Health Policy and Legislation

1

Authors:

Andy Gray[i]
Yousuf Vawda[ii]
Caron Jack[iii]

Although the statute books reflect no new health-related Acts passed in 2010-2011, and no important amendments to existing legislation, this period has been marked by a flurry of secondary legislation. Many draft Regulations have been issued in terms of the National Health Act (Act 61 of 2003) and some have been issued in final form. The 2008 National Health Amendment Bill has been allowed to lapse, but a draft Bill which introduces an autonomous Office of Health Standards Compliance was published for comment and then tabled.

The various statutory health councils have also issued new Rules, some of which are still open for comment. However, the slow pace of implementation of the Nursing Act (Act 33 of 2005) is still a problem, not least in relation to the ability of nurses to prescribe and dispense medicines. A final dispensing fee for pharmacists that was acceptable to all parties was published in 2010. However, a number of elements of the medicines pricing landscape are still under consideration, including a cap on the logistics fee and a method for international benchmarking, and the first annual review of the dispensing fee for pharmacists has commenced. Draft Regulations to allow for regulation of medical devices and complementary medicines have also been published.

Outside of the health sphere, other legislation such as the Children's Act (Act 38 of 2005) and the Consumer Protection Act (Act 68 of 2008) also impact on healthcare workers. In August 2011 a draft National Environmental Health Policy was released for comment. The major policy focus remains the planned introduction of National Health Insurance, for which a Green Paper was released for comment in August 2011. Although missing many critical details, this draft policy document lays out a pathway to implementation of universal coverage by 2025.

The major policy focus remains the planned introduction of National Health Insurance, for which a Green Paper was released for comment in August 2011. Although missing many critical details, this draft policy document lays out a pathway to implementation of universal coverage by 2025.

i Department of Therapeutics and Medicines Management, Nelson R Mandela School of Medicine, University of KwaZulu-Natal

ii Faculty of Law, University of KwaZulu-Natal

iii Department of TeleHealth, Nelson R Mandela School of Medicine, University of KwaZulu-Natal

Introduction

Each year the Annual Report of the National Department of Health (NDoH) includes a list of the legislation for which the Minister of Health bears responsibility. The most recent listing, with the accompanying summaries of the scope of each Act, is provided in Table 1 below. Many but not all of these items have been amended over time, some since the transition to democracy in 1994. Some remain on the statute books only until new legislation can be brought into effect. The NDoH operates in compliance with a far wider range of legislation, such as labour laws and those governing the public service, and is required to comply with the Promotion of Access to Information Act (Act 2 of 2000) and Promotion of Administrative Justice Act (Act 3 of 2000).

This chapter focuses on those health-related legislative instruments that have been the subject of change since 2010, and draws attention to areas where progress with implementation of new legislation has been particularly slow. It also focuses on two important pieces of new legislation which fall outside of the Minister of Health's portfolio, but which have implications for the provision of health care: the Children's Act (Act 41 of 2007) and the Consumer Protection Act (Act 68 of 2008). Attention is also paid to laws governing intellectual property protection, as these have some implications for access to health technologies. Major new policy documents, notably the Green Paper on National Health Insurance (NHI), are also covered and placed in the context of the legislative instruments to which they refer or which will need to be amended in order to effect them.

Table 1: Legislation for which the Minister of Health bears responsibility

Act	Scope of the legislation
Medicines and Related Substances Act (Act 101 of 1965)	"Provides for the registration of medicines and other medicinal products to ensure their safety, quality and efficacy, and also provides for transparency in the pricing of medicines"
Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972)	"Provides for the regulation of foodstuffs, cosmetics and disinfectants, in particular quality standards that must be complied with by manufacturers, as well as the importation and exportation of these items"
Hazardous Substances Act (Act 15 of 1973)	"Provides for the control of hazardous substances, in particular those emitting radiation"
Occupational Diseases in Mines and Works Act (Act 78 of 1973)	"Provides for medical examinations on persons suspected of having contracted occupational diseases, especially in mines, and for compensation in respect of those diseases"
Pharmacy Act (Act 53 of 1974)	"Provides for the regulation of the pharmacy profession, including community service by pharmacists"
Health Professions Act (Act 56 of 1974)	"Provides for the regulation of health professions, in particular medical practitioners, dentists, psychologists and other related health professions, including community service by these professionals"
Dental Technicians Act (Act 19 of 1979)	"Provides for the regulation of dental technicians and for the establishment of a council to regulate the profession"
Allied Health Professions Act (Act 63 of 1982)	"Provides for the regulation of health practitioners such as chiropractors, homeopaths etc., and for the establishment of a council to regulate these professions"
Human Tissue Act (Act 65 of 1983)	"Provides for the administration of matters pertaining to human tissue"
National Policy for Health Act (Act 116 of 1990)	"Provides for the determination of national health policy to guide the legislative and operational programmes of the health portfolio"
SA Medical Research Council Act (Act 58 of 1991)	"Provides for the establishment of the South African Medical Research Council and its role in relation to health research"
Academic Health Centres Act (Act 86 of 1993)	"Provides for the establishment, management and operation of academic health centres"
Choice on Termination of Pregnancy Act (Act 92 of 1996)	"Provides a legal framework for the termination of pregnancies based on choice under certain circumstances"
Sterilisation Act (Act 44 of 1998)	"Provides a legal framework for sterilisations, including for persons with mental health challenges"
Medical Schemes Act (Act 131 of 1998)	"Provides for the regulation of the medical schemes industry to ensure consonance with national health objectives"
Tobacco Products Control Amendment Act (Act 12 of 1999)	"Provides for the control of tobacco products, the prohibition of smoking in public places and of advertisements of tobacco products, as well as the sponsoring of events by the tobacco industry"
National Health Laboratory Service Act (Act 37 of 2000)	"Provides for a statutory body that offers laboratory services to the public health sector"
Council for Medical Schemes Levy Act (Act 58 of 2000)	"Provides a legal framework for the Council to charge medical schemes certain fees"
Mental Health Care Act (Act 17 of 2002)	"Provides a legal framework for mental health in the Republic and, in particular, the admission and discharge of mental health patients in mental health institutions, with an emphasis on human rights for mentally ill patients"
National Health Act (Act 61 of 2003)	"Provides 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"
Nursing Act (Act 33 of 2005)	"Provides for the regulation of the nursing profession"

Source: National Department of Health, 2010.[1]

Provinces have also, to some extent, developed their own legislation, but no new provincial health legislation was produced in the period under review. Local government has responsibility for municipal health services, and municipal bylaws therefore have an important effect on some of the social determinants of health. However, these are diverse and numerous, and a review of changes here is beyond the scope of this chapter.

Overall shape of the health system

The National Health Act and 1997 White Paper

The fundamental health policy document issued by the Minister of Health remains the 1997 White Paper on the Transformation of the Health System in South Africa.[2] The 1997 White Paper included as an appendix the 1996 National Drug Policy for SA.[3] While the NDoH has committed to a review of the National Drug Policy, as item 9 on the 10 Point Plan for 2009-2014,[4] no similar effort has been made to update the overall health policy document. Instead, two related but separate efforts have been under way: the re-engineering of the primary health care (PHC) system and development of policy proposals on NHI. The first of these is the subject of a separate chapter in this Review.[5]

The NDoH's *Annual Performance Plan 2011/2012* states:

> A re-engineered primary healthcare (PHC) model for South Africa is at an advanced stage of development by a Ministerial Task Team appointed following a study tour to gain a better understanding of the Brazilian model. The model emphasizes a population-oriented service delivery approach (rather than a health facility-based one); deployment of multidisciplinary PHC teams across well-defined geographic areas; effective utilisation of the skills of community-based resources such as Community Health Workers (CHW), and greater community involvement in securing and promoting health.[6]

In relation to NHI the same report states:

> Work on the National Health Insurance (NHI) is at an advanced stage. A Ministerial Advisory Committee (MAC) was established in 2009 by the Minister of Health and has developed a report which was considered by Cabinet, and which led to the formation of an Inter-Ministerial Committee (IMC) on the NHI. Cabinet requested comprehensive work to be done (on costing, economic modelling, a description of the role of primary health care services in the NHI, and the elaboration of migration of funding mechanisms, and a communication strategy) and this has now been completed for consideration by the IMC. By 2011, it is anticipated that a detailed implementation plan for NHI will be produced.

While no detailed report has been released by the Ministerial Advisory Committee, the Minister released a Green Paper for comment on 12 August 2011.[7] Once implemented this would constitute a more radical reshaping of the health system than any intervention attempted since 1994.

Although the signalled review of the National Drug Policy has not yet commenced, attention has been paid to the issue of procurement, as mentioned in the *Annual Performance Plan 2011/2012*:

> A Task Team appointed to investigate these challenges completed its work and presented a set of recommendations to the NHC [National Health Council] on the reform of medicine procurement systems in the public sector. These included strategies to: improve drug procurement and payment systems to ensure reliable and uninterrupted supply; ensure a more cost-effective procurement of drugs through the centralization of the authority for procurement; and address systems failures resulting in medicine shortages.

Nonetheless, there has been some progress in the implementation of the National Health Act (NHA).[8] As with much South African legislation, this Act is written in enabling language, and therefore requires the development of substantial secondary legislation (in the form of Regulations made by the Minister) in order to be brought into operation. In April 2011 an extensive series of draft Regulations was published for comment within a period of three months; this period expired at the end of June 2011, but final Regulations have yet to be issued. The draft Regulations issued for comment related to:

- artificial fertilisation of persons;[9]
- the use of human biological material;[10]
- registration of microbiological laboratories and the acquisition, importation, handling, maintenance and supply of human pathogens;[11]
- stem cell institutions or organisations;[12]
- import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, zygotes and gametes;[13]
- tissue banks;[14]
- general conduct of human bodies, tissue, blood, blood products and gametes;[15]
- blood and blood products;[16] and
- rendering of clinical forensic medicine services.[17]

These Regulations are needed to give effect to a number of sections of the Act which were brought into effect on 10 May 2010, including section 55 ("Removal of tissue, blood, blood products or gametes from living persons"), section 56 ("Use of tissue, blood, blood products or gametes removed or withdrawn from living persons") and section 68 ("Regulations relating to tissue, cells, organs, blood, blood products and gametes").[18] The same commencement notice also provided for the repeal of section 23(b) of the Human Tissue Act (Act 65 of 1983). Also in May 2010 the Minister made a final Regulation "relating to the withdrawal of blood from a living person for testing", which enabled the drawing of finger-prick samples by trained persons other than health care providers[19] – an important enabling provision for the national HIV testing campaign.

In addition, the 1 April 2011 *Government Gazette* contained a draft Ministerial determination on revenue retention by central hospitals, also issued for comment within three months.[20] This was also issued in terms of the NHA, and provided that central hospitals would be able to retain any "surplus collected over and above the target set ... by the provincial treasury", or the entire amount collected if no such target was set, and that this arrangement would come into effect on 1 April 2012.

In September 2010 the Minister also issued the necessary Regulations to enable establishment of the National Health Research Committee,[21] charged in terms of section 69 of the NHA with the following:

- determining the health research to be carried out by public health authorities;
- ensuring that health research agendas and research resources focus on priority health problems;
- developing and advising the Minister on application and implementation of an integrated national strategy for health research; and
- coordinating the research activities of public health authorities.

The inaugural committee, consisting of 12 members under the chairmanship of Professor Bongani Mayosi, was appointed for the 2010-2013 period.

A chapter in the 2010 edition of the *South African Health Review (SAHR)* reported in some detail on the National Health Amendment Bill of 2008 (Bill 65 of 2008), which was allowed to lapse.[22,23] It was predicted that a revised version was to be tabled in 2010, dealing with the following issues:

- creation of an independent accreditation body for health facilities;
- a review of the current position on the licensing of blood transfusion services; and
- a review of the powers and functions of the national and provincial Departments of Health (DoHs).

The licensing of a single national blood transfusion service was included in the draft Regulations published for comment in April 2011[16] but no review of the powers and functions of national and provincial departments has been attempted. Instead, in January 2011 the Minister published a draft National Health Amendment Bill for comment, allowing three months for submissions.[24] The intent of the Minister was clearly spelled out in a press release on 24 January 2011, which dealt with the development of the Office of Health Standards Compliance (OHSC):[25]

> Once established, the Office of Health Standards Compliance will ensure that complaints received from healthcare users or the public (patients and families) are properly and independently investigated. The Bill proposes that the Office be headed by a qualified Executive Director and supported by competent personnel including Health Officers. The OHSC is also expected to pave the way for the implementation of the National Health Insurance as the provision of quality care will be one of the core requirements for the NHI.

Structurally the Bill provides a substitute for chapter 10 of the NHA, creating the OHSC as "an organ of state at the national sphere of government" instead of a part of the NDoH. Although the Office was described as independent, the Bill provides (in section 78(2)) that "the Minister exercises final responsibility over the Office". The Executive Director of the OHSC was to be required (in section 81A) to "develop and recommend" a range of standards and systems "to the Minister for approval". Drawing extensively on a Constitutional Court 2011 ruling relevant to issues of "the operational and structural attributes of independence",[26] SECTION27 provided detailed input on this draft Bill[27] and submitted that several elements of its construct constituted "serious encroachment on the Office's autonomy".

An amended version of the Bill was tabled in Parliament in November 2011, but has yet to be considered by the Portfolio Committee on Health.[28]

Most recently the Minister has issued one more set of final Regulations in terms of the NHA, dealing with the creation of a National Cancer Registry located within the National Health Laboratory Services.[29] Of relevance to the Green Paper on NHI (see below), the Minister also issued a draft policy document and accompanying draft Regulations for comment dealing with the classification of hospitals and qualifications of hospital managers in the public sector.[30,31] The classification scheme described referred only to public sector hospitals, although the draft Regulations did include two categories of private hospitals (for profit and not for profit). The draft Regulations were issued in terms of section 35 of the NHA.

Public sector hospitals were classified in the following categories, with apparent maximum bed establishments stated:

- District hospitals: small – 50-150 beds; medium – 150-300 beds; large – 300-600 beds;
- Regional hospitals – 400-600 beds;
- Tertiary hospitals – 400-800 beds;
- Central hospitals – up to 1200 beds; and
- Specialised hospitals – up to 600 beds.

All existing public sector hospitals were then listed, with a category assigned and current number of beds stated. A transitional measure was proposed, where time to "effect changes to their structures, number of beds, services or any other matter" would be allowed by the Minister, on application by the relevant Member of the Executive Council (MEC). The draft Regulation also enabled management of public hospitals to be "in accordance with national policy". The accompanying policy document therefore provided more details on the minimum requirements for appointment, post levels and salary scales for managers of different categories of hospitals, and composition and functions of hospital boards.

Classification of all health establishments in terms of section 35 is a necessary step towards implementation of the remaining provisions in chapter 6 of the Act, notably the Certificate of Need (section 36). However, the mere designation of private hospitals as 'for profit' or 'not for profit' would not seem sufficient for this purpose.

The Green Paper on NHI

The health policy landscape was fundamentally changed in August 2011 with release of the much anticipated Green Paper on NHI.[7] As explained on the Parliamentary Monitoring Group's website:

> The process of making a law sometimes begins with a discussion document, called a Green Paper. This is drafted in the Ministry or department dealing with the particular issue in order to show the way that it is thinking on a particular policy. It is then published so that anyone who is interested can give comments, suggestions and ideas. The Green Paper is sometimes followed by a more refined discussion document, called a White Paper, which is a broad statement of government policy. This is drafted

> by the relevant department or a task team designated by the Minister of that department. Comment may again be invited from interested parties. The relevant parliamentary Committees may propose amendments or other proposals and then send the policy paper back to the Ministry for further discussion and final decisions.

Before its release there was widespread expectation that a White Paper would be produced instead. That shift alone could be interpreted as evidence of both caution and a degree of flexibility in terms of content.

In essence the Green Paper did not deviate significantly from overall structures outlined in the Discussion Document released after the 2010 National General Council of the African National Congress (ANC) in September 2010.[32] This document and its implications were extensively covered in the *SAHR 2010*.[33] Having reprised the problems facing the delivery of health care in SA and having traced the long history of policy considerations on this matter, the Green Paper listed the following principles on which it would base the intended intervention:

- the right to access, as enshrined in section 27 of the Bill of Rights of the Constitution;
- social solidarity, by ensuring "sufficient cross-subsidisation between the rich and the poor, and the healthy and sick";
- effectiveness, through the use of "evidence based interventions, strengthened management systems and better performance of the healthcare system";
- appropriateness, predominantly by implementing a re-engineered PHC model;
- equity;
- affordability; and
- efficiency, through "creating administrative structures that minimise or eliminate duplication across the national, provincial and district spheres".

The objectives of NHI were stated as follows:

- To provide improved access to quality health services for all South Africans irrespective of whether they are employed or not.
- To pool risks and funds so that equity and social solidarity will be achieved through the creation of a single fund.
- To procure services on behalf of the entire population and efficiently mobilise and control key financial resources. This will obviate the weak purchasing power that has been demonstrated to have been a major limitation of some of the medical schemes, resulting in spiralling costs.
- To strengthen the under-resourced and strained public sector so as to improve health systems performance.

A direct link was created with the plans for re-engineering PHC, to be delivered in 'three streams': district-based clinical specialist support teams, school-based services and municipal ward-based PHC agents. As before, a role for private providers was envisaged. However, whereas the ANC Discussion Document, in line with the 1997 White Paper, seemed to wish to restrict this to group practices, the Green Paper was more flexible:

> There are several ways in which private providers could participate in providing PHC services to the population. The salient feature of contracting private providers in the delivery of primary health care services will entail the specification of the range of services that will be provided. These may include services by the general practitioners to patients who must get the full range of primary care services required in one facility or comparable arrangement which does not inconvenience or require travel costs on the part of the patient.

Some flexibility was also indicated in relation to co-payments (e.g. to cover non-generic medicines), but user fees at the point of care were again identified as unacceptable. Another area in which options were apparently being considered was the mechanism for payment. Whereas the ANC document committed to a single-payer system, the Green Paper appeared to entertain the possibility of a multi-payer option:

> The main responsibility of the National Health Insurance Fund will be to pool funds and use these funds to purchase health services on behalf of the entire population from contracted public and private health care providers. Nonetheless, a multi-payer system in a National Health Insurance will also be explored as an alternative to the preferred single-funder, single-purchaser publicly administered Fund.

However, as with the ANC document, there were few details on how the NHI Fund would be constituted or governed, or where the funding would be obtained:

> All revenue collection would be undertaken by the South African Revenue Services (SARS), including the mandatory contribution. All funding for personal health care services will flow through the National Health Insurance Fund. Treasury will allocate general tax revenue for personal healthcare services and the payroll-linked mandatory contribution to National Health Insurance in consultation with the Minister of Health and the National Health Insurance.

The reliance on a much-improved public sector and the application of nationwide standards was again emphasized, albeit with reference to an OHSC now located outside of the NDoH.

The most glaring difference between the ANC document and the Green Paper related to the expected costs of NHI once fully implemented in 2025. Whereas both documents started at similar points in 2012 (R128bn and R125bn respectively), based on existing fiscal allocations, the anticipated costs in 2025 were R376bn and R255bn respectively. No detailed reasons for this difference were provided. As before, the "operational costs" of the NHI, once fully implemented, were estimated at 2.9% of total costs, with the balance allocated to "healthcare costs" (in the form of non-AIDS-related services (58.4%), AIDS-related services (17.5%) and additional services (21.2%)).

Transitioning from the existing divided public and private health care systems to a single national system based on universal coverage would, as the Green Paper intimates, require a "well-articulated implementation plan". While not providing a detailed plan, the draft policy document did outline some of the elements

and a three-phased approach. Some of the key elements identified were:

- strengthening of district health structures, not only in terms of the re-engineered PHC approach but establishing the District Health Authorities that would need to contract with the NHI Fund and with accredited private providers;
- comprehensive quality improvement, assurance and compliance by all providers, supported by the OHSC;
- increasing human resources in the health system (including increasing the capacity of training facilities for various health professionals);
- piloting the system in 10 selected health districts (initially funded by an NHI conditional grant);
- completion of an assessment of existing health infrastructure;
- implementing hospital management reforms in relation to governance reforms, financial management, autonomy and accountability;
- developing the necessary purchasing and procurement processes;
- developing processes for population registration;
- refinement of the "financial resource envelope" and the "revenue mobilisation strategy and pooling systems" (including alignment with the Road Accident Fund, Compensation for Occupational Diseases and Injuries, Compensation Commission for Occupational Diseases and the Occupational Diseases in Mines and Works Act);
- refinement of the "provider payment mechanisms";
- development of an integrated health information system; and
- review of existing legislation and creation of an enabling legislative framework (including legislation to establish the NHI Fund, initially at a national level and later at sub-national levels).

The plan for phase 1 (2011-2015) was included, with some ambitious targets. For example, under establishment of the OHSC the steps identified were: parliamentary process on the OHSC Bill – August 2011; and appointment of staff (10 inspectors) – January 2012. As has been noted, a draft Bill to establish the OHSC has been published for comment, but has yet to be tabled in Parliament. Completion of this task in time to appoint staff in January 2012 seems unlikely, especially given the questions that have been raised about the extent to which the OHSC will truly be autonomous.

The newly described municipal ward-based PHC agents also presented challenges. The plan envisaged training the first 5 000 PHC agents by December 2011, appointing them by March 2012 and establishing PHC teams by April 2012. Similarly, 72 of 122 nursing colleges scheduled for refurbishment would be completed by the end of the 2011-2012 financial year and a new National Health Information Repository and Data warehousing system was to be implemented by November 2011.

A particularly challenging prospect was the planned piloting of the new system, to commence in April 2012 (in the new financial year, funded by a conditional grant) in 10 selected districts, expanding to 20 districts in June 2013. This would entail not only the development of NHI district management and governance structures but also development and testing of the service package to be offered under NHI. Over the same period the costing model would be refined and revised estimates provided in 2013. The first private providers would be accredited in 2014, after criteria are developed in 2013.

The plans for phases 2 (2016-2020) and 3 (2021-2025) were less well developed. However, as a whole, this would entail nothing less than a total overhaul of the health system. Initial reactions were predictable, with the ruling party welcoming the announcement and the official opposition questioning whether this "expensive, complex and layered system" would be the solution.[34,35]

In September 2011 the comment period on the Green Paper was extended to 30 December 2011.[36]

Other policies – the draft National Environmental Health Policy

In August 2011 the NDoH published a draft National Environmental Health Policy for comment.[37] The Introduction noted that:

> "since the establishment of new municipalities in 2000, the legislative and institutional development focus has been on developing the necessary planning and financial frameworks and on enhancing the intragovernmental cooperation essential for effective functioning", but also that "[i]n the field of environmental health, this process is ongoing and incomplete, which continues to impact adversely on EHS delivery".

Beyond listing the complexities introduced by the NHA in terms of the definition of "municipal health services", the policy appeared to offer few practical solutions. It located environmental health services within the context of constitutional and international obligations, and identified the wide range of government departments which might contribute to a better environment. Noting and committing to a World Health Organization norm of one environmental health practitioner per 10 000 members of the population, it mentioned a "national norm" of 1:15 000. More practically, it did include a requirement that provincial DoHs monitor municipal health services rendered by metropolitan and district municipalities. Accordingly, local government managers would be required to submit data via the District Health Information System. A National Environmental Health Indicator Dataset was also proposed, but not detailed in any way. As with the 1996 National Drug Policy, a commitment to a review of the policy every three years was included.

Medicines-related matters

Since 1994 much attention has been given to regulating medicines matters, not least as a means to reduce costs in the private sector. A major change to medicines legislation was enabled by the passage of the Medicines and Related Substances Amendment Act (Act 72 of 2008), which created the South African Health Products Regulatory Authority.[38] Although assented to by the President in April 2009, this Act has not been promulgated. It is known that a task team has been established within the NDoH to facilitate creation of the new authority, but little progress has been evident and no timelines announced as yet.

However, progress has been made with the challenging issue of regulating medicine prices in the private sector. Previous chapters in issues of the *SAHR* have provided extensive coverage of court actions relating to this area of legislation.[39-41] In July 2010 a draft set of dispensing fees for pharmacists was published for comment.[42] With deletion of an onerous requirement for annual reporting by retail pharmacies only, this set of dispensing fees was finally issued in November 2010,[43] and the fees declared acceptable by organised pharmacy. However, the dispensing fees applicable to licensed dispensing practitioners (holders of section 22C (1)(a) dispensing licenses) remain contested, despite having been increased in December 2010.[44] In July 2011 a notice was published by the Minister calling for submission of prescribed data by pharmacists in order to enable the annual review of the dispensing fee.[45]

The single exit price for medicines may be adjusted annually to a maximum determined by the Minister of Health. On 24 January 2011 the Minister announced that no increase would be allowed between 2 January 2011 and 31 December 2011.[46] Two more elements of the medicine pricing system have also received attention. In December 2010 the Minister published a draft methodology for international benchmarking of medicine prices for comment, allowing three months for such submissions.[47] According to the proposed methodology, the price of originator medicines would be benchmarked against the prices of these medicines in Australia, Canada, New Zealand and Spain. These countries were specifically selected because of their effective medicines regulatory systems, effective regulation of medicine pricing and compliance with intellectual property rights protection.

A phased approach was proposed. In the first two years after application of the benchmarking system, the South African price would not be permitted to exceed the average of the three lowest prices in the basket of comparator countries. However, after two years the South African price would not be permitted to exceed the lowest price in the basket of comparator countries. A mechanism for exemption was also proposed, where the manufacturer would be required to show that the benchmark price calculated was "distorted and prejudicial". Detailed procedures were proposed on how to deal with medicines of different strengths and pack sizes, with alternatives (such as therapeutic class reference pricing at ATC 4 level) for where no direct comparators existed. As a "last resort", pharmaco-economic analyses were to be allowed as the basis for a price determination. Although the comment period has passed, no final version of this regulation has yet been issued.

The last remaining issue of contention in relation to medicine pricing has been the continued opacity of the logistics fee determination. Logistics fees are negotiated by wholesalers and distributors and paid by manufacturers, without inflating the factory-gate single exit price. However, such fees vary considerably and are not disclosed, despite there being a logistics fee component in the medicines price database provided by the NDoH. In March 2011 the Minister addressed this issue on the recommendation of the Pricing Committee by proposing draft Regulations to cap logistics fees.[48] A maximum logistics fee was proposed for bands of single exit prices (e.g. not to exceed 6% when the single exit price was less than R100, exclusive of VAT). However, a weighted average method was to be allowed where manufacturers had negotiated different logistics fees with different logistics service providers for the same medicine. A two-month period for comment was provided for, but no final version of this Regulation has yet been issued.

In late July 2011 two additional sets of draft Regulations were issued for comment by the Minister in terms of the Medicines Act. The first proposed a regulatory system for assessment of medical devices,[49] with a risk-based approach (classified as low risk, low moderate risk, moderate high risk and high risk) and categorisation system. For example, Category C1 devices would be "non-invasive medical devices which do not penetrate the body", whereas Category C7 would be "medical devices used for contraception or the prevention of the transmission of sexually transmitted diseases". A notification process for those devices already on the market was provided for, as was "abbreviated assessment" of devices "already registered by a regulatory authority outside of the Republic". In many respects these draft Regulations seemed to echo the design of the Act itself. For example, the mechanism for making a device subject to registration appeared to follow the same logic as section 14 of the Medicines Act:

> no person shall sell any medicine which is subject to registration by virtue of a resolution published in terms of subsection (2) unless it is registered
>
> and
>
> no person shall sell any medical device which is subject to registration by virtue of a resolution published in terms of sub-regulation (2) unless it is registered.

The draft Regulations also included provisions for post-marketing surveillance; licensing of manufacturers, exporters, importers and distributors; control over advertising and promotion; and labelling of devices and instructions for use.

On the same day the Minister also published draft changes to the General Regulations made in terms of the Medicines Act.[50] Some of the proposed changes were uncontroversial, although necessary (e.g. extending the quantity of medicines allowed to be carried into and out of the country by travellers from thirty days' to three months' supply; regulating the acquisition and use of medicines by emergency services, masters of ships and officers in charge of aircraft; and correcting typographical errors in the 2003 General Regulations relating to the registers for specified Schedule 5 and Schedule 6 medicines). However, the most pressing change was that which created a new definition for "complementary medicine", as

> a medicine that is used – (a) or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal; and (b) in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982).

The labelling of such medicines would need to include the "discipline of the medicine" and the statement "use according to the principles of the discipline". However, the guidelines to accompany this change, which would specify how "complementary medicines" would be assessed for safety, efficacy and quality, were not released at the same time.

Statutory Health Councils

Health Professions Council of South Africa

No major changes to the primary legislation governing professions registered with the Health Professions Council of South Africa (HPCSA) have occurred in the period under review. However, the newly appointed President of the HPCSA, Professor Sam Mokgokong, was quoted as having described "complaints of under-representation of doctors at Council level as 'worth probing'".[51] Although major changes were made to the composition and process for appointing the Nursing Council when the Nursing Act was amended in 2005, the expected changes to other statutory health councils' enabling legislation have not occurred.

The Minister of Health and the HPCSA have, however, issued a steady stream of secondary and tertiary legislation in the form of Regulations and Board Notices. These have included Rules relating to additional qualifications for oral hygienists,[52] and draft versions have been published for comment in relation to speech therapists, audiologists, biokineticists, medical and dental practitioners, and medical technologists. Proposed amendments to medical subspecialty categories have also been released for comment.[53] Other draft Regulations issued for comment but not yet finalised concern the scope of the professions of oral hygiene, dental assistants, dental therapy and optometry.[54-57] Draft Regulations have also been issued dealing with registration of intern psychologists and various categories of medical technicians.[58-61] Changes were also made to the ethical rules applied by the HPCSA and to Regulations regarding indemnity insurance for independent practitioners.[62,63]

South Africa's Constitution includes a commitment to the progressive realisation of fundamental rights such as the right to access health care, autonomy, equity and dignity.[64] The right to health care and autonomy implies that a citizen can choose where and from whom he or she will obtain health care services. Equality in health care implies that the level of health care and services offered should not be dependent on geographical location or socio-economic status. Telemedicine has been perceived as one way to advance the attainment of such goals.

It has been argued that failure to use telemedicine to provide access to specialist services is unethical. However, telemedicine can also be perceived as a threat. Legislators and regulators who strive to protect people and maintain suitable levels of clinical and ethical practice have tended to view telemedicine as something new, and therefore requiring close and more stringent regulation. While well-intentioned, this can be viewed as paternalistic and also contradictory to the rights of autonomy and access to health care as enshrined in the Constitution. In order to flourish, telemedicine requires an enabling legislative and regulatory environment.[65]

The NDoH has stated its desire for telemedicine to be used to improve access to and the quality of health care. However, events in mid-2011 showed clearly how advances in technology and associated changes in clinical practice can result in conflict. Section 23(5) of the Health Professions Act (Act 56 of 1974) requires a practitioner to have "ascertained the diagnosis of the patient concerned through a personal examination of the patient or by virtue of a report by another practitioner under whose treatment the patient is or has been...".[66] This precludes the use of store-and-forward telemedicine and, in many instances, synchronous telemedicine between nurses as referrers and doctors. Recent reports of allegedly unethical telemedicine practices by doctors providing services by telephone and text messages have highlighted several issues which until now have remained dormant.[67]

Clarity is required, and a review of existing legislation and possible amendments to facilitate telemedicine are urgently needed.

South African Pharmacy Council

Commensurately fewer notices have emanated from the South African Pharmacy Council (SAPC). Of relevance to the pricing of medicines, the SAPC gazetted Rules relating to the services for which a pharmacist may levy a fee, as well as guidelines for levying such fees, in December 2010.[68] These Rules were intended to supplement the fees charged for dispensing and to cover costs associated with compounding non-sterile and sterile preparations, preparing cytotoxic preparations or parenteral nutrition products, or performance of various clinical tasks (such as blood glucose monitoring, peak flow measurements, or provision of pharmacist-initiated therapy). It is, however, unclear how many pharmacists are charging the fees described, or how many medical schemes have agreed to reimburse claims for such services.

Also in December 2010, the SAPC gazetted amendments to the Rules relating to Good Pharmacy Practice, dealing with the destruction and disposal of medicines.[69] However, these were subsequently withdrawn and revised after representations from the profession.[70,71] Other amendments to the Good Pharmacy Practice Rules were issued in May 2011,[72] dealing, *inter alia*, with the issue of a pharmacy located within another business, as well as another business or practice located within a pharmacy. The former is increasingly common in corporate-owned pharmacies located within supermarkets, for instance.

Also in May 2011 the Minister of Health issued draft Regulations relating to continuing professional development for persons registered with the SAPC.[73] Unlike the HPCSA's points-based system, the SAPC has opted for a portfolio-based approach to continuing professional development. Once final Regulations are in place this system will become mandatory for all registered pharmacists and pharmacist's assistants.

In July 2011 the SAPC published two notices indicating that they would be requesting the Minister to amend Regulations in order to enable a new category of authorised pharmacist prescribers, as well as new categories of pharmacy support personnel (to be termed pharmacist's assistants, pharmacy technical assistants and pharmacy technicians).[74,75] Comments were invited for submission to the SAPC prior to submission to the Minister. The first of these will, no doubt, prove controversial. There has been a *de facto* moratorium on the issue of section 22A(15) permits to pharmacists by the Director-General of Health for some years, despite existence of SAPC-accredited Primary Care Drug Therapy qualifications for this purpose. In its notice the SAPC points to similar provisions being introduced in the United Kingdom and Canada.

This development again underlines the need for urgent review of the National Drug Policy which, while it proposed a clear separation of prescribing and dispensing functions, also indicated that at primary care level prescribing would be competence- and not occupation-based. The expanded set of pharmacy support personnel categories

may be less controversial, as it does not appear to significantly increase possibilities for support personnel to work outside direct supervision by a pharmacist.

South African Nursing Council

The South African Nursing Council (SANC) presents an altogether more pressing challenge. An entirely new Nursing Act (Act 33 of 2005) has been brought into effect by three promulgation notices (Government Notice R.4, *Government Gazette* No. 29634, 16 February 2007; Government Notice R.18, *Government Gazette* No. 30159, 8 August 2007; and Government Notice R.6, *Government Gazette* No. 3086, 13 March 2008).[76] Consequently the 1978 Nursing Act has been repealed in its entirety. However, the new Act has yet to be supplemented with many of the Regulations necessary to allow its effective operation.

An example of how this has hampered progress is provided by the continuing confusion over prescribing and dispensing by nurses. Although of far wider application, this has been particularly acute in terms of nurse-initiated and managed antiretroviral therapy. The General Regulations issued in terms of the Medicines and Related Substances Act (Act 101 of 1965) define 'authorised prescriber' as "any person authorised by the Act to prescribe any medicines".[77] The Act itself (in section 22A(5)) limits the prescribing of any Schedule 2 - 6 substance to a medical practitioner, dentist, veterinarian and to "a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist". However, this last category may "prescribe only the Scheduled substances identified in the Schedule for that purpose" and may "compound and dispense … only if he or she is the holder of a licence contemplated in section 22C(1)(a)".[78] Further, s22A(14) of the Act states that "no nurse … may prescribe a medicine or Scheduled substance unless he or she has been authorised to do so by his or her professional Council concerned". This construct is echoed in section 56 of the Nursing Act, which enables the SANC to register a professional nurse, midwife or staff nurse to "assess, diagnose, prescribe treatment, keep and supply medication for prescribed illnesses and health related conditions", but only on "proof of completion of prescribed qualification and training".[76] The Act also specifies that such a nurse may only "acquire, use, possess or supply medicine" and "dispense medicines" subject to the provisions of the Medicines and Related Substances Act.

In addition, section 56(6) of the Nursing Act enables the national Director-General, the head of a provincial DoH, the medical officer of health of a municipality or the medical practitioner in charge of an organisation authorised for this purpose to issue a permit to a nurse employed in such settings to engage in "the physical examination of any person", "the diagnosing of any physical defect, illness or deficiency in any person" and "the keeping of prescribed medicines and their supply, administering or prescribing on the prescribed conditions". However, such acts are to be performed only "if the services of a medical practitioner or pharmacist, as the circumstances may require, are not available".

Without the necessary regulations to allow for the operation of section 56(1) to (5), the only mechanism available to enable nurses to prescribe is section 56(6). Section 61 of the Nursing Act provided for transitional arrangements. Accordingly, any nurse issued with a section 38A permit in terms of the 1978 Nursing Act can continue to practise as enabled by that permit. In addition, the Regulation that covered such permits is still being used in relation to section 56(6) permits.[79] However, the SAPC has made it clear that "nurses who are registered in terms of Section 38A (old Nursing Act)/Section 56 (new Nursing Act) are permitted to dispense medicines they have prescribed, i.e. nurse initiated treatment in terms of prescribed regulations", but that "pharmacists cannot dispense nurse initiated treatments unless such prescription has been authorized by a medical practitioner".[80] The consequences have been described thus: "Failing to develop the necessary qualification and Regulations and further delaying the process of amending the Schedules to the Medicines Act will continue to leave nurses exposed and deprive patients of access to a full pharmaceutical service, even where such a service is available".[81]

In August 2011 the Minister published draft Regulations in terms of the Nursing Act dealing with the conduct of inquiries into alleged unfitness to practice due to disability or impairment.[82]

Bringing the Children's Act into effect – final steps

Although some provisions of the Children's Act (Act 38 of 2005), namely those dealing with capacity to consent and access to contraceptives, have been in effect since 1 July 2007, the remaining sections came into full force on 1 April 2010.[83] Although these provisions have not yet been tested in a court of law, it is unclear how many parents and health care workers are aware of and actually enforce and encourage the rights of children enshrined in this legislation.

The main objective of the Children's Act is to give effect to children's constitutional rights.[64] The Children's Act has repealed a wide range of previous laws affecting children. For example, in terms of section 17, a child now attains the age of majority at 18 years of age instead of 21 years; a person of 18 years of age is therefore considered liable and responsible for his or her actions and omissions under the law.

Section 9 of the Act requires that "In all matters concerning the care, protection and well-being of a child the standard that the child's best interest is of paramount importance, must be applied." However, as with any law or ethical issue, it is the interpretation of the facts that is important and these are largely influenced by individual perceptions, values and belief systems. Nonetheless, section 7 of the Act contains a comprehensive list of factors that need to be considered when a health care worker decides what will be in the best interests of the child. This is dependent upon the child's capacity to make a fully autonomous decision and capacity for understanding. Assessing a child's ability to make a decision is extremely difficult and there are no standards to judge such competency.

The Act allows for children to be actively involved in healthcare decision-making and recognises that they, according to their age, development and experience, have the capacity to do so. This is in line with the Convention on the Rights of the Child, ratified by SA in 1995.[84] Accordingly, every child has the right of access to not only his or her medical records and health information but also to health information on health promotion and prevention, sexuality, reproduction and disease. Information provided to children must be in a form that will be accessible to them and special consideration

must be given to special-needs children. The Children's Act is very clear that the rights of confidentiality that adults enjoy are equally applicable to children. Any information pertaining to the health status of the child must remain confidential, unless the child has given consent for that information to be disclosed, or the health care worker has determined that maintaining confidentiality would not be in the best interests of the child.

Section 12 of the Act deals with social, cultural and religious practices. Genital mutilation or circumcision of females is strictly prohibited, as is virginity testing of female children who are under the age of 16. Virginity testing may only be done under strict conditions. Guidance on these and the more routine aspects of the Act has been provided by the Children's Institute at the University of Cape Town.[85] The Regulations published in April 2010 provided *pro forma* consent forms, including for virginity testing, social or cultural circumcision, and religious circumcision.[86] The Regulations also state the manner in which virginity testing may be performed and that the results of the test may not be disclosed without the consent of the child, and that the body of the child who has undergone virginity testing may not be marked in any way.

Section 12 (8) prohibits the circumcision of male children except when "performed for religious purposes in accordance with the practices of the religion concerned" or "for medical reasons on the recommendation of a medical practitioner". In the case of male children older than 16, circumcision may only be performed "if the child has given consent to the circumcision", and "after proper counselling of the child". These sections pose interesting challenges in terms of male medical circumcision to reduce HIV acquisition. Although current programmes are targeting adults, it could be asked whether parents should be encouraged to circumcise their male children as neonates. While this may be seen as a viable public health intervention to reduce the risk of HIV transmission, and is medically safer in the neonate, it does appear to infringe on rights to bodily integrity protected by this Act.[87]

The parts of the Act which pose the most immediate challenges to healthcare workers are those dealing with informed consent. The Act has, in prescribed circumstances, allowed parents, caregivers and guardians to give consent on behalf of children. Of particular relevance, caregivers with no formal parental responsibilities or rights may consent to medical and surgical care of children who are under the age of 12 years (or those over the age of 12 who do not have the capacity to consent). A caregiver may therefore be anyone who in fact cares for a child, including grandmothers, aunts, foster parents and/or a person who cares for a child with the implied or express consent of the parent or child. This should greatly assist children who are not being cared for by their own parents but need to access health services. If a child is under the age of 12 years, but capable of understanding the treatment that she or he will undergo, the healthcare worker must obtain assent from the child and consent from the parent, guardian or caregiver.

The capacity to consent to health care services also implies the capacity to refuse such services. This poses significant challenges for a health care worker trying to decide how much weight to attach to a child's refusal. A higher standard is set for consent to surgery: whereas section 129(2) states that "a child may consent to his or her own medical treatment or to the medical treatment of his or her child if the child is over the age of 12 and is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the treatment", section 129(3) states that a child may consent to the performance of a surgical operation if "(a) the child is over the age of 12 and (b) the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation and (c) the child is duly assisted by his or her parent or guardian". Nonetheless, sections 129 (6) and (7) provide that the superintendent of a hospital (or the person in charge of the hospital, in the absence of the superintendent) may consent to the medical treatment of, or surgical operation on, a child if that treatment is necessary to save the child, to preserve life, save from lasting disability, or if treatment cannot be deferred until proper consent from those legally authorised can be obtained. In addition, the Minister of Social Development may consent to medical treatment of, or surgical operation on, a child if the parent or guardian refuses or is incapable of giving consent. This section also authorises the Minister to consent if the child unreasonably refuses to give consent. As was the case with previous legislation, the Children's Act does not define the terms "medical treatment" or "surgery", giving recourse to their ordinary meaning.

Section 130 of the Act provides that no child may be tested for HIV except when it is in the best interests of the child and the child has given consent for testing or consent has been given by the child's parent or caregiver. In the event of an occupational exposure injury where a healthcare worker or any other person may have come into contact with any substance from the child's body that may transmit HIV, the test may be performed provided authorisation from the court is obtained. Children must also be provided with pre- and post-test counselling by appropriately trained persons. However, in terms of section 133 the results of an HIV test may not be disclosed without the consent of the child if the test was done with the child's consent only. A child under the age of 12, who may be able to consent to HIV testing, is however unable to consent to HIV treatment – and this may pose a serious problem if the child then refuses disclosure of his or her results. A child's rights whether or not to disclose are enshrined in the Constitutional rights to privacy and bodily integrity. However, such rights may be subject to limitation, taking into account a host of factors including what is determined to be in their best interests.

In terms of section 134 no person may refuse to sell or provide condoms upon request to a child who is over the age of 12. Other forms of contraception may be provided to the child on request with or without the consent of the parent or caregiver if the child is over the age of 12 and has had a proper medical examination and advice. A child who obtains contraception is entitled to confidentiality, unless sexual abuse or neglect is suspected, in which case the health care worker has an obligation to report this, as set out in section 110(1) of the Act.

In summary, even though the Children's Act is a progressive piece of legislation which has the potential to significantly improve children's access to health care, implementing the Act will be an enormous challenge for health care workers. In addition, other legislation will need to be amended to ensure alignment with the Children's Act. For example, in terms of the Medicines and Related Substances Control Act (Act 101 of 1965), medicines may not be supplied to persons under the age of 14 years except upon prescription. The NHA requires parental or legal guardian's consent for research on children. In the case of non-therapeutic research on children under the age of 18 years, Ministerial consent is also required.

Implications of the Consumer Protection Act for health care

The intent of the Consumer Protection Act (Act 68 of 2008) is to "promote a fair, accessible and sustainable marketplace for consumer products and services … and establish national norms and standards".[88] Accordingly, a consumer is defined as "in respect of any particular goods or services … a person to whom those particular goods or services are marketed in the ordinary course of the supplier's business." Goods include "anything marketed for human consumption". Hence medicines and medical devices fall within the ambit of this legislation, unless specifically excluded.

The prospect has been raised that section 41, which deals with "false, misleading or deceptive representations", may be applied to categories of medicines which have not been adequately assessed for safety, quality and efficacy by the Medicines Control Council. Specifically, section 41 proscribes the types of conduct which "falsely state or imply, or fail to correct an apparent misapprehension on the part of a consumer to the effect, that … any goods or services … have ingredients, performance characteristics, accessories, uses, benefits, qualities, sponsorship or approval that they do not have." In the medicines context, this provision places an obligation on the seller (or dispenser), either explicitly or implicitly, not to ascribe properties to a product that it does not have.

Section 110(1) of the Act further makes it an offence to "alter, obscure, falsify, remove or omit a displayed price, labelling or trade description without authority". In terms of section 111(b), such a contravention attracts the penalty of a fine or a term of imprisonment not exceeding 10 years or both. Furthermore, section 115(2)(b) enables any "person who has suffered loss or damage as a result of prohibited conduct, or dereliction of required conduct" to institute a civil action after having exhausted the procedures under the National Consumer Tribunal established under section 26 of the National Credit Act (Act 34 of 2005).[89]

The Act provides strong protections for consumers, and this is also evident in the introduction of a strict standard of liability. Another key provision with potential impact on health care delivery relates to the issue of legal liability for damage caused by goods (section 61). Subject to some exceptions, the "producer or importer, distributor or retailer of any goods is liable for any harm … caused wholly or partially as a consequence of (a) supplying unsafe goods; (b) a product failure, defect or hazard in any goods; or (c) inadequate instructions or warnings … associated with the use of any goods, irrespective of whether the harm resulted from any negligence on the part of the producer, importer, distributor or retailer, as the case may be". The effect of this provision is that health care providers such as doctors and pharmacists could open themselves up to liability if a patient has suffered adverse effects from any medicine prescribed or dispensed by them. The patient will not be required to prove that the provider was negligent, only that the product was defective and caused damages. There is, however, a defence available to these providers if they can establish that they could not reasonably have known about the "unsafe product characteristic, failure, defect or hazard". In such instances liability will fall upon the manufacturer or importer alone.

Other provisions of the Consumer Protection Act relevant to health care include: the consumer's right to choose or examine goods (section 18), the right to information in plain and understandable language, disclosure of the price of goods and services, and of product labelling and trade descriptions, as well as the rights to demand a quality service, and to safe, good-quality goods.

The Minister of Trade and Industry recently promulgated Regulations in terms of the Act which contain provisions regarding product labelling and trade descriptions.[90] These cover textiles, clothing, shoes and leather goods (Regulation 6) and genetically modified organisms (Regulation 7), but there is no specific reference to medicines, medical products and devices. However, deliberations of the committee charged with deciding which goods fall under the ambit of these Regulations suggest that their application includes vaccines for measles and tuberculosis (and possibly other conditions).[91]

Intellectual property – protecting traditional knowledge

Although there has been considerable attention in the past to the potential role of intellectual property protection measures in hindering access to various health care-related commodities, such as generic medicines, recent attention in SA has been mostly on the issue of protecting traditional knowledge. The Memorandum on the Objects of the Bill of the Intellectual Property Laws Amendment Bill (Bill 8 of 2010) states that, *inter alia*, it seeks to protect "the different species of traditional intellectual property and geographical indications … establish a national council to advise … on traditional intellectual property … (and) a national trust fund to facilitate the commercialisation of traditional intellectual property and the application of income generated to the benefit of indigenous communities".[92] The Bill is primarily concerned with making substantive amendments to various intellectual property laws. These laws have no direct bearing on health care. However, the Patents Act (Act 57 of 1978), which relates more directly to protection of medicinal inventions, underwent the necessary amendments in respect of traditional knowledge in 2005.[93] In terms of those amendments, protection is afforded to indigenous knowledge and use within the context of the protection of indigenous genetic and biological resources covered by the National Environmental Management: Biodiversity Act (Act 10 of 2004).[94]

The effect of the current Bill is to incorporate application of above-stated objectives, institutions and functions in the Patents Act. Thus the council to be established must *inter alia* also advise the registrar of patents "on any matter regarding the registration of intellectual property relating to indigenous knowledge"; the patents office is to maintain a database of traditional intellectual property relating to traditional innovations; and the registrar of patents shall also be responsible for the promotion, preservation, and commercialisation and exploitation of such traditional intellectual property for the purpose of generating income, which is to be paid into a fund "to be used for the benefit of indigenous communities in the prescribed manner".

The aim of this legislation is to prevent exploitation of traditional knowledge, benefit indigenous communities and, in the case of traditional medicines, prevent biopiracy.

An important aside – the Protection of Information Bill

Much of the legislative process for the period under review has been dominated by the controversy surrounding the Protection of Information Bill (Bill 6 of 2010).[95] While certain disputed aspects of the Bill have recently been removed, other contested provisions remain in the version under consideration by Parliament. In particular, it is feared that the classification of information regarding, for example, the state of health services in public facilities, would render disclosure punishable, and visit hefty penalties (including imprisonment) on any person making such disclosure. As the draft stands, a person so charged will not be able to raise the 'public interest' defence.[96] At time of writing, this Bill had been passed by the National Assembly and was being considered by the National Council of Provinces.

Conclusion

Although the previous year has seen no health-related Bills tabled in Parliament, it has been marked by a flurry of secondary legislation. In particular, there have been many draft Regulations issued in terms of the National Health Act (Act 61 of 2003) and some have been issued in final form. There has been some progress in relation to medicines legislation, with respect to medicines pricing and the regulation of medical devices and complementary medicines. However, there is also the possibility of considerable contestation with regard to these regulatory interventions. The slow pace of implementation of the Nursing Act (Act 33 of 2005) is still the cause of many problems. However, the health policy and legislative landscape was fundamentally altered in August 2011, with the publication of the Green Paper on National Health Insurance. A Bill to amend the NHA, specifically to create the OHSC, has also been tabled. In addition, regulations dealing with hospital designation and management are expected to receive priority attention, as part of the re-engineering of the entire health system.

References

1 National Department of Health. Annual Report 2009/2010. Pretoria: National Department of Health; 2010.

2 Minister of Health. White Paper on the Transformation of the Health System in South Africa. Pretoria: National Department of Health; 1997.

3 Minister of Health. National Drug Policy for South Africa. National Department of Health, Pretoria.

4 National Department of Health. Government's Programme of Action 2009. Human Development Cluster: Health. Pretoria: National Department of Health; 2009.

5 Naledi T, Barron P, Schneider H. Primary Health Care in SA since 1994 and implications of the new vision for PHC re-engineering. In Padarath A, English R, editors. South African Health Review 2011. Durban: Health Systems Trust; 2011.

6 National Department of Health. Annual Performance Plan 2011/2012. Pretoria: National Department of Health; 2011.

7 Minister of Health. National Health Insurance in South Africa Policy Paper. Government Notice 657. Government Gazette No. 34523, 12 August 2011.

8 Republic of South Africa. National Health Act (Act 61 of 2003).

9 Minister of Health. Regulations relating to the artificial fertilization of persons: draft. Government Notice R. 262. Government Gazette No. 34159, 1 April 2011.

10 Minister of Health. Regulations relating to the use of human biological material: draft. Government Notice R. 263. Government Gazette No. 34159, 1 April 2011.

11 Minister of Health. Regulations relating to the registration of microbiological laboratories and the acquisition, importation, handling, maintenance and supply of human pathogens: draft. Government Notice R. 264. Government Gazette No. 34159, 1 April 2011.

12 Minister of Health. Regulations relating to stem cell institutions or organisations: draft. Government Notice R. 265. Government Gazette No. 34159, 1 April 2011.

13 Minister of Health. Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, zygotes and gametes: draft. Government Notice R. 266. Government Gazette No. 34159, 1 April 2011.

14 Minister of Health. Regulations relating to tissue banks: draft. Government Notice R. 267. Government Gazette No. 34159, 1 April 2011.

15 Minister of Health. Regulations regarding the general conduct of human bodies, tissue, blood, blood products and gametes: draft. Government Notice R. 268. Government Gazette No. 34159, 1 April 2011.

16 Minister of Health. Regulations relating to blood and blood products: draft. Government Notice R. 269. Government Gazette No. 34159, 1 April 2011.

17 Minister of Health. Regulations relating to the rendering of clinical forensic medicine services: draft. Government Notice R. 270. Government Gazette No. 34159, 1 April 2011.

18 President of the Republic of South Africa. Commencement of certain sections of the National Health Act, 2003 (Act 61 of 2003). Government Notice R20. Government Gazette No. 33187, 14 May 2010.

19 Minister of Health. Regulations relating to the withdrawal of blood from a living person for testing. Government Notice R. 401. Government Gazette No. 33188, 14 May 2010.

20 Minister of Health. Ministerial determination on revenue retention by central hospitals: draft. Government Notice R. 270. Government Gazette No. 34159, 1 April 2011.

21 Minister of Health. Regulations relating to the establishment o the National Health Research Committee. Government Notice R. 840. Government Gazette No. 33575, 23 September 2010.

22 Rispel L, Moorman J. Health legislation and policy: context, process and progress. In Fonn S, Padarath A (eds). South African Health Review 2010. Health Systems Trust, Durban, 2010.

23 Republic of South Africa. National Health Amendment Bill (Bill 65 of 2008).

24 Minister of Health. National Health Amendment Bill, 2011. General Notice 44 of 2011. Government Gazette No. 33962, 24 January 2011.

25 National Department of Health. Way paved for the establishment of Office of Health Standards Compliance. Pretoria: National Department of Health; 24 January 2011.

26 Glenister v President of the Republic of South Africa and Others (CCT 48/10) [2011] ZACC 6; 2011 (3) SA 347 (CC) (17 March 2011).
URL: http://www.saflii.org/za/cases/ZACC/2011/6.html .

27 SECTION27. Submission on the Draft National Health Amendment Bill, 2011. 22 April 2011.
URL: http://www.section27.org.za/2011/05/04/submission-on-the-draft-national-health-amendment-bill-2011/

28 Republic of South Africa. National Health Amendment Bill (Bill 24 of 2011).

29 Minister of Health. Regulations relating to cancer registration. Government Notice R. 380. Government Gazette No. 34248, 26 April 2011.

30 Minister of Health. Regulations relating to categories of hospitals. Government Notice R. 655. Government Gazette No. 34521, 12 August 2011

31 Minister of Health. Policy on the management of public hospitals. Government Notice 656. Government Gazette No. 34521, 12 August 2011.

32 ANC National General Council. Additional Discussion Documents: National Health Insurance. Durban: African National Congress; 21 September 2010.

33 Fonn S, Padarath A, editors. Chapters 15-20. South African Health Review 2010. Durban: Health Systems Trust; 2010.

34 Statement issued by Zweli Mkhize, Chairperson of the African National Congress NEC Education and Health Sub-Committee, 11 August 2011.
URL: http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page72308?oid=250381&sn=Marketingweb+detail&pid=90389

35 Waters W. Statement issued by DA Shadow Minister of Health, 11 August 2011.
URL: http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page72308?oid=250375&sn=Marketingweb+detail&pid=90389

36 Minister of Health. National Health Act: National Health Insurance in South Africa Policy Paper: Draft - Extension of deadline for comments. Government Notice No. 743. Government Gazette No. 34606, 15 September 2011.

37 National Department of Health. Invitation for public comments on the National Environmental Health Policy. Government Notice 517. Government Gazette No. 34499, 3 August 2011.

38 Republic of South Africa. Medicines and Related Substances Amendment Act (Act 72 of 2008).

39 Gray A, Pillay K. Health legislation and Policy. In Ijumba P, Padarath A, editors. South African Health Review 2006. Durban: Health Systems Trust; 2006.

40 Gray A, Govender M, Gengiah T, Singh J. Health Legislation. In Ijumba P, Barron P, editors. South African Health Review 2005. Durban: Health Systems Trust; 2005.

41 Pearmain D. Health policy and legislation. In Harrison S, Bhana R, Ntuli A, editors. South African Health Review 2007. Durban: Health Systems Trust; 2007.

42 Minister of Health. Regulations relating to a transparent pricing system for medicines and scheduled substances: amendment (dispensing fee for pharmacists): draft. Government Notice R.647. Government Gazette No. 33407, 23 July 2010.

43 Minister of Health. Regulations relating to a transparent pricing system for medicines and scheduled substances: amendment (dispensing fee for pharmacists). Government Notice R.1090. Government Gazette No. 33775, 19 November 2010.

44 Minister of Health. Regulations relating to a transparent pricing system for medicines and scheduled substances: amendment (dispensing to be charged by persons licensed in terms of Section 22C(1)(a)). Government Notice R.1256. Government Gazette No. 33906, 24 December 2010.

45 Minister of Health. Medicines and Related Substances Act: Regulations: Transparent pricing system for medicines and scheduled substances: Information to be supplied by pharmacist for review of annual dispensing fee. Government Notice R. 584. Government Gazette No. 34468, 18 July 2011.

46 Minister of Health. Regulations relating to a transparent pricing system for medicines and scheduled substances: amendment (single exit price adjustment for the year 2011). Government Notice R.30. Government Gazette No. 33961, 24 January 2011.

47 Minister of Health. Regulations relating to a transparent pricing system for medicines and scheduled substances: methodology for international benchmarking of prices of medicines and scheduled substances in South Africa: draft. Government Notice R. 1211. Government Gazette No. 33878, 17 December 2010.

48 Minister of Health. Regulations relating to a transparent pricing system for medicines and scheduled substances: logistics fee component of a transparent pricing system: draft. Government Notice R. 184. Government Gazette No. 34071, 4 March 2011

49 Minister of Health. Regulations relating to medical devices: draft. Government Notice R.586. Government Gazette No. 34463, 22 July 2011.

50 Minister of Health. General Regulations made in terms of the Medicines and related Substances Act, 1965 (Act No. 101 of 1965): Amendment. Government Notice R.587. Government Gazette No. 34463, 22 July 2011.

51 Bateman C. Doctors' political powers unfairly diluted – new HPCSA President. South African Medical Journal. 2011; 101(4): 220-222.

52 Health Professions Council of South Africa. Rules relating to the registration by oral hygienists of additional qualifications. Board Notice 63 of 2011. Government Gazette No. 34158, 1 April 2011.

53 Minister of Health. Regulations relating to the specialities and sub-specialities in medicine and dentistry: amendment: draft. Government Notice R.341. Government Gazette No. 34205, 15 April 2011.

54 Minister of Health. Regulations defining the scope of the profession of oral hygiene: amendment: draft. Government Notice R. 212. Government Gazette No. 34103, 11 March 2011.

55 Minister of Health. Regulations defining the scope of the profession of dental assistants: amendment: draft. Government Notice R. 214. Government Gazette No. 34103, 11 March 2011.

56 Minister of Health. Regulations defining the scope of the profession of dental therapy: amendment: draft. Government Notice R. 802. Government Gazette No. 33544, 15 September 2010.

57 Minister of Health. Regulations defining the scope of the profession of optometry: amendment: draft. Government Notice R. 804. Government Gazette No. 33544, 15 September 2010.

58 Minister of Health. Regulations relating to the registration of medical technicians in the category immunology: draft. Government Notice R. 211. Government Gazette No. 34100, 11 March 2011.

59 Minister of Health. Regulations relating to the registration of medical technicians in the category tuberculosis (bacterium): draft. Government Notice R. 213. Government Gazette No. 34102, 11 March 2011.

60 Minister of Health. Regulations relating to the registration of internal psychologists: draft. Government Notice R. 631. Government Gazette No. 33385, 23 July 2010.

61 Minister of Health. Regulations relating to the registration of medical technicians in the category virology: draft. Government Notice R. 215. Government Gazette No. 34104, 11 March 2011.

62 Health Professions Council of South Africa. Amendment of ethical rules of conduct for practitioners registered under the Health Professions Act, 1974. Government Notice R. 654. Government Gazette No. 33400, 30 July 2010.

63 Minister of Health. Regulations relating to indemnity cover for registered health practitioners. Government Notice R. 7455. Government Gazette No. 33498, 30 August 2010.

64 Republic of South Africa. The Constitution of the Republic of South Africa Act (Act 108 of 1996).

65 Mars M, Jack C. The Act, the Regulator, the Constitution and Telemedicine. Presented at the 2nd South African Telemedicine Conference, 14-16 September 2011.

66 Republic of South Africa. Health Professions Act (Act 56 of 1974) Ethical Rules of Conduct for Practitioners Registered under the Health Professions Act, 1974.

67 Health Professions Council of South Africa. HPCSA condemns unethical telemedicine practice[press release]. Health Professions Council; 5 May 2011.

68 South African Pharmacy Council. Rules relating to the services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees. Board Notice 193 of 2010. Government Gazette No. 33898, 20 December 2010.

69 South African Pharmacy Council. Rules relating to Good Pharmacy Practice. Board Notice 194 of 2010. Government Gazette No. 33898, 20 December 2010.

70 South African Pharmacy Council. Rules relating to Good Pharmacy Practice: Withdrawal of Board Notice. Board Notice 104 of 2011. Government Gazette No. 34330, 27 May 2011.

71 South African Pharmacy Council. Rules relating to Good Pharmacy Practice. Board Notice 105 of 2011. Government Gazette No. 34330, 27 May 2011.

72 South African Pharmacy Council. Rules relating to Good Pharmacy Practice. Board Notice 106 of 2011. Government Gazette No. 34330, 27 May 2011.

73 Minister of Health. Regulations relating to continuing professional development: draft. Government Notice R. 395. Government Gazette No. 34254, 6 May 2011.

74 South African Pharmacy Council. Scope of practice and qualification for authorised pharmacist prescriber. Board Notice 122 of 2011. Government Gazette No. 34428, 1 July 2011.

75 South African Pharmacy Council. Scope of practice, supervision of pharmacy support personnel and qualifications. Board Notice 123 of 2011. Government Gazette No. 34428, 1 July 2011.

76 Republic of South Africa. Nursing Act (Act 33 of 2005).

77 Minister of Health. General Regulations made in terms of the Medicines and Related Substances Act (Act 101 of 1965), as amended. Government Notice R.510. Government Gazette No. 24727, 10 April 2003.

78 Republic of South Africa. Medicines and Related Substances Act (Act 101 of 1965), as amended.

79 Minister of Health. Regulations relating to the keeping, supply, administering or prescribing of medicines by registered nurses. Government Notice No. R. 2418, 2 November 1984.

80 Correspondence from Ms D Hoffman (Senior Manager: Legal Services and Professional Conduct, SA Pharmacy Council) to Mr A Louw (Assistant Manager: Pharmaceutical Services, Eastern Cape Department of Health), 12 May 2010 (D Hoffmann/nv/ag).

81 Gray A. Prescribing and dispensing by nurses – neglected steps in the legislative process. HIV Nursing 2010; 1(2): 28-31.

82 Minister of Health. Nursing Act: Regulations: Conducting inquiries into alleged unfitness to practice due to disability or impairment of persons registered: Draft. Government Notice R. 619. Government Gazette No. 34494, 5 August 2011.

83 Republic of South Africa. Children's Act (Act 38 of 2005).

84 United Nations Children's Fund. The Convention on the Rights of the Child (1998). Geneva: United Nations Children's Fund; 1998.

85 Children's Institute. A guide to the Children's Act for health professionals (4th Edition). Children's Institute; 1 June 2010.

86 Minister of Social Development. Children's Act: Regulations. Government Notice R. 261. Government Gazette 33076, 1 April 2010.

87 Vawda YA, Maqutu LN. Neonatal circumcision- violation of children's rights or public health necessity? South African Journal of Bioethics and Law 2011; 14(1): 36-42.

88 Republic of South Africa. Consumer Protection Act (Act 68 of 2008).

89 Republic of South Africa. National Credit Act (Act 34 of 2005).

90 Minister of Trade and Industry. Consumer Protection Act: Regulations. Government Notice R. 293. Government Gazette No. 34180, 1 April 2011.

91 Executive Council for Genetically Modified Organisms (Act 15 of 1997). Minutes of meeting held on 23 September 2008.
URL: http://www.nda.agric.za/doaDev/sideMenu/biosafety/doc/ECMinutes_230908.pdf

92 Minister of Trade and Industry. Intellectual Property Laws Amendment Bill (Bill 8 of 2010).

93 Republic of South Africa. Patents Amendment Act (Act 20 of 2005).

94 Republic of South Africa. National Environmental Management: Biodiversity Act (Act 10 of 2004).

95 Minister of State Security. Protection of Information Bill [B6-2010]. Government Gazette No. 32999, 5 March 2010.

96 Kahn T. Health exposé 'would be a crime' under Information Bill. Business Day, 9 September 2010.
URL: http://allafrica.com/stories/201009090334.html