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Health Policy and Legislation

Abstract

The regulation of the private health sector since 1994 has been systematic and profound. Legislative changes have been consistent with policy documents that were formulated even prior to 1994 as well as those that were published subsequently. Many of the legislative changes necessary to effect transformation of the health sector are now in place and the implementation phase should take on a greater emphasis. Legislation on the provision of private health care, the funding of private health care and the pricing of medicine is in place, and in some cases, merely requires elaboration by means of Regulations in order to be implemented.

Court challenges to legislation on dispensing licences and medicine pricing were largely unsuccessful since the principles embodied in the legislation remain intact. Regulations in terms of existing legislation will continue to be written and in some cases these are critically important such as those relating to the certificate of need, quality and standards and health care technology, as provided for in the National Health Act. The next phase in the journey towards Social Health Insurance is underway with the creation of a funding risk pool consisting of the membership of all medical schemes. The Risk Equalisation Fund is the vehicle for this identified in the Medical Schemes Amendment Bill which should go through Parliament later this year. Technical alignment of the Pharmacy Act with the Medicines and Related Substances Act is also necessary as is a comprehensive review of the Prescribed Minimum Benefits.

i Board of Healthcare Funders of Southern Africa

Introduction

The importance of the role of the private health sector within the South African health system has repeatedly been acknowledged by government since 1994.

In 2001, the Minister of Health highlighted the fact that the most glaring challenge facing the South African health system is the disparity in the resources available to the public and private sector relative to the population each sector serves. The Minister of Health emphasised that government cannot tackle this challenge alone and it requires that both sectors work hand in hand to use combined resources to meet the health needs of all South Africans in a more equitable and efficient manner.[1]

Similarly, in the opening address at the Risk Equalization International Review Panel Workshop of 2004, the Minister of Health emphasised that the private health sector is a significant part of the health system as it plays a complementary role to the public system and that medical schemes would continue to act as the main financial intermediaries in the private sector. The Minister stated that it was clear that the private sector would continue to play a key role in the provision and financing of health care for South Africans and for this reason government would continue to take a keen interest in the functioning of this sector.[2]

The relationship between policy and legislation

The Constitution states that the President exercises executive authority together with the other members of the Cabinet by developing and implementing national policy and by preparing and initiating legislation. Policy is not enforceable since it is, by definition, not law. The Supreme Court of Appeal has observed that laws, regulations and rules are legislative instruments whereas policy determinations are not. As a matter of sound government, in order to bind the public, policy should normally be reflected in such instruments. Policy determinations cannot override, amend or be in conflict with laws (including subordinate legislation).[3]

Legislation thus represents the crystallisation of policy objectives into an enforceable medium. It can be used as some measure of the extent to which policy is being implemented. However, it must be emphasised that legislation is just the first step in policy implementation. Other important steps are education of relevant stakeholders, empowerment of government agencies, monitoring, evaluation and enforcement. Whilst sector reform can be driven by legislation it cannot be achieved by legislation alone. Policy is not static and neither is legislation because the environment to which they are applicable is dynamic. However, certain policy principles are enduring because they are based on the values contained in the Constitution and these are unlikely to be changed in the long-term.

Compliance with the legislation once it is effected is a critical issue that is often more difficult to address than the formulation of policy and legislation. It is not enough to legislate. Compliance needs to be monitored and where necessary, enforced by appropriate means. Court challenges to transformative legislation are to be expected and interpreted as an indication of a functioning democracy. They are not necessarily pathological but rather a testing and exploration by society of certain policy principles against the values and tenets of the Constitution. The private sector has taken government to court on the issue of dispensing licences and the medicine pricing system.[4,5] The challenges in both cases reached the Constitutional Court which, for the most part, upheld the principles and systems contained in the legislation.

Policy Objectives

National Drug Policy

A National Drug Policy (NDP) for South Africa was published in 1996.[6] Some of the objectives as stated in the policy document are to:

- ensure the availability and accessibility of essential drugs to all citizens;
- lower the cost of drugs in both the public and private sectors;
- promote the cost-effective and rational use of drugs;
- establish a complementary partnership between government bodies and private providers in the pharmaceutical sector; and
- optimise the use of scarce resources through cooperation with international and regional agencies.

In particular, the NDP states the following with regard to rationalisation of the medicine pricing structure.

- A Pricing Committee with clearly defined functions to monitor and regulate drug prices will be established within the Ministry of Health. Committee members will include health economists, pharmacoeconomists, representatives from the Department of Finance, the Department of Trade and Industry, the Procurement Unit of the Department of Health, the Department of State Expenditure and consumer representatives.
- There will be total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services (such as dispensers of drugs), as well as private clinics and hospitals.
- A non-discriminatory pricing system will be introduced.
- The wholesale and retail percentage mark-up system will be replaced with a pricing system based on a fixed professional fee.
- In public sector facilities, all drugs at the primary care level will be supplied free of charge. At the secondary and tertiary levels a fixed, affordable co-payment for drugs supplied by the State will be levied.
- A system of exemption will be established for patients without the resources to meet such payment to ensure that they are not deprived of treatment.
- A data base will be developed to monitor the cost of drugs in the country in comparison with prices in developing and developed countries.
- Price increases will be regulated.
- Where the State deems that the retail prices of certain pharmaceuticals are unacceptable and that these pharmaceuticals are essential to the well-being of any sector of the population, the State will make them available to the private sector at acquisition cost plus the transaction costs involved.

The Pricing Committee is a technical expert body as opposed to an industry representative body. The only representative allowed on the committee is one that represents consumers and who would have to be an expert concerning the needs and views of consumers on medicines and not merely someone who participates as a consumer of medicines. The Minister of Health called for nominations for the Pricing Committee in February 2003, but made it clear that nominees should be knowledgeable in various areas.[7]

Patients in the public sector are required to pay for treatment in accordance with a means test. If they are indigent they are generally not required to pay at all.[8] The fact that the single exit price (SEP) holds throughout the supply chain is due to the transparency requirement in the Medicines and Related Substances Act (Act 101 of 1965) as reflected in the NDP.

The medicine pricing system is based on a SEP that applies throughout the supply chain and at the point of retail it is combined with a dispensing fee for professional services which is paid by the end user. The dispensing fee may be charged only by those who dispense medicines. The medicine pricing Regulations contain a specific definition of the term 'dispense'. Distributors and wholesalers who supply medicines to persons other than the end user may charge a logistics fee in terms of the medicine pricing Regulations. The SEP remains the same from the manufacturer through to the end user. It is the manufacturer that determines the SEP of the medicine which, by definition, includes the logistics fee. The manufacturer therefore determines the price at which the medicine should be sold, as well as the amount it will have to pay for distribution and then sets this as the SEP which holds throughout the supply chain. Provision is, however, made for these manufacturer-determined prices to be subjected to international benchmarking.

Policy on transformation of the health system

In 1997, policy goals were identified in the White Paper for the Transformation of the Health System in South Africa.[9] The goals relevant to the private sector include:

- integration of the activities of the public and private health sectors in a way which maximises the effectiveness and efficiency of all available health care resources;
- 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;
- distribution of health personnel throughout the country in an equitable manner;
- reduction of alcohol and other drug abuse, with particular emphasis on tobacco, glue, cocaine, mandrax, heroin and marijuana;
- promotion of healthy behaviour to prevent sexually transmitted infections (STIs) and HIV transmission;
- prevention of the transmission of communicable

diseases such as tuberculosis and the development of hypertension and diabetes;

- helping the disabled to become independent and reach their potential for achieving a socially and economically productive life;
- reduction of the incidence of intentional and unintentional injuries; and
- development of the human resources available to the health sector.

Legislation

The wave of health legislation between 1994 and 2004 represents the first steps taken by government towards implementation of the policies referred to in the White Paper. Table 1 provides a summary of the legislation that was passed during this period.

In **1995**, legislative amendments focused on the health professions and the statutory councils governing them. Four amending Acts were passed which took into account the abolition of the so-called 'homelands' and re-united the health professionals practising within them under the auspices of the South African professional bodies. This was in compliance with the goal of unifying the fragmented health services and to promote equity and accessibility to health services.

In **1996**, the major legislative development was the passage of the Choice on Termination of Pregnancy Act (Act 92 of 1996) which for the first time made terminations of pregnancy available to women on demand within certain parameters. This was in accordance with the constitutional mandate to take reasonable legislative and other measures to progressively realise the right of access to reproductive health services. The Choice on Termination of Pregnancy Act also recognises the constitutional right of women to reproductive choice. The Act has proved to be controversial in certain quarters. Although it does not contain provisions compelling medical practitioners or other health professionals to terminate pregnancies irrespective of their beliefs, the legislation also does not expressly recognise the right of such persons to refuse to carry out procedures on the basis of their constitutional right to freedom of conscience, religion, thought, belief and opinion. If a health professional is unwilling to terminate a pregnancy or participate in such a procedure, they should refer the patient to one who is willing to do so or report the matter to their superior to arrange for a replacement. Abandoning the patient is not an option in terms of both the Act and ethical and professional rules governing health professionals. Unsuccessful legal challenges to the Act were mounted on two separate occasions by the Christian Lawyers Association in 1998 and 2001.[10,11]

The year **1997** saw considerable legislative innovation in amendments to the Medicines and Related Substances Act of 1965, in keeping with the NDP relating to the pricing of medicines. The amendments included provisions for the parallel importation of medicines, the establishment of a medicine pricing committee and the introduction of a transparent, non-discriminatory pricing system for medicines. The bonusing and sampling practices in the sale of medicines were prohibited by amendments to the Act.

The legislation was challenged in a court action in 1998 by the Pharmaceutical Manufacturers' Association, but the court challenge was withdrawn in April 2001. These legislative amendments subsequently had far reaching implications for the private pharmacy sector when the medicine pricing Regulations were introduced for the first time in 2004. The Regulations, as opposed to the provisions of the Medicines and Related Substances Act itself, were challenged in court, this time by New Clicks South Africa (Pty) Ltd and the Pharmaceutical Society of South Africa. The Regulations as a whole withstood the challenge but the court ordered certain technical amendments to be made and referred the quantum of the dispensing fee for pharmacists back to the pricing committee and the Minister of Health due to insufficient evidence before the court.

Amendments to the Pharmacy Act (Act 53 of 1974) in 1997 saw the opening up of pharmacy ownership in South Africa to non-pharmacists subject to regulatory requirements to be imposed by the Minister of Health. It was the hope of government that this move would increase access to pharmacy services and encourage the opening of pharmacies in rural and under-served areas.[12] Initially, it seemed that this hope would not materialise.[13] Instead there was consolidation and some growth within the existing, mainly urban market with acquisition of ownership of existing pharmacies by large corporate entities such as New Clicks Holdings, Pick 'n Pay and Shoprite Checkers.[14] The reason for this is that the private-for-profit sector decides where it is most feasible to establish a pharmacy and then applies for the necessary licence. Government does not dictate where pharmacies must be established. Since entrepreneurs wish to operate in areas most likely to bring them large numbers of customers, they continue to seek licences in urban areas or areas where

there is likely to be large volumes of business. Under-served areas cannot offer the same business volumes and it is not only South Africa that faces the challenge of attracting health professionals to these areas.[15] However, it seems that growth is evident in under-served areas. In March 2007, the Department of Health (DoH) reported that in the past year 162 pharmacy licences were issued and that 30% of these new licences were for pharmacies located in historically disadvantaged areas. Cited as examples were licences for new pharmacies at Nquthu in rural northern KwaZulu-Natal and Qumbu in the former Transkei region of the Eastern Cape (Nquthu Central Pharmacy and Qumbu Pharmacy).[16] The powers of the Pharmacy Council were extended to public sector pharmacies by the amending legislation with a view to standardising conditions for the operation of pharmacies across both the public and private sectors.

In **1998**, the Medical Schemes Act (Act 131 of 1998) was passed into law, replacing the previous Medical Schemes Act (Act 72 of 1967). The Medical Schemes Act of 1998, re-introduced community-rating into a medical schemes environment that was practising predominantly risk-rating on the heels of a 1993 amendment to the previous legislation. This was in a bid to promote equity of and access to medical scheme benefits for the sick and elderly. There was also a concern on the part of government that medical schemes were designing their benefits in such a way that the acutely ill and injured were being 'dumped' into public health sector facilities when their treatment became too expensive. The stated objects of the Prescribed Minimum Benefits (PMB) are:

- to avoid incidents where individuals lose their medical scheme cover in the event of serious illness and the consequent risk of unfunded utilisation of public hospitals; and
- to encourage improved efficiency in the allocation of private and public health care resources.

This is consistent with the policy objective in the White Paper of integrating the activities of the public and private health sectors in a way which maximises the effectiveness and efficiency of all available health care resources.

As a consequence, a package of PMBs with a focus on catastrophic care was developed as Annexure A in the Regulations to the new Act in 2000. In terms of the Regulations, the PMB package was to be reviewed every two years by the DoH. This review must involve the Council for Medical Schemes (CMS), stakeholders, provincial departments of health and consumer representatives. In terms of the Regulations the reviews must provide recommendations for the revision of the Regulations and Annexure A on the basis of:

- inconsistencies or flaws in the current Regulations;
- the cost-effectiveness of health technologies or interventions;
- consistency with developments in health policy; and
- the impact on medical scheme viability and its affordability to members.

However, no such comprehensive review has taken place following the publication of the Regulations in 2000.

Another significant legislative development in 1998 was the passage of the Sterilisation Act (Act 44 of 1998) which deals mainly with the circumstances under which sterilisation and in particular, sterilisation of persons incapable of consenting or incompetent to consent due to mental disability. The previous legislation had combined legislative provisions on abortion and sterilisation and required revision due to the passage of the Choice on Termination of Pregnancy Act in 1996 and the Constitution of 1996.

In the year **2000**, amendments to the Pharmacy Act (Act 53 of 1974) required newly qualified pharmacists to perform community service for the first time. This legislation would have temporarily delayed the number of pharmacists taking up employment or establishing pharmacies in the private sector in subsequent years. No other legislation was passed in 2000, which significantly impacted on the private health sector except the amendments to the Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act (Act 50 of 2000), which abolished the existing statutory council in favour of a new Allied Health Professions Council and various professional boards to regulate the complementary health professions.

In **2001**, the Medical Schemes Act of 1998 was amended. The amendments extended certain rights of members to their dependants, further regulated the practice of re-insurance and strengthened the powers of the Council and the Registrar to act in the interests of beneficiaries. The Act also made provision for the regulation of marketing of medical schemes, for more frequent reporting by schemes to the Registrar and defined the circumstances in which schemes may be inspected. These amendments constituted a refinement of the existing Act rather than the introduction of any new policy principles.

The year **2002** saw the passage of a major new piece of legislation in the form of the Mental Health Care Act (Act

17 of 2002). This Act entirely replaced the previous Mental Health Act (Act 18 of 1973) and set out new procedures for the admission of the mentally ill to health establishments and the steps to be taken by family members and caregivers to ensure that they obtain the necessary treatment. The new procedures included significantly more 'checks and balances' and gave more rights to the South African Police Service to intervene in mental health cases. The overarching goal of the new Act was to make mental health care services in the country more accessible and to prohibit unfair discrimination against the mentally ill.

In **2003**, a significant portion of the policy contained in the White Paper was enacted into law in the National Health Act (Act 61 of 2003). This legislation provides for the monitoring and evaluation of the quality of health services by an Office of Standards Compliance to be established by the Director-General within the national DoH. This office has not yet been established.

The National Health Act also provides for a licensing mechanism for health establishments in order to improve allocation and distribution of health resources throughout the country. The Regulations which are to give more substance to the legislative provisions have not yet been published for public comment. However, the certificate of need (CoN), the most comprehensive licensing system ever contemplated within the South African health sector will take considerable resources to implement. The CoN requirement applies to all health establishments whether in the public or private sector. According to section 36(3) of the Act the Director-General is required to take into account such factors as:

- consistency of health services development in terms of national, provincial and municipal planning;
- equitable distribution and rationalisation of health services and health care resources, and the need to correct inequities based on racial, gender, economic and geographical factors;
- the demographics and epidemiological characteristics of the population to be served; and
- the need to ensure the availability and appropriate utilisation of human resources and health technology.

Licensing systems promote access to health care services in a number of different ways.

- They promote rational distribution of health care services in accordance with the needs of the local population.
- They encourage providers to draw up business plans and do feasibility studies before simply setting up a health establishment. This in turn promotes the long-term viability of the practice and sustained health care services to the relevant community.
- They reduce the likelihood of over servicing in one community and under servicing in another.
- They are a means of ensuring the quality of the health services delivered at health establishments. Health services of poor quality can be worse for the patient than no health services at all given such risks as nosocomial infection and other pathogenic conditions which can run amok in poorly managed health establishments.
- They are a means of eliminating wasteful and unnecessary expenditure within the system arising from competition between health establishments.
- They are a means of excluding providers who have demonstrated themselves unfit or unworthy to conduct a health establishment on the basis of their professional ethics and failure to observe legal requirements.
- They are a basis for ongoing monitoring and evaluation of health establishments in terms of their adherence to safety and operational standards.

There is also provision in the National Health Act for the Minister of Health to prescribe mechanisms to enable a coordinated relationship between private and public health establishments in the delivery of health services. The Act requires the National Health Council to develop policy and guidelines for and monitor the provision, distribution, development, management and utilisation of human resources within the national health system.

As yet no Regulations have been published for public comment in terms of the relevant sections of the National Health Act. These sections cannot be brought into effect without Regulations to provide the mechanisms for the implementation of the licensing system. The reasons for the delay in implementation of this section of the Act are unknown. The South African Medical Association (SAMA) is opposed to this aspect of the Act and has threatened litigation on the grounds that this section is potentially unconstitutional.[17] When the section is brought into effect a major change will occur in that the licensing decisions will shift from provincial to national government.

The National Health Act contains provision for health information systems, the keeping of health records and the submission of returns bearing prescribed information in order that

the national health system, which includes the private health sector, can be monitored and evaluated on a continuous basis.

With the passage of the National Health Act the legislative phase of development was largely completed. Many of the Regulations contemplated in the Act have yet to be written. However, the majority of the policy principles contained in government's early policy documentation have now been enacted and the next few years should be geared towards practical implementation and legislative consolidation as opposed to major legislative changes.

The Medical Schemes Amendment Bill (Bill 80 of 2001) was published for public comment on 24 November 2006. The Bill makes provision for the establishment of a Risk Equalisation Fund (REF). The REF will be administered by the CMS. Medical schemes whose risk profile is below the norm will pay into the REF while those whose risk is higher than the norm will receive payments from the REF. The norm which will be determined on the basis of certain PMB conditions aims to equalise risks in terms of the membership profile to which schemes are exposed. Schemes with younger, healthier members will subsidise those with older, sicker members. Whilst the principle has been fairly well accepted within the industry there has been some criticism about the perceived impact that the REF will have on schemes which are efficient in managing the health of their members as opposed to those that are not. The REF and its likely impact, is addressed in greater detail in the chapter on Medical Schemes. The Medical Schemes Amendment Bill is likely to go through Parliament in late 2007 for implementation in 2008.

The Bill almost casually makes provision for Low Income Medical Schemes (LIMS) in a few lines.[18] The Bill proposes an amendment to section 67 of the Medical Schemes Act in terms of which the Minister of Health can prescribe variations from the requirements of certain regulations to be applied to medical scheme products which cater specifically for 'low income earners' provided that such variations are reasonably necessary to create conditions for the emergence of such medical scheme products in the market and in the best interests of 'low income consumers'. This phrase was not defined in the Bill as published for public comment.

The National Health Act allows the Minister of Health to make Regulations as to the manner in which the Director-General may publish reference price lists for use by medical schemes and providers of health care services. The Regulations were published in final form on 23 July 2007.[19] They allow the Director-General to call for a wide range of information from stakeholders and to hear representations on and to enter into correspondence with interested parties in order to evaluate the information submitted. The Regulations stipulate that where a consultant is commissioned to conduct a costing survey for the purpose of submitting information to the Director-General, the consultant must be free from any interest and any business relationship which could interfere with his ability to objectively evaluate the costs. The Regulations require the Director-General to take into account certain parameters when determining the reference price list and some of these include:

- the advice of an advisory committee appointed by the Minister of Health in terms of section 91(1) of the National Health Act;
- the need for private health establishments and health agencies to have a return on investment;
- the need for certainty, sustainability, affordability and stability within the medical schemes environment and among private sector consumers; and
- the need to eliminate perverse incentives, unethical business practices and unprofessional conduct from the health care industry.

Despite this, the reference price list determined by the Director-General remains a reference price list for stakeholders to use or ignore as they see fit.

The vast majority of Regulations under the National Health Act have yet to be written despite the fact that this Act was first published in 2004. Section 47 of the Act allows the Minister of Health to make Regulations on quality requirements and standards relating to human resources, health technology, equipment, hygiene, premises, the delivery of health services, business practices, safety and the manner in which users are accommodated and treated. None of these Regulations has been published for comment.

Section 39(1) of the National Health Act allows the Minister of Health to *"make regulations relating to:*

(a) the requirements for the issuing or renewal of a certificate of need;

(b) the requirements for a certificate of need for health establishments and health agencies existing at the time of commencement of this Act;

(c) the requirements for a certificate of need for health establishments and health agencies coming into being after the commencement of the Act;

(d) *and any other matter relating to the granting of a certificate of need and the inspection and administration of health establishments and health agencies."*[20]

These Regulations would have to be made before the relevant chapter (Chapter 6) of the Act is brought into effect. Once this occurs, health establishments have a period of 24 months from the effective date to acquire a CoN. This means that all the necessary systems and mechanisms must be in place to grant certificates of need before the Chapter becomes effective. The Director-General has not yet even established the Office of Standards Compliance in the national DoH as required by section 78 of the Act. This entity is likely to play a key role in the implementation of this Chapter. The reasons for the three year delay in the implementation of material sections of the National Health Act are not apparent.

The Tobacco Products Control Amendment Act (Act 12 of 1999) has taken a fair amount of time to get to Parliament. This was due to South Africa's accession to the Framework Convention on Tobacco Control. The Bill was amended to bring it into line with this international convention as pointed out by the Deputy Minister of Health in her speech on the introduction of the Bill into the National Assembly on 29 March 2007. The Bill prohibits advertising, promotion and sponsorship of any kind by the tobacco industry except under limited conditions. It also prohibits the entry of anyone under the age of 18 years into a designated smoking area and increases the age of the legal sale of tobacco products from 16 to 18 years. The Bill amends the definition of tobacco product to include any product containing tobacco that is intended for human consumption as well as any device, pipe, water pipe, papers, tubes, filters, portion pouches or similar object manufactured for use in the consumption of tobacco. It also provides that no one may smoke any tobacco product in a private dwelling if it is used for any commercial childcare activity, schooling or tutoring.

Future possible legislative changes include:

- amendments to the Pharmacy Act to bring it into alignment with the Medicines and Related Substances Act;
- amendments to the Medicines and Related Substances Act to correct certain anomalies arising from existing provisions around the pricing of medicines and the pricing committee;
- the repeal of the Human Tissue Act by the proclamation of Chapter 8 of the National Health Act dealing with this topic;
- the regulation of health professionals and the supply of human resources within the national health system;
- the regulation of health technology in accordance with the provisions of Chapter 6 of the National Health Act; and
- legislation establishing a Social Health Insurance (SHI) system.

Conclusion and Recommendations

Whilst the DoH has clearly achieved a great deal and a lot of work has already been undertaken in the area of private health care regulation, there is still critically important work outstanding which needs to be completed without delay.

- The Office of Standards Compliance should be established within the DoH.
- The Regulations around the CoN should be written and published for public comment as soon as possible in order that they can be finalised and Chapter 6 of the National Health Act can be proclaimed into effect.
- The Regulations on quality standards permitted in the National Health Act should be developed and published for public comment as soon as possible in order to facilitate solutions to the challenge of ensuring the quality of health care in the private sector.
- The Regulations required in terms of Chapter 8 of the National Health Act should be written and finalised so that this chapter, dealing with human stem cells and cloning, a single national blood transfusion service, trade in human tissue, and similar matters can be brought into effect to replace the outdated Human Tissue Act.
- Compliance with the medicine pricing Regulations needs to be monitored and enforced.
- The Pharmacy Act needs to be amended to bring it into line with the Medicines and Related Substances Act.
- The PMB package in the Regulations to the Medical Schemes Act needs to be reviewed urgently in the manner contemplated in those Regulations.

Table 1: Summary of legislation passed between 1994 and 2004

Year	Act No.	Title	Objects
1995	5	Nursing Amendment Act[21]	To amend the Nursing Act of 1978, to provide for the establishment of the South African Interim Nursing Council; to further regulate the objects and powers of the Council; to provide for the constitution of the Council; to further regulate the filling of vacancies on the Council; to provide for the abolition of the various nursing Councils in the Republic; and to provide for the rationalisation of certain laws relating to nursing that remained in force in various areas of the national territory of the Republic by virtue of section 229 of the Constitution.
1995	6	Pharmacy Amendment Act[22]	To amend the Pharmacy Act of 1974, to provide for the establishment, constitution and objects of the Interim Pharmacy Council of South Africa; to provide for the abolition of the South African Pharmacy Council; and to provide for the repeal of certain laws in respect of the pharmaceutical profession which remained in force in the various territories of the national territory of the Republic by virtue of section 229 of the Constitution.
1995	18	Medical, Dental and Supplementary Health Service Professions Amendment Act[23]	To amend the Medical, Dental and Supplementary Health Service Professions Act of 1974, to provide for the establishment, constitution and objects of the Interim National Medical and Dental Council of South Africa; to provide for the abolition of certain medical councils; and to provide for the repeal of certain laws in respect of medical, dental and supplementary professions which remained in force in the various territories of the national territory of the Republic by virtue of section 229 of the Constitution.
1995	40	Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act[24]	To amend the Chiropractors, Homeopaths and Allied Health Service Professions Act of 1982 to provide for the establishment of the Chiropractors, Homeopaths and Allied Health Service Professions Interim Council; to provide for the abolition of the Chiropractors, Homeopaths and Allied Health Service Professions Council; and to provide for the rationalisation of certain laws relating to chiropractors, homeopaths and allied health service professions that remained in force in various areas of the national territory of the Republic by virtue of section 229 of the Constitution.
1996	92	Choice on Termination of Pregnancy Amendment Act[25]	To determine the circumstances in which and conditions under which the pregnancy of a woman may be terminated.
1997	19	Nursing Amendment Act[26]	To amend the Nursing Act of 1978, in relation to the definitions; to make provision for the establishment, constitution and objects of the South African Nursing Council; and the abolition of the South African Interim Nursing Council.
1997	43	Dental Technicians Amendment Act[27]	To amend the Dental Technicians Act of 1979, in order to provide for the recognition of the professions of dental technologist and clinical dental technologist; to constitute a new South African Dental Technicians Council and to make transitional arrangements therefore; to provide for the re-appointment or re-election of a member of that Council for one further term only; to provide for the extension of the acts which may be performed by a dental laboratory assistant; to provide for the registration of dental laboratory assistants; to provide for the direct billing of patients or medical aid schemes by dental technician contractors; to provide that a business in which acts specially pertaining to the profession of dental technician or dental technologist are performed, may be carried out by associations or juristic persons; to provide that a fine may also be imposed upon a conviction of misconduct; to increase penalties so as to cope with inflation; to amend certain obsolete references; to provide for the rationalisation of certain laws relating to dental technicians that have remained in force in the various territories of the national territory of the Republic by virtue of the Constitution of the Republic of South Africa, 1996.
1997	88	Pharmacy Amendment Act[28]	To amend the Pharmacy Act of 1974, so as to provide for the establishment of the new South African Pharmacy Council and for its objects and general powers; to extend the control of the Council to the public sector and to amend the provisions relating to pharmacy education and training, requirements for registration, the practice of pharmacy, the ownership of pharmacies and the investigative and disciplinary powers of the council.
1997	89	Medical, Dental and Supplementary Health Service Professions Amendment Act[29]	To amend the Medical, Dental and Supplementary Health Service Professions Act of 1974, to provide for the establishment of the Health Professions Council of South Africa and professional boards for health professions; to abolish the Interim National Medical and Dental Council of South Africa; to provide for control over the education, training, registration and practices of health professionals.

Year	Act No.	Title	Objects
1997	90	Medicines and Related Substances Control Amendment Act[30]	To amend the Medicines and Related Substances Control Act of 1965 to provide that the council shall be a juristic person; to make other provision for the constitution of the council; to provide that a member of the council or a committee shall declare his or her commercial interest related to the pharmaceutical or health care industry; to provide that the appointment of members of the executive committee shall be subject to the approval of the Minister; to make further provision for the prohibition on the sale of medicines which are subject to registration and are not registered; to provide for procedures that will expedite the registration of essential medicines, and for the re-evaluation of all medicines after five years; to provide for measures for the supply of more affordable medicines in certain circumstances; to require labels to be approved by the council; to prohibit bonusing and sampling of medicines; to further regulate the control of medicines and scheduled substances; to provide for the licensing of certain persons to compound, dispense or manufacture medicines; to provide for generic substitution of medicines; to provide for the establishment of a pricing committee; to regulate the purchase and sale of medicines by wholesalers; to make new provision for appeals against decisions of the Director-General or the council; to further regulate the powers of inspectors; to increase the jurisdiction of magistrates' courts in respect of penalties in terms of this Act; to provide that the council may acquire and appropriate funds; to regulate anew the Minister's power to make regulations; and to provide for the rationalisation of certain laws relating to medicines and related substances that have remained in force in various territories of the national territory of the Republic by virtue of section 229 of the Constitution of the Republic of South Africa, 1993.
1997	91	Chiropractors, Homeopaths and Allied Health Service Professions Act[31]	To amend the Chiropractors, Homeopaths and Allied Health Service Professions Act of 1982, in order to extend the terms of office of members of the Chiropractors, Homeopaths and Allied Health Service Professions Interim Council.
1998	1	Medical, Dental and Supplementary Health Service Professions Amendment Act[32]	To amend the Medical, Dental and Supplementary Health Service Professions Act of 1974, so as to further regulate the period of office of the members of the Interim National Medical and Dental Council of South Africa.
1998	44	Sterilisation Act[33]	To provide for the right to sterilisation; to determine the circumstances under which sterilisation may be performed and, in particular, the circumstances under which sterilisation may be performed on persons incapable of consenting or incompetent to consent due to mental disability.
1998	131	Medical Schemes Act[34]	To consolidate the laws relating to registered medical schemes; to provide for the establishment of the Council for Medical Schemes as a juristic person; to provide for the appointment of the Registrar of Medical Schemes; to make provision for the registration and control of certain activities of medical schemes; to protect the interests of members of medical schemes; to provide for measures for the coordination of medical schemes.
1999	12	Tobacco Products Control Amendment Act[35]	To amend the Tobacco Products Control Act of 1993, to provide for the prohibition of advertising and promotion of tobacco products; to provide further, for the prohibition of advertising and promotion of tobacco products in relation to sponsored events; to prohibit the free distribution of tobacco products and the receipt of gifts or cash prizes in contests, lotteries or games to or by the purchaser of a tobacco product in consideration of such purchase; to provide for the prescription of maximum yields of tar, nicotine and other constituents in tobacco products; to increase fines.
2000	1	Pharmacy Amendment Act[36]	To amend the Pharmacy Act of 1974, so as to provide for the performance of community service by persons registering for the first time as pharmacists.
2000	6	Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act[37]	To amend the Chiropractors, Homeopaths and Allied Health Service Professions Act of 1982, in order to extend the terms of office of the members of the Chiropractors, Homeopaths and Allied Health Service Professions Interim Council, retrospectively.
2000	37	National Health Laboratory Services Act[38]	To provide for the establishment of a juristic person to be known as the National Health Laboratory Service; to provide for the abolition of the South African Institute for Medical Research, the National Institute for Virology, the National Centre for Occupational Health, certain forensic chemistry laboratories and all provincial health laboratory services.
2000	50	Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act[39]	To amend the Chiropractors, Homeopaths and Allied Health Service Professions Act of 1982, to abolish the Chiropractors, Homeopaths and Allied Health Service Professions Interim Council; to establish the Allied Health Professions Council of South Africa; to provide for the establishment of professional boards; to regulate the relationship between the new Council and the professional boards; to make provision for matters relating to the responsibility, accountability, democratisation and transparency of the Council and professional boards.

Year	Act No.	Title	Objects
2001	24	National Health Laboratory Service Amendment Act[40]	To amend the National Health Laboratory Service Act of 2000, so as to provide for pension options to employees of bodies that are to be replaced by the National Health Laboratory Service.
2001	55	Medical Schemes Amendment Act[41]	To amend the Medical Schemes Act of 1998, so as to extend certain rights of members to their dependants; to broaden the definition of complaint; to explicitly prohibit discrimination on the basis of age; to further regulate the practice of re-insurance; to regulate the circumstances under which waiting periods may be applied; to improve the powers of the Council and the Registrar to act in the interests of beneficiaries; to regulate the marketing of entities doing the business of a medical scheme; to provide for more frequent submission of returns to the Registrar; to determine the circumstances under which inspections may be made; to further define the persons who may be appointed as auditors of medical schemes; to further define the persons who may serve as trustees of a medical scheme and to further clarify their duties; to define the persons who may serve as principal officers of a medical scheme; to limit the purposes for which medical schemes may compensate brokers and provide for the regulation of their professional conduct; to regulate the transfer of business of medical schemes to any person; to remove the requirement for staff of the Council to be members of the Government Employees Pension Fund; to amend the transitional provisions with regard to certain schemes.
2002	17	Mental Health Care Act[42]	To provide for the care, treatment and rehabilitation of persons who are mentally ill; to set out different procedures to be followed in the admission of such persons; to establish Review Boards in respect of every health establishment; to determine their powers and functions; to provide for the care and administration of the property of mentally ill persons; to repeal certain laws.
2002	31	Health Donations Fund Repeal Act[43]	To provide for the disestablishment of the Health Donations Fund and for the repeal of the Health Donations Fund Act of 1978.
2002	59	Medicines and Related Substances Amendment Act[44]	To amend the Medicines and Related Substances Act of 1965, so as to provide for some definitions; to provide for the appointment of one or more Deputy Registrars; to provide for a term of office of members of the Pricing Committee; to provide for the delay of the coming into operation of provisions requiring a licence before a person can compound and dispense or manufacture medicines, or act as a wholesaler or distributor; to provide for appeals against the decisions of the Director-General and the Council; to provide for Regulations relating to the marketing of medicines.
2002	60	Occupational Diseases in Mines and Works Amendment Act[45]	To amend the Occupational Diseases in Mines and Works Act of 1973, so as to provide that if a person was medically examined within a period of 24 months immediately preceding an application for medical examination, the Director of the Medical Bureau for Occupational Diseases may refuse that person's application for medical examination.
2002	62	Medical Schemes Amendment Act[46]	To amend the Medical Schemes Act of 1998, to broaden the definition of 'broker' and the circumstances under which such a person must be accredited in terms of this Act.
2003	61	National Health Act[20]	To provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services.
2004	24	Dental Technicians Amendment Act[47]	To amend the Dental Technicians Act of 1979, so as to define 'informally trained person'; to provide for the restricted registration of informally trained persons as dental technicians; to make direct billing by a dental technician contractor discretionary; to restrict the performance of certain acts by members of certain juristic persons.
2004	35	Traditional Health Practitioners Act[48]	To establish the Interim Traditional Health Practitioners Council of South Africa; to provide for a regulatory framework to ensure the efficacy, safety and quality of traditional health care services; to provide for the management and control over the registration, training and conduct of practitioners, students and specified categories in the traditional health practitioners' profession.
2004	38	Choice on Termination of Pregnancy Amendment Act[49]	To amend the Choice on Termination of Pregnancy Act of 1996, to empower a Member of the Executive Council to approve facilities where a termination of pregnancy may take place; to exempt a facility offering a 24-hour maternity service from having to obtain approval for termination of pregnancy services under certain circumstances; to provide for the recording of information and the submission of statistics; to enable a Member of the Executive Council to make regulations.
2005	3	Sterilisation Amendment Act[50]	To amend the Sterilisation Act of 1998, to make provision for a medical opinion in certain circumstances; to provide for additional information to be considered when contemplating sterilisation.
2005	33	Nursing Act[51]	To regulate the nursing profession.

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