

HEALTH

LEGISLATION

1994 - 2003



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Introduction

In 1994, the newly elected democratic government faced the tremendous challenge of transforming a highly inequitable and fragmented health care system. This challenge has been exacerbated by deepening poverty and inequality, and the metastatic growth of the national HIV/AIDS epidemic, to become, in the words of the constitutional court, the greatest threat to public health in our country.¹ This chapter traces the government's efforts in the subsequent decade to achieve a unified and equitable health care system in light of existing and emerging challenges, as they have found expression in health care-related legislative reform. Such a review is timely as we approach the anniversary of ten years of freedom and democracy.

The difficulties inherent in isolating all legislation that impacts upon public health have been noted in previous reviews² and this chapter therefore adopts a narrow focus on health care specific legislation passed since 1994. It is not an exhaustive account of all health care related legislation passed, but rather addresses those Acts which have served significant equity goals.

Legislation plays a critical role in achieving health reform goals, and has a multidirectional and dialogic relationship with policy. On the one hand, legislation depends on the development of policy to guide its nature and content.³ Yet health legislation can also "express and formulate health policies", and through statutes and regulations it can shape the way that health policy is translated into health programmes and services.⁴

Legislation however plays a distinct role from policy, and serves to coordinate health sector activities, and to create a 'management and administrative framework for the development of health care systems'.⁵ It establishes structures and

mechanisms to put policy into practice and provides for sanctions should the policy (encapsulated in the legal provisions) be breached.⁶ Health legislation creates certainty with respect to what is expected from various role-players and what the user of health services can expect. More generally it plays an essential public health role, 'which translates into public health terms the idea of making health accessible to all'.⁷

In South Africa (SA), the imperative to take reasonable legislative measures to ensure that everyone has access to health care services is constitutionally entrenched, making health care legislation to ensure equitable access an explicit constitutional obligation.⁸

Bearing in mind this constitutional imperative, and the role played by legislation in its achievement, this chapter reviews key pieces of health legislation passed and implemented since 1994, and assesses their impact on increasing equity in health care in SA, particularly insofar as they fulfil the goals of equitable transformation expressed in early policy. Assessing equity in health care must incorporate a constitutional analysis to the extent that the Constitution both mandates equity and gives it content. Therefore relevant provisions of the Constitution and their judicial interpretation are examined insofar as they provide greater clarity to the state's obligations to provide equitable access to health care services. Besides listing some of the key pieces of legislation the chapter also critically reviews the implementation of some of the legislation.

The Goals of Health Care Transformation in SA

In 1994, health care in SA was “highly fragmented, biased towards curative care and the private sector, inefficient and inequitable.”⁹ The newly elected ANC government’s plan for the health sector, reflected in the Reconstruction and Development Programme (RDP), was “a complete transformation of the national health care delivery system and all relevant institutions.”¹⁰ While several key legislative acts and policies preceded the formulation of the 1997 White Paper for the Transformation of the Health System in SA, this policy document elaborated the government’s plan for achieving transformation and operationalising a universal right of access to equitable health care, and sets the framework within which to assess the government’s fulfilment of these goals in the subsequent decade.

The White Paper is based on the overarching objective of developing a unified health system capable of delivering quality health care to all, guided by the strategic approach of providing comprehensive primary health care.¹¹ To this end, the White Paper set out a range of implementation strategies for health, “designed to meet the basic needs of all our people, given the limited resources available” and “based on the belief that the task at hand requires the pooling of both our public and private resources.”

A unified health system capable of providing quality health care to all would be achieved through the implementation of a broad range of policies and strategies including:

- ◆ decentralising the management of health services with an emphasis on the creation of a district health system;
- ◆ increasing access to services by making primary health care available to all;
- ◆ ensuring the availability of safe, good quality essential drugs in health facilities; and
- ◆ rationalising health financing through budget reprioritisation.

The national, provincial and health district levels would play distinct and complementary roles, although health districts would be the major locus of implementation, and would emphasise the primary health care approach. The White Paper envisaged a participatory process for meeting these objectives, including NGOs, the private sector, and especially communities. It also emphasised the development of a caring ethos amongst health care workers, with every effort made to ensure the improvement in the quality of services at all levels. A comprehensive package of primary health care interventions would be made universally accessible, with particular emphasis placed on reaching the “poor, the under-served, the aged, women and children, who are

amongst the most vulnerable.” This approach emphasised maternal, child and women’s health services, focusing particularly on the rural and urban poor and farm workers.

Unifying the fragmented health service included integrating the activities of the public and private health sectors, including NGOs and traditional healers, to maximise the effectiveness and efficiency of all available health care resources.

Measures to promote equity, accessibility and utilisation of health services, included establishing health care financing policies to promote greater equity between people living in rural and urban areas, and between people served by the public and private health sectors; and distributing health personnel throughout the country in an equitable manner. The White Paper envisaged new sources of funding for public health care coming from the retention of fees in the public sector, and the introduction of social health insurance, which would require all formally employed people to be insured for the costs of treatment of themselves and their dependants in public hospitals.

Specific proposals for integrating the public and private sectors included regulating medical schemes to prohibit exclusions on the basis of health risks, and discontinuing the practice of transferring private patients to the public sector once their benefits had been exhausted.

In 1996, there were 1.8 million people with HIV and AIDS. The White Paper envisaged a national HIV/AIDS programme to reduce the transmission of sexually transmitted infections (STIs) and HIV infection, and provide appropriate care, treatment and support for those infected. HIV and AIDS strategies were to be based on the principles that civil society and government would be involved mutually in containing the spread and impact of HIV and AIDS, including through the involvement of people living with HIV or AIDS in all prevention, control and care strategies. The policy also promoted the prohibition of discrimination against people infected with HIV and AIDS, and the protection of their legal rights.

The extent to which government has met these goals is not simply reflected in the promulgation of related legislation, since not all health care reform designed to introduce equity necessitates legislation, and the promulgation of legislation does not necessarily signify successful implementation or equitable outcomes. Nonetheless the range of legislation promulgated over the past decade broadly reflects the successes and failures of the government’s compliance with these initial strategies for transformation and increased equity in health care.

The Constitutional Context for Equitable Health Care Legislation

Health care legislation does not ensue from within a legal vacuum, and must in all respects comply with the Constitution. The government's duty to comply with its provisions flows from section 2 which holds the Constitution as the supreme law of the land, indicating that law (and conduct) inconsistent with it is invalid and the obligations imposed by it must be fulfilled.¹²

Constitutional supremacy has profound implications for the substance and process of health care legislation, and indeed for the way that equity itself is understood. This nexus is suggested in the notion of equity itself, which is commonly defined as being about fairness, and implies that "the most vulnerable and needy groups within a society require access to greater resources than those communities that are more robust."¹³ The focus on fairness and meeting the needs of the most vulnerable and needy lies at the heart of the range of protections in the Bill of Rights and the broader Constitution, which have an overriding commitment to creating an open, accountable and responsive democracy based on individual equality, dignity and freedom.

The Constitution therefore influences health care legislation in several ways. First, the state is duty bound to bring both existing and prospective pieces of legislation into compliance with various constitutional obligations. Second, the Constitution imposes specific obligations on the state to ensure equity in health care, explicitly requiring health care legislation as a fundamental – although not on its own sufficient – measure to achieve this goal. Third, the Constitution governs the process whereby legislation is formulated and implemented, requiring effective, transparent, accountable and coherent government¹⁴ and the active participation of the public in legislative¹⁵ and policy¹⁶ processes.

During the period under consideration the state was bound by both the interim and final Constitution, and the following section overviews their respective entrenchments on health. The state must also comply with judicial interpretations of its constitutional obligations, especially those ensuing from the constitutional court, the highest court in all constitutional matters.¹⁷

The past seven years have seen important developments in judicial interpretation of health care rights, and the cases of Soobramoney, Grootboom and the Treatment Action Campaign (TAC) have given greater specificity to the general obligation to provide everyone with access to health care services. Aspects of these cases have been documented in previous South African

Health Reviews (SAHR) chapters on health legislation,¹⁸ and this review will not repeat their facts and orders, but rather draws out some of their more salient holdings. Legislative competence on health services under the Constitution is described, and problems faced in this respect are explored.

The protection of health rights in the interim and final constitution

The interim Constitution came into operation on 27 April 1994. While it did not entrench a universal health care right, it did contain a number of rights relevant to health, including rights to life, dignity and equality, as well as the right to an environment which is not detrimental to one's health or well-being.¹⁹ In addition, it entrenched health rights for specific populations, including children's rights to basic nutrition and basic health and social services, as well as detainees' rights to adequate medical treatment at state expense.²⁰

The final Constitution, signed into law on 10 December 1996, went much further by entrenching a universal right to access health care services, as well as retaining in substantially the same form, children's and prisoners' rights.²¹ Section 27(1)(a) provides that everyone has the right to have access to health care services, including reproductive health care. Section 27(3) states that no-one may be refused emergency medical treatment. The state's obligations are qualified by the limitations clause contained in section 27(2), which requires the state to take "reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of [this right]."

This right provides the primary legal basis for claims relating to health care, and is a primary source of the state's health care related obligations. It must be noted however that the Constitution as a whole demands governance (on health care as on all other issues) that is participatory, accountable, non-discriminatory and respectful of individual rights, especially equality, dignity and freedom. This implies that section 27 does not describe the full range of the state's constitutional obligations relating to health, although this chapter confines itself to this narrower focus.

Obligations in relation to health care

As with all rights, the state must respect, protect, promote and fulfil the health care rights,²² implying a range of positive and negative obligations.²³ The duty to respect imposes a negative obligation to desist from interfering with people's enjoyment of rights. Thus in the TAC decision, the government's restriction of access to Nevirapine in public hospitals outside test sites breached its negative obligation to desist from preventing or impairing the right of access to health care services.

The duty to protect requires the state to prevent third party interference with people's right to access health care services. This applies to any third parties, including the providers of private health care. This is intimated in section 27 which does not state the government's obligation as being to provide health care services, but to provide *access* to such services.²⁴ The state's health care obligations therefore extend into the private sector, and it must ensure that people can access adequate health care services there. While the state's obligation is to "create the conditions for access (to health care) for people at all economic levels in our society,"²⁵ for people who can afford to pay for health care, the state's primary obligation lies in "unlocking the system," including through ensuring a legislative framework to facilitate access.²⁶

The duty to promote and fulfil describes the state's positive obligation to progressively realise access to health care services within available resources. Judicial interpretation has provided more precise definitions of the nature of obligations that this phrase creates.

Scope of the right to health

The Soobramoney judgment indicated that the right to access health care services is not an entitlement to claim any health care at state expense, particularly given limited state resources and high levels of poverty. In this context, not all health care needs could be met, particularly those claims that threatened the state's ability to provide other needs.²⁷ The decision indicates that rationing of health care may be constitutionally permissible if based on 'rational decisions taken in good faith by the political organs and medical authorities whose responsibility it is to deal with such matters'.²⁸

Reasonableness is the legal standard chosen by the constitutional court in Grootboom and applied in TAC, to judge whether particular health care legislation, policies or programmes fulfil the requirements of section 27. Reasonableness is determined on a case by case basis, but the general context provided by poverty and the Constitution provides general guidelines.

This context indicates that while the state is expected to address health care needs throughout society, its primary obligation is to meet the basic needs of those living in deplorable conditions, great poverty and experiencing immense vulnerability.²⁹ In Grootboom the court stressed that socio-economic rights were entrenched because "we value human beings and want to ensure that they are afforded their basic human needs," and that "the poor are particularly vulnerable and their needs require special attention."³⁰ While the constitutional court has acknowledged that government could not conceivably meet even all basic needs, its obligation is to seek to meet these

needs, acting reasonably to provide access on a progressive basis.³¹

These cases and the specific entrenchment of separate children's and prisoners' rights, imply that the state's positive obligation is primarily to meet the needs of people who for reasons including poverty, youth or imprisonment, are entirely dependent on the state for their health care.³² This is apparent from the interpretation in both TAC and Grootboom, that the state's obligations to children under section 28 is primarily an obligation which must be met by parents or families and that the state's obligations arise where a parent or family's care is lacking or insufficient to enable the child's access to health care.³³

The obligation to take reasonable measures to progressively realise health within available resources

The obligations placed on the state by section 27(2) were extensively interpreted in Grootboom, and applied in TAC, and each phrase of the limitations clause is explored below.

Reasonable legislative and other measures

At a minimum, the state must devise a comprehensive and workable plan to meet its obligations, providing for all needs, including short, medium and long term needs as well as crises.³⁴ Thus, legislation, policies and programmes that exclude "a significant segment of society" will be unreasonable.³⁵ A particular emphasis is placed on meeting the needs of the most vulnerable, especially the poor, as well as people experiencing particularly urgent and desperate needs.³⁶ This suggests that it would be difficult to justify as reasonable, failures to address the health care needs of large segments of the population in health care legislation, policy or programmes, particularly where those needs are experienced by poor people, and are both urgent and desperate.

Legislation is clearly a key measure for achieving the realisation of rights. It is not enough however sufficient on its own, and 'must be supported by appropriate, well-directed policies and programmes implemented by the executive'.³⁷ Conversely it is questionable whether policies and programmes implemented without the benefit of supportive legislation are sufficient to meet this obligation, and where the state fails on an unreasonable basis to implement legislation necessary to give effect to policies and programmes, this may fall short of the standard of reasonableness.

Reasonableness applies to all elements of governance, not only the content of legislation, programmes and policies, but also their manner of implementation.³⁸ So for instance, programmes should be balanced and flexible, with national government

bearing the responsibility of ensuring sufficient laws and policies to fulfil their obligations.³⁹ This was a core part of the court's decision in TAC, where the court found the state's policy on preventing access to Nevirapine in public hospitals outside pilot sites to be unreasonable because it was a rigid and inflexible policy that denied new born children and their largely poor mothers access to a potentially life-saving drug.⁴⁰

Progressive realisation

While progressive realisation recognises that full realisation of everyone's right to access health care services is not always immediately possible, it clearly places time bound and explicit obligations on the state. These include "taking steps" to ensure that basic needs can be met, and progressively facilitating access, with legal, administrative, operational and financial hurdles examined and where possible lowered over time.⁴¹ In addition, the state must move expeditiously and effectively in doing so, and cannot take any deliberately retrogressive measures.⁴² TAC in particular emphasised the need for urgent and timely action where people's lives literally depend on timely access to health care services.⁴³ While not mentioned in the decisions, it is worth also noting section 237 of the Constitution, which requires that all constitutional obligations be performed diligently and without delay.

Resources

Resources are a primary feature of reasonableness, and the state is not required to do more than its available resources permit.⁴⁴ Resources would therefore govern "the content of the obligation in relation to the rate at which it is achieved as well as the reasonableness of the measures employed to achieve the result."⁴⁵

If however the state is to rely on a lack of resources as the basis for refusing a particular health care service, it must provide clear and compelling justification for why this is the case, particularly where the refusal of health care is for poor people experiencing particularly desperate or urgent needs. Thus, while health rights are not necessarily an entitlement to all levels of health care services claimed, they are an unambiguous entitlement to government's justifications for its decisions. In this way the right to health plays an important democratic function by ensuring responsiveness and accountability for health care decision making.

Implications of the cases

These cases illustrate the constitutional court's willingness to subject health care decision making which falls short of constitutional standards to rigorous judicial review, and to order appropriate outcomes where necessary. They fundamentally dispel concerns that the constitutional health rights lack

substance.⁴⁶ They provide further guidance to the state on what it is expected to do to fulfil its constitutional obligations. The decisions also provide guidance to civil society as to what they can reasonably expect the state to do in providing health care, and more importantly what they can approach a court to enforce should the state be perceived to not be fulfilling its obligations. These rulings emphasise the importance of the development and implementation of health policies that seek to implement the provisions of the Constitution and that health legislation cannot be unconstitutional. They certainly underscore that SA is now a democratic and constitutional state.

It is important to note that these three decisions do not reflect the full range of constitutional court decisions relating to health care, and especially health care legislation. For instance, the South African Medicines and Medical Devices Regulatory Authority Act (No. 132 of 1998) was successfully contested in the constitutional court and its proclamation into law declared unconstitutional in *Pharmaceutical Manufacturers Association of SA and Another: In Re Ex Parte Application of the President of the Republic of South Africa and Others*.⁴⁷

The courts have also been the site of contestation over specific pieces of legislation – a challenge to the constitutionality of the Choice on Termination of Pregnancy Act by religious groups was dismissed in the Pretoria High Court,⁴⁸ and the Medicines and Related Substances Act was delayed for over three years during a challenge bought by thirty nine pharmaceutical companies.

Constitutional competence over health services

The interim and final Constitutions designate "health services" as a concurrent legislative and executive competence of national and provincial government.⁴⁹ The first ever SAHR, published in 1995, included a chapter on health legislation in which the author, Stephen Harrison, reviewed aspects of the Constitution that relate to health. He noted that provinces will also be able to draft and pass health legislation and cautioned:

"ten separate Health Acts may develop in South Africa – one national and nine provincial. Unless this process is carefully managed and properly coordinated administrative chaos and increased fragmentation of the health system may ensue".⁵⁰

Besides the need for coordination Harrison also noted that the other challenge was to find ways of involving communities in the formulation of health legislation. It is clear to these reviewers that despite the fact that many provinces, e.g. Eastern Cape, Free State, Gauteng, KwaZulu-Natal, Limpopo, North West and Western Cape, have passed provincial legislation, administrative chaos has not ensued. One reason for this may be that the

National Health Bill has not, at the time of writing this chapter, been promulgated into law. A more plausible reason is that national policy on most major issues has been determined and that the relationship between the national department and the nine provinces has been such that both policy and legislative issues are discussed and consensus reached.

Nonetheless the failure to implement a National Health Act has had negative implications, causing confusion as to the allocation of functions between the provinces and local government in respect of health services. The final Constitution allocates to local authorities executive authority in respect of municipal health services, and the right to administer such services.⁵¹ Sait indicates that confusion arose because these services have not been defined, and was exacerbated by the fact that the Health Act of 1977 allocated the provision of curative primary health care services to both provinces and local authorities.⁵²

This lack of definition has led to functional overlaps and fragmentation in service provision.⁵³ This issue is clarified in the National Health Bill, which defines municipal health services as a list of environmental health services.

Overview of a Decade of Legislation

A rather long list of legislation and regulations has been passed since 1994. The national health legislation catalogued below does not reflect the full range of legislation passed but is selected on the basis of the most important.

Box 1: Overview of a decade of legislation

- ◇ Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act, 1995 (Act No. 40 of 1995)
- ◇ Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act, 1997 (Act No. 91 of 1997)
- ◇ Chiropractors, Homeopaths and Allied Health Service Professions Second Amendment Act, 2000 (Act No. 50 of 2000)
- ◇ Choice on Termination of Pregnancy Act, 1996 (Act No. 92 of 1996)
- ◇ Dental Technicians Amendment Act, 1997 (Act No. 43 of 1997)
- ◇ Extension of Terms of Office of Members of Certain Council's, 1997 (Act No. 45 of 1997)
- ◇ Health Donations Fund Repeal Act, 2002 (Act No. 31 of 2002)
- ◇ Medical Schemes Act, 1998 (Act No. 131 of 1998)
- ◇ Medical Schemes Amendment Act, 2001 (Act No. 55 of 2001)
- ◇ Medical Schemes Amendment Act, 2002 (Act No. 62 of 2002)
- ◇ Medical, Dental and Supplementary Health Service Professions Amendment Act, 1995 (Act No. 18 of 1995)
- ◇ Medical, Dental and Supplementary Health Service Professions Amendment Act, 1997 (Act No. 89 of 1997)
- ◇ Medical, Dental and Supplementary Health Service Professions Amendment Act, 1998 (Act No. 1 of 1998)
- ◇ Medicines and Related Substances Control Amendment Act, 1997 (Act No. 90 of 1997)
- ◇ Medicines and Related Substances Control Amendment Act, 2002 (Act No. 59 of 2002)
- ◇ Mental Health Care Act, 2002 (Act No. 17 of 2002)
- ◇ National Health Laboratory Service Act, 2000 (Act No. 37 of 2000)
- ◇ Nursing Amendment Act, 1995 (Act No. 5 of 1995)
- ◇ Nursing Amendment Act, 1997 (Act No. 19 of 1997)
- ◇ Occupational Diseases in Mines and Works Amendment Act, 2002 (Act No. 60 of 2002)
- ◇ Pharmacy Amendment Act, 1995 (Act No. 6 of 1995)
- ◇ Pharmacy Amendment Act, 1997 (Act No. 88 of 1997)
- ◇ Pharmacy Amendment Act, 2000 (Act No. 1 of 2000)
- ◇ South African Medicines and Medical Devices Regulatory Authority Act, 1998 (Act No. 132 of 1998). This Act has now been repealed.
- ◇ Sterilisation Act, 1998 (Act No. 44 of 1998)
- ◇ Tobacco Products Control Amendment Act, 1999 (Act No. 12 of 1999)

The following section provides an overview of this legislation with a view to identifying the extent of its contribution to creating a unified and equitable health care sector, and categorises these Acts according to functions served.

Transforming and restructuring the health care professions

In 1994 the ANC National Health Plan described the political and statutory bodies which controlled the health care professions and facilities as having being 'built and managed with the specific aim of sustaining racial segregation and discrimination in health care'.⁵⁴ Accordingly, one of the first sets of Acts to be abolished were the different pieces of legislation that governed health professionals in the various homelands. Eight councils were consolidated into four interim councils: the Interim National Medical Council of South Africa; the South African Interim Nursing Council; the Interim Pharmacy Council of South Africa; and the Chiropractors, Homeopaths and Allied Health Service Professions Interim Council.⁵⁵ These interim councils were given a life-span of two years, later extended under the Extension of Terms of Office of Members of Certain Councils Act 1997.

These changes were intended to make the councils more transparent and representative, and in many cases to broaden their scope to include health care workers previously excluded from regulation. For instance, under the Dental Technicians Amendment Act, dental technologists were recognised under the council for the first time; and under the Nursing Amendment Act, representation on the Council was extended beyond professional nurses to include amongst others nursing assistants and community representatives.

This broader scope of representation in professional regulatory bodies found particular expression under the Medical, Dental and Supplementary Health Services Professions Amendment Act of 1997 which replaced the South African Medical and Dental Council with a Health Professions Council of South Africa (HPCSA) intended to be more representative of a wide range of health professions. In addition, the HPCSA included community representatives in order to increase accountability and transparency. Under regulations to the 1974 Health Professions Act, professional boards for a broad range of alternative health services have been included under the HPCSA, discussed in the 2002 SAHR,⁵⁶ ensuring greater accountability for health related services falling outside the ambit of traditional medicine.

Although it has taken significantly longer, traditional healers will shortly be similarly regulated. The long awaited and widely consulted Traditional Health Bill was gazetted as a draft bill in 2003. After allowing public comment for three months, comments were incorporated and the Bill is ready for introduction in Parliament. The Bill establishes an Interim Traditional Health

Practitioners Council of South Africa. It makes provision for the control of the registration, training and practices of traditional health practitioners. Measures to regulate traditional healing are introduced to protect the interests of members of the public who use the services of traditional health practitioners.

Some earlier Acts made other changes with important implications for equity; for example, the Pharmacy Amendment Act 1997 extended ownership of pharmacies to people other than pharmacists. As Harrison and Qose pointed out, this was an important measure to ensure adequate distribution in rural and under-served areas.⁵⁷ Similar goals underlie the introduction of mandatory terms of community service for graduating health care professionals, under the 1997 Medical, Dental and Supplementary Health Services Amendment Act. Community service was extended to include pharmacists under the 2000 Pharmacy Amendment Act, and in 2002 was extended in the government gazette to a range of health professionals, including dietitians, clinical psychologists, environmental health officers, physiotherapists, radiographers and speech language and hearing therapists.

However the legislative attempt to replace the Medicines Control Council with the South African Medicines and Medical Devices Regulatory Authority failed due to a series of administrative errors, and was set aside by the constitutional court in the Pharmaceutical Manufacturers Association: Ex Parte President decision. This council would have provided for the monitoring, evaluation, regulation, investigation and control of medicines, clinical trials and medical devices. It also would have explicitly provided for the registration and regulation of complementary medicines.

Ensuring constitutional compliance in existing and prospective legislation

Certain pieces of legislation have been amended to ensure a greater consistency with the Constitution, and a more human rights oriented approach. For example, the Sterilisation Act, 1998 was amended to ensure greater protection against sterilisation procedures in people unable to consent. The Mental Health Care Act, 2002, replaced the 1973 Act of the same name entirely, in order to provide for a more human rights-based approach to mental health, with a focus on appropriate care, treatment and rehabilitation services, and promoting the human rights of people with mental disabilities.

Proposed legislation has sometimes clashed with human rights standards, as was the case with the publication in 1999 of draft regulations to make AIDS a notifiable medical condition. The regulations would have required non-consensual disclosure of AIDS status to a broad range of health care workers, as well as to immediate family members and caregivers. The regulations

threatened the rights of people with HIV and AIDS, since disclosure or perceived infection remains a source of widespread discrimination and attracts negative social responses ranging from marginalisation to physical violence. These negative consequences were particularly difficult to justify given the likely inefficacy of the regulations as a means of data collection. After significant public opposition, they were not put into effect, demonstrating a welcome democratic responsiveness to the overwhelming expression of public opposition to the measure, despite the lack of participation in their initial formulation.

Institutions have been created to monitor and facilitate the state's fulfilment of its domestic and international health rights. The state's fulfilment of its domestic health rights is monitored by the Human Rights Commission in an annual report on human rights. The Joint Monitoring Committee on the Improvement of the Quality of Life and Status of Women has the objective of facilitating the fulfilment of the state's international obligations, particularly with commitments made at the Fourth World Conference on Women in Beijing, as well as under the Convention on the Elimination of Discrimination against Women.

Increasing consultation and public participation in the legislative process

A strong constitutional emphasis is placed upon the creation of a democratic and open society in which government is based in the will of the people.⁵⁸ As a result the Constitution makes ample provision for public participation in national and provincial legislative processes, and this participation plays an important democratic function. Public participation in health care legislative processes has been significantly facilitated by the National Assembly Portfolio Committee on Health, which has served as a vital "access point to the political process for public and professional concerns about health," and "has encouraged vibrant debate and high quality policy processes."⁵⁹ Similar provision is made for public participation in legislative processes at the National Assembly and the provincial legislatures, as well as in national policy processes.⁶⁰

The policy making process in SA has been highly consultative since 1994, despite some lapses as noted above. Indeed given the large scale consultation that preceded the finalisation of both the ANC's National Health Plan and the RDP, one can argue that consultation on health policies commenced even before the 1994 elections.

Key Pieces of Legislation to Transform Public and Private Health Care

Certain pieces of legislation have served central functions in the task of transforming health care in SA and creating a unified and equitable health care sector. One of the first actions of the democratic government was to publish a notice in the government gazette providing for free health services to children under the age of six and pregnant women.⁶¹ Another Act designed to increase access to reproductive health care services is the Choice on Termination of Pregnancy Act (1996), which provided for abortion on request up to twelve weeks gestational age, and under specified conditions after twenty weeks. The Act has seen a reduction in maternal deaths related to back street abortions since the provision of safe and legal terminations. The challenge however remains to: (a) increase access to these services; and (b) decrease use of terminations as contraception. In addition, public health laboratory services were restructured and transformed under the National Health Laboratory Service Act 2000, which sought to unify these services to ensure that the need for such services could be met in the most cost-effective manner possible.

However many of the major changes designed to introduce greater equity in the health sector have not necessarily been backed by supporting legislation. This is partly explained by the decade long delay in promulgating a National Health Act, which aimed to bring together under one legislative roof, many of the government's broader plans for transforming the public health care sector. Long and Reynolds described the Department of Health's initial ambitions for a comprehensive National Health Bill to address most aspects of its work including district health development; national health system restructuring; transformation of hospital services and management; medicines and essential drug programmes; health information systems as well as the Department's regulatory functions.⁶²

While the National Health Bill has not as yet been promulgated into law by the President, it has been passed by both the National Assembly and the National Council of Provinces. This process is described further below. Many commentators have critiqued and analysed the lack of overarching legislation. Harrison for example in 1995 suggested that a possible explanation for the lack of a National Health Act was that "the Department of Health ... is reluctant to amend legislation on a piecemeal basis and therefore has appointed a National Health Legislative Review Committee to develop a comprehensive, development-oriented Public Health Act."⁶³ Whilst a team to review legislation was established, their work did not result in the drafting and passage of a National Health Bill. Instead the Department decided to pass critical pieces of legislation as separate acts. One reason for this was the complexity of drafting a single, all encompassing

piece of legislation. Another was the decision to fight one battle at a time or to take on one constituency at a time.

In the lacuna created by the lack of an enabling legislative framework, in many cases the government used policy rather than legislation to pursue transformative goals. Thus the free provision of primary health care services since 1996; the restructuring of primary level care financing and delivery; the establishment of a district health system and the reform of hospital level services through policies and programmes have been pursued without the benefit of implementing legislation. While much progress has been made under these policies and programmes, the absence of a legislative framework for the creation of a unified health system throughout this past decade is a significant failure of reform.

The Medicines and Related Substances Control Amendment Act

The development of medicines and essential drug programmes was separated out of the umbrella of the National Health Bill and pursued instead under the 1997 Medicines and Related Substances Control Amendment Act, which gave legislative authority to the policy aims expressed in the 1996 National Drug Policy. In view of the political and legal firestorm that this act generated, and the resulting three year delay as it was challenged in court by pharmaceutical manufacturers, pursuing the issue of medicines as a separate legislative initiative to the National Health Bill seems a wise move in retrospect. The irony of course is that despite a three year delay due to the PMA litigation, and a long delay thereafter, the Medicines Act was promulgated sooner than the National Health Bill.

The Medicines Act was designed to enable the government to undertake a variety of acts to provide a supply of more affordable medicines. These measures include parallel importation of imported medicines; generic substitution of off-patent medicines, and the establishment of a pricing committee to introduce a pricing system for all medicines sold in SA, establishing a single exit price for medicines.⁶⁴ The Act also aimed to prevent perverse incentives like bonusing and sampling, and to license dispensing doctors.

This legislation was vigorously opposed by corporate pharmaceutical interests, who instituted litigation to prevent its promulgation, and by the US government, which threatened trade sanctions against SA if the Act were promulgated, and implemented what amounted to economic sanctions in any event by withholding preferential tariffs from certain South African exports.

The withdrawal of both the US trade threats and PMAs litigation resulted in large part from the sustained and effective advocacy of national and international groups, which drew public and

media attention to the human costs of restricting the government's legislative authority on medicines, particularly given the country's massive HIV and AIDS epidemic. The pressure placed on the government by the US and the pharmaceutical companies was from all accounts intensive and sustained.⁶⁵ Given these economic consequences and political and legal pressures, the fact that government did not withdraw its legislation (as other countries facing similar pressures did), illustrates significant political will to achieve transformative goals in health care.

Yet the withdrawal of the litigation in April 2001 only saw the Act signed into law in January 2003. In addition, the effect of certain sections has been delayed, including section 39 which provides for the state to be bound by the Medicines Act, which will only be effective on 1 July 2005. Although a host of regulations to this Act have been passed, and the pricing committee was appointed in August 2003, progress made in implementing this key piece of legislation has been slow.

Once effective, the legislation will play a critical role in ensuring the availability of essential medicines, and its utility will be tested in particular as the government implements its operational plan for a national antiretroviral programme. The constitutional imperative as stated by the constitutional court in the TAC decision is to act with appropriate urgency and prevent unnecessary loss of life where possible, and waiting for any protracted periods in implementing this programme will certainly constitute a breach of the government's constitutional obligations.

The Medical Schemes Act 1998

This was another critical piece of legislation with the specific goal of increasing equitable access to health care in the private sector. The Act prohibited risk-rating and exclusion from membership on the basis of age, gender and state of health, and introduced a prescribed set of minimum health care benefits. This effectively brought much of the operation of medical schemes into closer compliance with the Constitution, particular insofar as the legislation ensured the non-discriminatory provision of more equitable private health care. The prescribed minimum benefits ensured coverage on a range of services previously excluded by medical schemes, including health care related to HIV associated disease; sexually transmitted disease; inpatient psychiatric care for three weeks; substance abuse and drug rehabilitation; attempted suicide; infertility and imminent death comfort care and pain relief.⁶⁶

A coherent theme through these services is that the majority are highly stigmatised conditions, often characterised by the schemes as immoral or 'self-inflicted.' Their exclusion reflected either an unreasoned arbitrariness as to what would be covered, or a moral judgment as to what constituted unacceptable health

conditions – both practices manifestly in breach of the constitutional prohibition against unfair discrimination on any grounds, including disability.

Under regulations to the Act, the public sector has virtually achieved what Harrison (1999) described as “preferred provider status” for the private sector, with the potential to attract private patients and revenues. The extent to which this Act will provide a greater unity between the public and private health care sector in practice however remains to be seen.

The National Health Bill and Social Health Insurance

Two other critical pieces of the government’s legislative agenda have not yet been promulgated. Both the National Health Bill and the Social Health Insurance Bill have been highly anticipated since the 1996 edition of the South African Health Review. While it is likely that the National Health Bill will be promulgated in 2004, this is not a likely fate of any Bill related to social health insurance given that the policy framework has as yet not been finalised.

National Health Bill

Because it is highly likely that the long awaited National Health Bill will be promulgated into law in 2004, a review of the Parliamentary process of its review that commenced in 2003 is given. The National Health Bill No. 32 of 2003 was tabled in Parliament on 3 June 2003 and referred to the Portfolio Committee on Health for consideration. Before considering the Bill formally, the Committee organised a fact finding workshop for its members, conducted public hearings and called for written submissions. During the workshop and subsequent public hearings the Committee agreed with stakeholders such as the University of the Western Cape’s School of Public Health and the Health Systems Trust that the Bill needed to address the principle of equity in all sections. The Committee also accepted a proposal by stakeholders such as COSATU, Age in Action, the ANC’s Health Policy Unit, the Health Systems Trust and others to include the rights of health care personnel to be treated with dignity and respect by health service users.

The current draft of this Bill contains various provisions which could have significant implications for equity, including providing for the protection of the rights and duties of both users and health care personnel. The Bill will concretise in legislative terms the functions of national and provincial departments, as well as district health systems. It also provides for the establishment of national and provincial health councils. Two areas of the Bill have raised objections and threats of legal action. These were the certificate of need process which the Bill provides for to ensure rational planning and the creation of a single blood

transfusion service (at present two services exist, one of which is the Western Province Blood Transfusion Service). One of the issues that the Committee agreed to was to extend the period for which a license was valid from 10 to 20 years.

With amendments made by the Portfolio Committee, the Bill was sent to the National Council of Provinces. The amended Bill was debated by the Select Committee on Social Services and simultaneously each provincial standing committee on health was requested to consider the Bill and propose amendments. Some provincial standing committees also held public hearings on the Bill and proposed amendments to the Select Committee. After considering all submissions, the Select Committee added amendments for debate by the National Council of Provinces. This debate took place on 18 November 2003 after which the Bill was again referred to the House of Assembly for further debate and passage. The House of Assembly has passed the Bill with the amendments proposed by the National Council of Provinces and has been referred to the President for consideration and signing into law. A key challenge will be to ensure effective implementation of the provisions of the National Health Bill at both national and provincial levels.

Social Health Insurance

A Social Health Insurance Act has long been a proposed pillar of health care reform to ensure more equitable health care coverage in SA. This Act would serve as a parallel reform to the Medical Schemes Act, and as conceived in the Department of Health’s 1997 Social Health Insurance policy, would act as a mechanism for recouping fees from private patients using public hospitals but who fail to pay for services because of inefficient revenue collection systems.⁶⁷ The net effect would be an additional “tiering of health services” with Social Health Insurance-funded health care servicing low and middle income workers and their families, in addition to the tax-funded services for the poor and wealthier people continuing to purchase their health care in the private sector.⁶⁸

As Doherty et al. point out, the South African health system has not yet found a mechanism to address its largest inherent disparities namely those between private and public sector care, and since the Department of Health’s 1997 policy is unlikely to do so, they recommended re-examining the fundamental principles underlying social health insurance.⁶⁹

Other legislation impacting on health

Besides national health legislation, legislation drafted by other government departments also impacted on health service delivery in the past 9 years. These include the following which were reviewed in detail by Nadasen and Gray (2000): Public

Finance Management Act, No. 1 of 1999; Skills Development Act, No. 97 of 1999; Skills Development Levies Act, No. 9 of 1999; Promotion of Access to Information Act, No. 2 of 2000; Municipal Structures Act of 1998 and the Municipal Structures Amendment Act, No. 33 of 2000; Municipal Systems Act, No. 32 of 2000.

The Promotion of Equality and Prohibition of Unfair Discrimination Act is noteworthy in particular since it gave legislative effect to the constitutional imperative to ensure non-discriminatory access to health care. The Act prohibits the denial of access to opportunities including services, and specifically prohibits limiting women's access to social services or benefits including health. A schedule of illustrative unfair practices has examples directly related to health care including: unfairly denying or refusing any person access to health care facilities or failing to make health care facilities accessible to any person; refusing to provide emergency medical treatment to persons of particular groups identified by one or more of the prohibited grounds; and in insurance, unfairly disadvantaging a person or persons, including unfairly and unreasonably refusing to grant services to persons solely on the basis of HIV/AIDS status.

This Act provides an important guarantee of equitable access to health care, given high incidences of health care worker discrimination, based on actual or perceived HIV/AIDS infections, or other societal prejudices, for example against women presenting for abortions. Health sector discrimination has often resulted in the denial of services, particularly in the case of HIV/AIDS.⁷⁰

Provincial legislation

The first steps taken by the newly elected democratic government were to transfer health authority from the former provinces, self governing territories and "independent" states to the new provincial administrations, which were also assigned to administer the Health Act No. 63 of 1977. Many provinces have passed health legislation, and these are listed in Table 1.

Table 1: Provincial health legislation

Province	Name of Legislation
Eastern Cape	Eastern Cape Provincial Health Act, No. 10 (1999)
Free State	Free State School Health Services Act No. 11 (1998) Free State Provincial Health Act No. 8 (1999)
Gauteng	Gauteng District Health Services Act No. 8 (2000) Gauteng Ambulance Services Act No. 6 (2002)
KwaZulu-Natal	KwaZulu-Natal Health Act No. 4 (2000)
Limpopo	Northern Province Circumcision Schools Act No. 6 (1996) Northern Province Health Act No. 5 (1998)
North West	North West Health Developmental Social Welfare and Hospitals Governance Act No. 2 (1997)
Western Cape	Western Cape Health Facility Boards Act No. 7 (2001) Western Cape Health Amendment Act No. 6 (2002)

Forthcoming legislation for 2004

Below follows a list of Bills that have been tabled and introduced by the National Department for the Portfolio Committee on Health's consideration. It is likely that these Bills will however only be processed after the April 2004 elections. The Traditional Healers Bill mentioned above will be introduced into Parliament shortly.

The Dental Technicians Amendment Bill, 2003, amends the Dental Technicians Act of 1979, to allow for the recognition of informally trained persons and to allow them restricted registration as dental technicians on conditions which will be determined by the South African Dental Technicians Council and the Minister.

Amendments to the Sterilisation Act will be introduced. This is a result of constitutional problems that have arisen regarding the right of a person not to be discriminated against on the basis of age. The current Act does not allow for sterilisation where the person is under 18 years and further does not allow for any non-surgical procedures as sterilisation is defined as a surgical procedure in the Act. The Western Cape was ordered by the courts to approve a sterilisation procedure on a person who was under 18 years. The amendment Bill will therefore change the definition of sterilisation to include acts or processes that render a person incapable of fertilisation or reproduction.

Consent is clarified to mean informed consent and therefore obligates the service provider to explain the procedure and the

consequences. A person under the age of 18 years will be allowed to undergo sterilisation where it is evident that his or her health is threatened. A parent, guardian or primary caregiver or medical practitioner or court may give consent for sterilisation where it is proven to be in the best interest of the person.

The Choice on Termination of Pregnancy Act, 1996 is amended to allow for the designated facilities to be approved by the MECs instead of designation by the Minister. To ensure greater access to termination services, public and private facilities offering 24-hour maternity services will provide terminations of pregnancy services. Provision is also made for the recording of information and submission of statistics.

Conclusions

As we reach the 10th anniversary of freedom and democracy, the range of health legislation passed since 1995 must be considered impressive, and substantial progress has clearly been made in reaching many of the goals reflected in the White Paper and required in the Constitution. This progress is not only measured in the range of legislation passed, and much has been achieved without the need for implementing legislation, especially in the absence of the National Health Bill. However the absence of this foundational legislative instrument, and of a Social Health Insurance Act, represents a significant gap in the government's legislative achievements.

A clear tension emerging from the past decade's legislative experiences is the challenge of balancing the interests of diverse stakeholders with the goals of transformation and equity. At various points since 1994, proposed reforms have attracted strong dissent and legal contestation from diverse domestic and foreign actors. As the passage of the Choice of Termination of Pregnancy Act and the Medicines and Related Substances Act illustrate, sometimes leaders may need to make decisions that are not necessarily supported by the majority or are strongly opposed by external interests. Lessons from such pieces of legislation are important as the passage of the National Health Bill is finalised which, as noted above, includes provisions such as the certificate of need for the reshaping of both the public and private health care sectors.

Effectively mediating conflicting interests requires open and democratic processes of decision making, and where possible, accommodation of interests, if doing so does not invalidate the equitable components of laws in question. When all other avenues fail, the constitutional court may provide an appropriate forum within which to strike appropriate balances between

government interests in equity and the interests of affected stakeholders.

However care must be taken not to allow the need to stand firm on unpopular policy choices to restrict the democratic responsiveness which is such a fundamental feature of South African constitutional order. In particular, the Constitution demands that where proposed legislation or legislative omissions negatively affect the health, freedom and dignity of particularly vulnerable people, then government must consult widely with affected groups to seek alternative and less harmful ways of reaching desired goals. At the very least the constitutional imperative for open and democratic governance demands that the state must present strongly compelling justification for its actions. Where the government derogates from these duties, the constitutional court provides an effective forum for ensuring that government adhere to the constitutional dictates of reasonableness and rationality.

In this light, the ongoing tensions and controversies over HIV and AIDS policies and the slow movement in providing adequate health care services to infected people are a troubling aspect of the state's legislative record in the past decade. This is particularly so given the dramatic public health challenge posed by the epidemic, the vulnerability of the population involved and the urgency and desperation of their needs. This is not the only place where the state has exhibited glacial movement in appropriate implementation, and the delay in implementing key legislative instruments like the Medicines and Related Substances Control Act is a cause for concern, as well as a derogation of constitutional obligations.

While much has been done to create more equitable access to health care in both public and private sectors, little progress has been made in creating a single unified health care system for SA, despite the provisions of the Medical Schemes Act designed for this purpose. After ten years of democracy, the two-world disparities in health care appear if anything greater. Ensuring appropriate legislative reform to address this issue, including through Social Health Insurance, presents a tremendous challenge for the coming decade. It can only be hoped that the knowledge gained from this past decade's legislative experiences will enable the government to more effectively address these persistent inequalities in health care, and make greater gains in the movement towards an equitable and unified health sector.

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Commentary

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The vision for health delivery in 1994 of the newly elected democratic government of national unity was outlined in the White Paper for the Transformation of the Health Services. It provided for a district health system based upon a primary health care approach. In reflection on the past ten years the national and provincial health ministries must be congratulated on the successful integration of the many systems that they inherited.

Understandably a lot of work remains to be undertaken before the district health system is fully functional. A very significant challenge lies in the successful achievement of the delegation of appropriate authority by the ministries to the district health teams commensurate with the responsibilities of the task. The quality of the leadership, which has managed the transformation to date, has been appropriate to the task. But what of the future? Perhaps the answer lies in the words of J.F.Kennedy, "It's time for a new generation of leadership to cope with new problems and new opportunities. For there is a new world to be won." This new leadership is that, which will take the courageous steps to break with the old and place the power for effective delivery in the hands of the lower management, to fulfill the promise of decentralisation.

Transformation leadership is about people. Aristotle said, "we are what we repeatedly do." And in South Africa for decades health was delivered in a prescribed hospital-centric way. Large sections of the population were led to believe that they had little value. Suddenly transformation is asking health professionals to change the way they deliver health services in so many ways, simultaneously. In 1995, the authors of the 'Hospital Strategy' document referred to the behaviour pattern of 'no action without permission'.

The effective implementation of the district health system will be a long process. There is a great need to rebuild the self-esteem of health professionals. Champions must be nurtured to embrace the new. A supportive environment has

to be established, within which health professionals are encouraged to be proactive in problem-solving and to risk making mistakes. It is not enough to provide workshops on transformation or to legislate for new systems. A people-centred development process has to be sustained. As Aristotle continued to say, "excellence is not an act, it is a habit". This is a whole new paradigm. Mentoring and support of the health professionals over time is crucial. General management competencies must be developed for the 'new world' scenario.

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Positioning people centrally in the transformation process will see the successful development of the district health system. It will be the individuals, who have the self-awareness and the courage to accept the realities of life for what they are and not what they think they

are or should be, who will lead others to share the vision of an effective health system. They will be able to look back and say, "we have made a difference".