with the CoN are clear, although the policy intent is perhaps more clearly stated in the Health Act itself. Chapter 6 also contains a number of other provisions dealing with types of services to be provided at different public health establishments, the need for provincial legislation dealing with the establishment of clinic and community health centres committees, control over initiation schools and ceremonies, and referral between public facilities. Although not detailed in any way, there is provision for the Minister to prescribe "mechanisms to enable a coordinated relationship between the private and public health establishments in the delivery of health services". Finally, the chapter calls for the evaluation of the services provided at all health establishments and the creation of two new structures, the Office of Standards Compliance and the Inspectorate for Health Establishments. It enables the Minister, in consultation with the National Health Council, to prescribe quality requirements and standards in respect of "human resources, health technology, hygiene, premises, the delivery of services, business practices, safety and the manner in which users are accommodated and treated". This gives the Minister wide-ranging powers to improve the quality of care in both the public and private sectors.

Chapter 7 mandates the National Health Council to take concrete steps to manage human resources in the national health system. It has to develop a human resources policy and guidelines. One coordinating mechanism that is created is the Forum of Statutory Health Professional Councils. Both this section and that dealing with the establishment of academic health complexes have not been promulgated. The Department of Health is engaged in ongoing negotiations with the Department of Education and the Treasury about the means to address the human resource challenges of the national health system.

Chapter 8 is a complex series of provisions dealing with control of blood, blood products, tissues, gametes, post-mortem examinations and transplantation. Many provisions

are drawn directly from the Human Tissue Act, which will be repealed in its entirety with the passage of this Act. This chapter has not yet been brought into effect. One of these provisions prescribes that the Minister must license a single non-profit organisation to provide a blood transfusion service throughout the country. Another allows stem cell research, but prohibits reproductive cloning of a human being.

Chapter 9 deals with national health research and information systems. As in chapter two (section 11), the section dealing with research on or experimentation with human subjects (section 71) was excluded from the promulgation notice. Nonetheless, the parts of this chapter that have been brought into effect allow the Minister to create two important new structures – the National Health Research Committee (NHRC) and the National Health Research Ethics Council (NHREC). The first of these is tasked with setting national health research priorities. The second forms the apex of a new, over-arching research ethics system.

Section 69 outlines the nature and functions of the NHRC. Concern has been expressed about the high degree of control that section 69 entitles the Minister to exercise over the NHRC. For example, the Act makes it possible for a Health Minister to appoint members to the NHRC who are sympathetic to his or her own ideology and also to remove any dissenting voices. It does not provide explicit safeguards for researchers in the public sector who risk their careers by speaking out against government policy. There is, thus, the danger that misguided decision makers who are driven by ideology rather than scientific evidence could hijack the national research agenda. When section 71 becomes operational it will govern research on minors. Unfortunately, the Act uses the terms 'child' and 'minor' interchangeably, sometimes in the same sub-section. This is problematic since the Act offers no definitions for these terms. These terms have been defined differently in various pieces of South African legislation, although the recent passage of the Children's Bill in parliament could offer clarity on this issue. Alarmingly, the Act deprives minors of the right to participate autonomously in research for both 'therapeutic' and 'non-therapeutic' purposes. In addition to the minor's assent being required, in the case of research for 'therapeutic purposes', the solicitation of parental consent is mandatory while in the case of research for "non-therapeutic purposes", the solicitation of parental and the Minister of Health's consent is a mandatory prerequisite for the research to proceed. This conservative approach is short-sighted and, in some instances, potentially adverse to the interests of minor participants. For example, the solicitation of parental consent would be impractical or detrimental to minor's interest in studies examining incidence or prevalence of child abuse where the abusive parent will need to be asked consent for the participation of his or her child in the study. Similarly, the solicitation of parental consent in studies examining teenage pregnancy would be impractical or detrimental to the minor's interest in instances when the minor is accessing termination of pregnancy facilities without her parent's knowledge (which is the minor female's legal right in terms of the 1996 Choice on Termination of Pregnancy Act). Even before the full chapter 9 has been brought into effect, criticism has been directed at the quality of the legal drafting.[10] While recognising that the Act introduces "a platform for developing a wide range of legal norms for human subjects' research", these authors noted in particular that it did not set an age for independent consent to medical research. They also noted possible inconsistencies with the Child Care Act, which is itself in the process of reform. Noting that "in many respects the Act fails to meet its objectives, in part because of poor drafting and a failure to link with existing legal principles and processes", Strode et al. concluded that much would depend on the content of the regulations. The same could be said of much of the Act.

On the positive side, the chapters on research do have many redeeming features. Section 71(1) reinforces the sentiment espoused in section 12(2) of the Constitution which affirms everyone's right to bodily and psychological integrity, which includes the right to security in and control over their body; and not to be subjected to medical or scientific experiments without their informed consent. The Health Act clarifies the legality in South Africa of human reproductive and therapeutic cloning, as well as stem cell research (section 57). It empowers the NHREC to issue national research ethics guidelines. It also offers unprecedented and novel protections for researchers. It allows the NHREC to adjudicate complaints about the functioning of health research ethics committees and to hear any complaint by a researcher who believes that he or she has been discriminated against by a health research ethics committee. This will hopefully encourage thorough and considered protocol reviews by health research ethics committees.[11]

The NHREC will be responsible for setting norms, standards and providing guidelines to, as well as registering and auditing health research ethics committees. In early 2005 the Ministry of Health released the research ethics guidelines drafted by the Council's interim predecessor, the National Interim Health Research Ethics Committee. The Act provides that every institution, agency or health facility at which health research is conducted will have to either have or have access to a registered health research ethics committee. One of the

tasks set for the Council is to "set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials." This task has already been addressed by the Medical Research Council, the national Department of Health, and, to an extent, by the Medicines Control Council. Coordination, rather than ab initio development of guidelines, would therefore seem to be needed. The provisions for a national health information system are, by contrast, rather less prescriptive. The national department is tasked with facilitating and coordinating the development of a national system that includes data from all spheres as well as the private sector.

Chapter 10 deals with the inspectorate and compliance tasks of the national and provincial departments, but is to a large extent not yet in effect. The Office of Standards Compliance and the Provincial Inspectorates for Health Establishments have yet to be created. The means to inspect health establishments is primarily through the designation of 'health officers', who will have extensive powers. Once these structures are in place, the ability to issue certificates of non-compliance, and thereby suspend or even shut down the operation of the whole of part of a health establishment or agency, will be an important tool in ensuring compliance with this Act and all other applicable laws.

Chapter 11 enables the Minister to make a range of regulations and has accordingly been brought into effect for that purpose. Two provisions deserve mention. The Minister is enabled to make regulations on "the development of an essential drugs list and medical and other assistive devices list". The Minister is also enabled to prescribe the processes whereby the Director-General will determine and publish one or more reference price lists. These would not be binding on private sector providers, but would serve as a reference to determine their own fees and also by medical schemes when determining the benefits to be enjoyed by members and beneficiaries. **Chapter 12**, likewise, allows the Minister to appoint advisory and technical committees, and to delegate certain powers (except the power to make regulations). Given the incomplete promulgation of the Health Act, provision has also been made to retain necessary sections of other Acts that will eventually be repealed.

Other national health legislation

The 2003/04 SAHR identified a number of Bills that were expected to be processed during the remainder of 2004. A number of these have in fact been passed, but not all of them have as yet been brought into effect. Conversely, the Nursing Bill, a very significant piece of legislation, was published in draft form in 2003, but has not yet been tabled.[12] Those that have been dealt with are summarised in brief below.

In her briefing of the National Assembly Portfolio Committee in March 2005, the Minister laid out a very extensive legislative programme for the 2005 sessions. Each Bill and the proposed intent of the amendment are outlined in Table 1. The Minister indicated at the time that the Nursing Bill was with the office of the State Law Adviser for certification and would be tabled thereafter. A first draft of an Allied Health Professions Amendment Bill was also in preparation. An amendment to the Health Professions Act was also noted to be 'en route to the Cabinet via the Minister', and was expected to be before Parliament by September 2005. This Bill was intended to align the Health Professions Act with other proposed or current legislation, as well as to deal with issues of corporate governance, registration, professional boards, continuing professional development and unprofessional conduct. As can be seen in Table 1, the other health professional councils are also listed as needing 'clarification' of their roles.

Table 1: Planned health legislation in 2005

Identity of Bill	Status as at March 2005	Intent (as outlined by the Minister)
Tobacco Products Control Amendment Bill	Being drafted; intended for submission to the Cabinet in April 2005	✧ To create new offences and to increase penalties, to ensure compliance / implementation
Medical Research Council Amendment Bill	Being drafted; intended for submission to the Cabinet in May 2005	✧ To ensure that the role of the MRC is in line with the Department's public health initiatives
Medicines and Related Substances Amendment Bill	Being drafted; awaiting the outcome of the Constitutional Court case on pricing	✧ To ensure clarity on the role of the Pricing Committee ✧ To clarify the role of the Medicines Control Council
Pharmacy Amendment Bill	Being drafted; intended for submission to the Cabinet in July 2005	✧ To ensure clarity on pharmacy licenses ✧ To clarify the role of the Pharmacy Council
Foodstuffs, Cosmetics and Disinfectants Bill	With the State Law Advisers for certification, then to be tabled	✧ To tighten the regulation of foodstuffs' handling, storage and processing to avoid food borne diseases
Red Cross Bill	Being drafted; intended for submission to the Cabinet in September 2005	✧ To create a legal framework for the operations of the South African Red Cross in relation to the government ✧ To ensure there is no duplication of services around rescue and disaster management
Risk Equalisation Fund Bill	Being drafted; intended for submission to the Cabinet in October 2005	✧ To create a risk equalisation fund ✧ To stabilise medical schemes ✧ To correct imbalances between schemes caused by their membership profiles

Source: Minister's briefing to the Portfolio Committee, 8 March, 2005.

Dental Technicians Amendment Act, (Act 24 of 2004)[13]

This Amendment Act makes provision for the restricted registration of informally trained persons as dental technicians. An informally trained person is defined as a person who has been employed as a dental laboratory assistant for a period of at least 5 years by a dentist or dental technician and trained to perform the function of a dental technician. Discretionary direct billing to the patient or medical scheme for services rendered by a dental technician contractor is provided for in this legislation. Provision is also made for regulations setting out the conditions under which informally trained persons may be registered by the Council as dental technicians in terms of section 23A of the 1979 Act.

Sterilisation Amendment Bill, (Bill 12 of 2004)[14]

This Bill serves to align the 1998 Act with the constitutional requirement that a person not be discriminated against on the basis of age, by clarifying and confirming the rights of persons under the age of 18 years, and more importantly of persons who are incapable of giving consent due to mental disability. It ensures that the medical opinion of an independent medical practitioner is considered by a panel consisting of a psychiatrist or medical practitioner, psychologist and nurse. The Bill makes provision for factors that the panel must consider before approving sterilisation and obliges providers to fully explain the procedure and its potential consequences to the user.

Two categories of sterilisation are provided for in the Act. The first being where a person above the age of 18 years had consented to the procedure and the second being persons under the age of 18 or subject to "severe mental disability". The previous requirement was that, for both the severely mentally disabled person and the person under 18 years of age, their health must be under threat in order for sterilisation to be permitted, in addition to the requirement for a medical practitioner's recommendation. The Bill removes the requirement for the mental disability to be severe and the definition of threat to health includes physical, mental and social well-being. Thus, prior to a sterilisation procedure, consent would be obtained from the person involved or the consent of his / her caregiver or guardian where the person is mentally incapacitated or under-age. A written opinion of a medical practitioner recommending the procedure is required and a panel would discuss the merits of each case prior to a decision being made.

Traditional Health Practitioners Act, (Act 35 of 2004)[15]

This Act establishes the Interim Traditional Health Practitioners Council of South Africa for a period of 3 years and provides a regulatory framework to ensure the efficiency, safety and quality of traditional health care services. The registration, training and conduct of practitioners will in time also be regulated by this Act, in ways clearly premised on the same processes as are used by orthodox health professions. Traditional health practice is defined by the Act as "the performance of a function, activity, process or service based on a traditional philosophy that includes the utilisation of traditional medicine or traditional practice and which has as its object –

(a) the maintenance or restoration of physical or mental health or function; or

(b) the diagnosis, treatment or prevention of a physical or mental illness; or

(c) the rehabilitation of a person to enable that person to resume normal functioning within the family or community; or

(d) the physical or mental preparation of an individual for puberty, adulthood, pregnancy, childbirth or death".

Although assented to by the President, this far-reaching piece of legislation will require extensive negotiation and further regulation before any concrete evidence of its effects can be discerned. Draft regulations issued in terms of section 47(1) (a) have been developed, in order to create the Interim Council contemplated by the Act. All other regulations are to be made "after consultation with the Council". Critically these include the minimum training to be provided to traditional health practitioners. Also contemplated are regulations covering traditional medicines, "in order to protect the public and to ensure safety of use, administration or application." Potential overlaps are created with existing legislation covering the control of medicines. This may prove problematic.

Choice on Termination of Pregnancy Amendment Act, 2004 (Act 38 of 2004)[16]

This Amendment Act was designed to devolve the power to approve facilities where termination of pregnancy may occur to the Members of the Executive Council responsible for health in each province. Reporting will in future be handled provincially, although the rights of the national Minister and Department are retained. All facilities already designated for such services will be deemed to be so designated under the new arrangements. Although assented to by the President, the process of finalising provincial regulations is ongoing.

Mental Health Care Act, (Act 17 of 200)2[17]

Although assented to by the President in November 2002, the Regulations to this Act were only gazetted in December 2004, thus allowing the Act to be brought into effect.[18] The Act is all encompassing, and provides for the care, treatment and rehabilitation of the mentally ill. Procedures are set out in the Act that cover admission of such individuals and establishment of review boards and their powers in every health establishment. The care and administration of the property of the mentally ill also falls under the auspices of this Act. This piece of legislation has seen greater prominence lately, in the light of alleged inadequate quality of care at psychiatric institutions.[19]

The Children's Bill, Bill 70 of 2003 (reintroduced)[20]

Although the Children's Bill is not strictly-speaking a Health Bill, and has not been assented to by the President at the time of writing, it will undoubtedly have a major impact on the health of children and associated matters. That part of the Bill that is of national impact only was passed by Parliament in June 2005. The Children's Bill has been several years in the making, and is the most significant post-apartheid legal instrument governing the affairs of children. Upon promulgation the Bill will repeal several key statutes that currently govern the affairs of children, including the Children's Act, (Act 33 of 1960), the Age of Majority Act (Act 57 of 1972), and the Child Care Act (Act 74 of 1983). The Children's Bill seeks to give effect to certain rights of children as contained in the Constitution and to set out principles relating to the care and protection of children. Only those provisions that specifically pertain to children's health will be reviewed here.

The Bill provides that all proceedings, actions or decisions in a matter concerning a child must protect the child from unfair discrimination on any ground, including health status or disability (sub-section 6(2)(d)), and recognise a child's disability and create an enabling environment to respond to the special needs of that child (sub-section 6(2)(f)). The Bill also prescribes measures to be taken for children with disability or chronic illness (section 11) and offers explicit direction on

social, cultural and religious practices that affect children (section 12). In this respect the Bill outlaws genital mutilation or the circumcision of female children as well as the virginity testing of children. It offers every male child the right to refuse circumcision, taking into consideration the child's age, maturity and stage of development. A person who contravenes these measures is guilty of an offence. The Bill entitles every child to the right to information on health care (section 13) and also provides caregivers who do not hold parental rights over a child the right to consent to any medical examination or treatment care of a child while that child is in their care (section 32). The latter measure is particularly welcome given the large number of children in the country who fall under the care of caregivers who currently can exercise no recognised legal right over that child.

The Bill also outlines the rights of children conceived by artificial fertilisation (section 40) and the right of children to access biographical and medical information concerning genetic parents (section 41). The Bill empowers Children's Courts to make protection orders, including orders giving consent to medical treatment of, or to an operation to be performed on a child, as well as instructing a hospital to retain a child who on reasonable grounds is suspected of having been subjected to abuse or deliberate neglect, pending enquiry (sub-section 46(1)(h)). Part 3 of the Bill is explicitly dedicated to matters relating to the health of children. Section 129 of the Bill governs consent to medical treatment or surgical operation of a child. In a break with current law, the Bill lowers the age of consent for medical treatment. It provides that a child may consent to his or her own medical treatment (or to the medical treatment of his or her child) if over the age of 12 years and of sufficient maturity and with the mental capacity to understand the benefits, risks, social and other implications of the outcome. Similarly, the Bill also provides that a child may consent to the performance of a surgical operation on him or her (or his or her child) if over the age of 12 years, of sufficient maturity and mental capacity to understand the benefits, risks, social implications and other implications of the surgical operation, and where duly assisted by his or her parent or guardian. The Bill also prescribes circumstances under which the parent, guardian, caregiver, hospital superintendent and Minister of Social Development may consent to the medical treatment or surgical operation of a child. Sections 130 to 133 of the Bill govern HIV testing of a child and the confidentiality of information related thereto. Section 134 of the Bill governs the child's right to access contraception. Sections 292 to 304 of the Bill govern surrogacy agreements and matters related thereto. While the scope and substance of most of the Bill's provisions are praiseworthy it is unfortunate that the legislature missed the opportunity to regulate research involving children in this instrument.

Subordinate legislation

As the post-apartheid legislative reform process matures, increasingly the changes made will be incremental rather than wholesale in nature. Instead of whole new Acts and substantial amendments to existing Acts, changes will be brought about by regulation or other forms of subordinate legislation (such as rules made by the various health professions councils). A good example of how far-reaching such changes can, nonetheless, be, was provided by an amendment to the General Regulations to the Medical Schemes Act that came into effect on 1 January 2005. In terms of this change, the prescribed minimum benefit list was altered by including an additional element in the management of HIV infection.[21] Medical schemes are now expected to provide for "medical management and medication, including the provision of antiretroviral therapy", to the extent that this is provided for in established national guidelines applicable in the public sector. Table 2 shows some of the health-related subordinate legislation that has been brought into effect in the last year or published for comment.

Table 2: Regulations and notices 2004/05

Regulation and notices	Year
Medicines and Related Substances Act: Regulations: Transparent pricing system for medicines and scheduled substances (Regulation 37 of 2004).	2004
Medicines and Related Substances Act: draft amendment of the general regulations (Regulation 844 of 2004); published for comment.	2004
Compensation for Occupational Injuries and Diseases Act: Draft circular instruction regarding compensation for occupationally acquired HIV (Notice 1349 of 2004).	2004
Pharmacy Act: The South African Pharmacy Council: Rules relating to the services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees (Notice 106 of 2004); subsequently withdrawn.	2004
Pharmacy Act: South African Pharmacy Council: rules relating to good pharmacy practice (Notice 2 of 2004).	2004
Health Professionals Act: Regulations relating to the registration and training of interns in medicine (Regulation 57 of 2004).	2004
Health Professionals Act: Health Professionals Council of South Africa: Regulations relating to indemnity cover for psychologists (Regulation 294 of 2004).	2004
Medicines and Related Substances Act: Regulations: Transparent pricing system for medicines and scheduled substances (Notice 553 of 2004).	2004
Compensation for Occupational Injuries and Diseases Act: Draft circular instruction regarding compensation for pulmonary tuberculosis associated with silica dust exposure: Circular instruction 179 (Notice 852 of 2004).	2004
Occupational Health and Safety Act: Facilities regulation (Regulation 924 of 2004).	2004
Compensation for Occupational Injuries and Diseases Act (130/1999): Increase of maximum amount of earnings on which the assessment of an employer shall be calculated (Notice 199 of 2005).	2005
Compensation for Occupational Injuries and Diseases Act (130/1993) Circular instruction regarding compensation for work-aggravated asthma (Notice 336 of 2005).	2005
Council for Medical Schemes Levies Act: Proposed levies on medical schemes (Notice 414 of 2005).	2005
Regulations regarding the rendering of forensic pathology services (Regulation 341 of 2005).	2005

Provincial legislation

A comprehensive review of provincial health legislation is beyond the scope of this chapter. However, a single example is provided of how complex the situation can become. The Free State legislature passed the Free State Initiation School Health Act (Act 1 of 2004) and set the date of commencement as 5 March 2004. This Act provides definitions of 'traditional practice' and 'traditional surgeon.' Permission to hold an initiation school and treat an initiate is to be provided by the District Medical Officer, according to procedures to be specified by the Member of the Executive Council responsible for health. Included in these procedures would be steps to ascertain the experience and expertise of the traditional surgeon. There are thus clear overlaps between this provincial legislation and the national Traditional Health Care Practitioners Act. The consent processes included in the Act, specifically those for initiates under the age of 18 years, cover the same ground as the National Health Act. Such legislative overlap is not necessarily negative, but requires very careful coordination.

A growing jurisprudence

There have been a number of challenges to health-related legislation. Two prominent examples are covered – challenges to the Choice on Termination of Pregnancy Act and challenges to aspects of Medicines legislation. In addition, the use of the Promotion of Access to Information Act is highlighted, in relation to the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa.

Christian Lawyers' Association v National Minister of Health and Others

In May 2004, judgment was handed down by the Pretoria High Court in a matter involving a challenge to the right given to minors by the Choice on Termination of Pregnancy Act (Act 92 of 1996) (the ToP Act) that allowed them to terminate their pregnancies without parental consent.[22] The relevant section (section 5(3)) of the Act stated: "In the case of a pregnant minor, a medical practitioner or a registered midwife, as the case may be, shall advise such minor to consult with her parents, guardian, family members or friends before the pregnancy is terminated: **Provided that termination shall not be denied because such minor chooses not to consult with them**." (authors' emphasis).

The action was brought by the Christian Lawyers Association (the CLA), a civil society group that argued that

(a) section 5(3) was in conflict with the Constitution because it infringed the right of every child to family and parental care and to be protected from maltreatment, neglect or degradation (Section 20 of the Constitution),

(b) minors are not capable of making informed decisions about abortions without parental consent.

The CLA based this argument on the effects of an abortion on a minor; the vulnerability of the minor when making such decisions and both the changes in the developmental stages of a minor and the effects of such changes. Because of these special considerations, they believed that a pregnant minor deserves special state protection which required that the state ensure that she is not deprived in any way of the support, guidance and care of her parents, guardian or counsellor.

The defendants' in the action filed an exception to the claim on the basis that the CLA's case did not disclose a cause of action. In upholding the exception, the court had regard to two important aspects of the ToP Act:

(a) the promotion of counselling before and after the abortion; and

(b) the requirement of informed consent.

In essence, the court said that the ToP Act promotes counselling before and after the abortion, and minors, in particular, are advised to consult with significant others, either parents, guardians, family members or friends. Even if a woman, including a minor, chooses not to consult with anyone, including a counsellor, she must still be informed of her rights under the Act by the medical practitioner or midwife. This, read together with the provision requiring informed consent, meant that important mechanisms were in place to regulate the ToP Act, ensuring that the women, including competent minors were able to make informed decisions. The court pointed out that a valid consent may only be given by "someone with the intellectual and emotional capacity for the required knowledge, appreciation and consent". In circumstances where young and immature children lack this capacity, as shown not by a rigid age determination but by an assessment of intellectual and emotional maturity, they would be excluded from giving independent consent. In such circumstances, if a medical practitioner is not satisfied that the minor has the capacity to give informed consent, that practitioner should not carry out the abortion: to do so would be unlawful.

The Affordable Medicines Trust and others v the Minister of Health of the RSA and another

The applicants in this matter sought a declaratory order from the Pretoria High Court regarding certain sections of the Medicines and Related Substances Act, 101 of 1965 as amended (the Medicines Act) and its regulations, which they argued were unconstitutional.[8] The basis of the challenge was certain aspects of the dispensing licence system introduced by the government, and in particular subsection 22C(1)(a) of the Medicines Act and sub-regulations 18(3)(b), (f), (g), (h) and (i); 18(4); 18(5); 18(6); and regulation 20 of the Regulations made under the Medicines Act and published in Government Gazette 24727 under Government Notice R510 of 10 April 2003. The basis of the licensing system was that authorised prescribers, such as medical practitioners, dentists and certain nurses, would not be allowed to dispense medicines unless they obtained a licence. The scheme further regulated the premises from which such medicines would be dispensed. The applicants, all of whom represented the interests of medical practitioners, challenged the constitutional validity of the provisions of the Medicines Act that gave the Director-General the powers to make these decisions. Broadly, the applicants argued that:

- The conditions of the Act which gave the Director-General these powers were too broad and had the effect of giving the Director-General arbitrary legislative powers.
- The linking of the licence to compound and dispense medicines with the requirements of specified premises was not authorised by the Act and therefore the Minister exceeded her powers when making the regulation that gave the Director-General this right.

- In the alternative, they argued that the requirement of this linkage falls outside the authority to regulate the practice of the medical profession, and they attacked the regulations *in toto* on the ground that they were vague and thus gave the Director-General powers to make arbitrary decisions.

The High Court dismissed the application for the following reasons:

- The purpose of increasing access to safe medicines for the public was a legitimate government purpose. This purpose was necessarily linked to the regulation of the premises from which the medication was dispensed. There was thus a rational relationship between the government purpose and the envisaged licensing system.
- The Minister did not exceed her powers in making the regulations. The court believed that the legislature would have considered the possible specialised nature of the regulations, which might be better dealt with by experts in the field. Thus they would have foreseen the inclusion in the regulations of conditions determined by the Minister in consultation with specialist bodies.
- The court held that the regulations were necessarily vague because of the wide variety of circumstances that had to be covered. This did not mean that they were arbitrary or capricious.
- Finally the court held that there was no infringement of any constitutional rights.

On appeal, the Constitutional Court found that the offending provisions had to be seen in light of the government objective to increase access to safe medicines. Therefore, although the provisions in both the Medicines Act and the enabling regulations did confer wide powers upon the Minister (to make regulations) and the Director-General (to determine conditions upon which a licence may be issued) respectively, both had to be seen in light of the government's main objective. Furthermore, the statutory framework giving rise to the regulations provided sufficient guidance to enable the Director-General to adequately determine conditions upon which to issue licences. As regards the linking of the dispensing licence to particular premises, the Constitutional Court agreed with the High Court that this requirement facilitated regular inspection for compliance – if the public is to have access to safe medicines, the dispensing of medicines cannot be separate from the premises where dispensing takes place.

However, the Constitutional court considered the purpose of the factors in the regulations to which the Director-General had to have regard when deciding whether to grant these dispensing licences. It found that the factors, when construed in light of the National Drugs Policy of the Department of Health, which provides *inter alia* that medical practitioners are not permitted to dispense where there are pharmacies in the neighbourhood, had the effect of protecting pharmacies from competition with medical practitioners. According to the court, this purpose was not authorised by the Act and the Minister was not authorised by the statute to develop such a policy using the regulations. The court also noted that representatives of the respondent (the Minister) denied the existence of such a policy, coming to the conclusion that the policy as outlined in the National Drug Policy had been 'discarded.' Therefore those regulations dealing with the factors to be considered when adjudicating such an application (sub-regulations 18(5)(a), (c), (d), and (e)) went beyond the powers conferred upon the Minister and were declared invalid.

At first glance, the requirements struck down seem to have certain commonalities with the CoN provisions in the Health Act, as well as with the requirements for a pharmacy licence provided for in Regulations issued in terms of the Pharmacy Act (Act 53 of 1974). As stated earlier, a CoN will, in time, be required before health practitioners' practices or hospitals are established in a particular area. According to the Minister the reason for this is to "ensure that, over time, health services are distributed evenly and equitably in South Africa, thereby bringing about a structurally unified and integrated health system, equity in health care, improved access to health services, the implementation of norms and standards and optimal utilisation of resources".[23] The National Health Act, like the regulations that were declared invalid by the Constitutional Court, contains provisions that the Director-General must have regard to before issuing a CoN (section 36 (3)). This issue has not come before the court, though strong reactions from medical practitioners have been heard. Many argue that the CoN will force medical practitioners to practise where they do not wish to, and force health establishments to move to rural areas. What is clear from the Constitutional Court judgment in the Affordable Medicines case is that the court is broadly supportive of government's objectives to create equality of access in health care as well as equality of access to quality health care. Legal arguments surrounding the CoN would have to show that some other unfair and thus invalid purpose is also being achieved by section 36.

Medicine pricing cases

The 2003/04 SAHR noted that the Medicines and Related Substances Control Amendment Act (Act 90 of 1997) was a key piece of legislation to transform both public and private health care.[1] The authors also noted that a deliberate decision was made by government to separate the medicines-related issues from the National Health Bill and to deal with them alone, so as to avoid delaying the implementation of the fundamental health legislation. Despite this, the process of implementing the Medicines Amendment Acts (there was another in 2002, as well as the ill-fated South African Medicines and Medical Devices Regulatory Authority Act in 1998) has not been smooth. In addition to challenges to the dispensing licence provisions, the interventions made by government in relation to medicine pricing have also been the subject of a court challenge. The relevant enabling section of the Medicines Act was due to come into effect on 2 May 2004, a year after the bulk of the Amendment Act was brought into effect. In order for this to happen, regulations had to be prepared, on the advice of a Pricing Committee appointed by the Minister. At a press briefing held in Parliament on 18 August 2003, six months after the closing date for nominations, the Minister announced the appointment of all members of the pricing committee with the exception of the nominees of the Minister of Trade and Industry and the Minister of Finance. The remaining two members were appointed in December 2003. The pricing committee submitted its first report during December 2003. This was necessary, bearing in mind the deadline of 2 May 2004 and the period of three months that had to be set aside for public comment on the draft regulations. The final regulations were published on 30 April 2004, just in time for the commencement of section 22G on 2 May 2004.[24] In accordance with these regulations, wholesalers and distributors would not be able to charge a separate fee (as provided for in the 2002 amendment to the Act), but instead should be able to negotiate a 'logistics fee' with manufacturers. The fee, which would cover the costs of wholesaler and / or distributor services, would be included in the single exit price (SEP). In the case of Schedule 1 and 2 medicines sold without a prescription, pharmacists would be able to charge a maximum fee of 16% of the SEP, with a cap of R16. In the case of Schedule 1 and 2 medicines sold with a prescription and Schedule 3 to 6 medicines, pharmacists would be able to charge a maximum fee of 26% of the SEP, with a cap of R26. Doctors and other practitioners licensed to dispense medicines would be able to charge a maximum fee of 16%, with a cap of R16. Later the Medicines Control Council was persuaded to exempt all registered Schedule 0 medicines from the application of sections 22G (pricing) and 18A (bonusing) of the Act.[25]

Two legal challenges to these regulations were launched, and were heard simultaneously by a full bench of the Cape High Court in June 2004. Until the judgment was given, interim relief was provided by suspending the operation of the regulations. In August 2004 the applications were dismissed, with one of the three judges dissenting.[26] Leave to appeal was immediately sought by the applicants. Both applications were heard on 20 September 2004. However, before judgment could be handed down, the parties filed an application directly with the Supreme Court of Appeal, which heard their case on 30 November 2004. On 3 December 2004, the Cape High Court refused leave to appeal. On 20 December 2004, the Supreme Court of Appeal ruled in favour of the applicants, and declared the pricing regulations invalid and of no force and effect. The Minister then appealed to the Constitutional Court, seeking to overturn the decision of the Supreme Court of Appeal. Judgment is that case is expected soon, but was not available at time of writing.

Treatment Action Campaign v Minister of Health

In November 2003 the Department of Health published its Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa (Operational Plan). The published version of the Operational Plan referred to two annexures, 'A1' and 'A2.' According to this, annexure 'A1' was a week-by-week schedule for the pre-implementation period with deliverables for each of the main focus areas and annexure 'A2' was the Detailed Implementation Plan. However neither annexure was attached to the Operational Plan. The application was launched in court because, despite various requests from the Treatment Action Campaign (TAC) for access to both annexures, the requests were ignored. Only after this application was launched, and several weeks out of court time, did the Minister of Health respond in her answering affidavit that neither of these annexures in fact existed in an approved format, and reference to them in the Operational Plan was made in error. As soon as the TAC was informed of the status of the documents, it contacted the Minister's legal representatives and stated that it would withdraw its application for access to these documents but expected the Minister to tender its costs up to that point on an attorney and client scale.[27] The respondents failed to tender any costs and argued in court that the TAC should

in fact tender costs because the action was frivolous and vexatious with no meaningful purpose. The court considered the right of the public of access to information in terms of the Constitution and the Promotion of Access to Information Act, 2000. The court found that the application was not unreasonable in the circumstances. On the other hand, the actions of the department officials, and ultimately the Minister, were found to be unconstitutional in that they did not attempt to correct the version of the Operational Plan that was publicly available until shortly before the application was launched and they failed to respond to the TAC's various requests by clarifying the true state of affairs. Had the Department of Health done so, the application would not have been made. Thus the court ordered that, notwithstanding the fact that the TAC subsequently withdrew their application, the Minister was ordered to pay the TAC's costs on a scale as between attorney and client[a] and the costs of one counsel. This case was regarded as a major victory for the TAC against the Minister. It believed that such an unprecedented judgment was "a signal to the Minister to treat civil society with the seriousness that it deserves."[28] The potential use of the Promotion of Access to Information Act goes far further, however, and in particular could challenge the secrecy provisions in the Medicines Act.

Conclusion

In contrast to previous editions of the SAHR, this edition can report that the Health Act has not only been passed by Parliament, but is already being brought into effect. The inaugural meeting of the National Health Council has been held. This does not, however, signify that all hurdles have been overcome. As the continuing stream of amendments, both to Acts and Regulations, show, much still needs to be achieved in health legislation. As the growing jurisprudence also shows, although the courts recognise the transformatory intent of the government, they sometimes find fault with the mechanics of what is done. The Constitution poses serious tests for any new legislation and many more challenges using these provisions can be expected.

a There are a number of cost orders that a court can make. These include 'party and party costs', 'attorney and client costs', 'attorney and own client costs'. The scale that is most used is that between party and party – these are costs that are necessary in the matter. Usually when a court uses another scale, the costs order is regarded as being punitive against the party who is required to pay these costs. This is because the costs involved are greater as they include all the other costs that were involved in bringing the litigation to court.

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