Health Legislation

1

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Health legislation continued to be a highly contested terrain in 2001. While some progress was noted in advancing the policy goals of the Department in two areas – Medical Schemes legislation and the operation of the new National Health Laboratory Services, other areas were less successful. Strains in government thinking around the issue of drugs for HIV/AIDS continued to be evident, with legislative structures sending out mixed signals, and the government becoming embroiled in a court action with the Treatment Action Campaign over the provision of Prevention of Mother-to-Child-Transmission (PMTCT) Programme using nevirapine. Continued conflict around the provisions of the Medical Schemes Act and its articulation with financial legislation can also be expected. Although the year was notable for the withdrawal of the court action blocking implementation of the Medicines Amendment Act, progress with implementation has remained slow and no parts of the 1997 Amendment Act are yet in operation. Perhaps the most outstanding legislative event was the publication of the Draft National Health Bill. However, implementation of a national system based on Primary Health Care principles and delivered by means of the District Health Systems approach still faces considerable challenges. In particular, continued transformation of the local government sphere will have considerable potential impacts on the provision of district-based health care services.

Introduction

Health legislation is acknowledged the world over as being both complex and fraught with stakeholder interests.

The World Health Organisation, states, 'the careful and responsible management of the well being of the population is the very essence of good government' - for this reason, government must play a key stewardship role in ensuring that the public continue to enjoy equitable access to good quality health care. For South Africa this means establishing the best and fairest health system possible with available resources. This is the goal that has informed the health legislation that has been adopted in South Africa since 1994. It is this objective of achieving the fairest and most humane system that underpinned the health legislation dealt with in 2001 – the Medical Schemes and Mental Health Care legislation.

Before considering the specific health-related legislation dealt with in 2001, some background on the structures involved is provided.

National Assembly Portfolio Committee on Health

The National Assembly Portfolio Committee on Health is a formal organ of, and accountable to, the South African Parliament. It is comprised of Members of Parliament from all political parties represented in Parliament. The Committee is responsible for scrutinising all health legislation emanating from the Department of Health (DoH) but also plays a broader 'watch dog' role in terms of the analysis of health affairs. An essential function of the Committee is to serve as an access point to the political process for public and professional concerns about health. In doing so it is attempting to change the culture of limited interaction between parliamentary institutions and the public and thereby encouraging vibrant debate and high quality policy processes.

Since 1994, the Committee has processed 19 pieces of ground-breaking legislation. During 2001, two of the three Bills dealt with by the Committee generated enormous public and media interest. The Medical Schemes Amendment Bill and the Mental Health Care Bill were tabled in Parliament in September 2001. Full day public hearings were held in October 2001 and many written and oral submissions were received. On the basis of submissions by stakeholders, the Committee amended both Bills.

More generally, the Committee expressed concern at the annual budget hearings in April 2001 about the lack of spending on vital programmes such as poverty alleviation, the integrated nutrition programme, the hospital rehabilitation and reconstruction programme, and the HIV/AIDS programmes. Also of concern as well was the lack of synergy between the national DoH's policy and the implementation thereof in the respective provinces. The Committee noted that seven years after they were created it

was not satisfied with explanations about a lack of capacity in the provinces. The committee also expressed concern about the DoH's deficient strategy on human resources. The Committee plans to convene hearings on a Human Resources Strategy for South Africa in 2002.

Joint Monitoring Committee on the Improvement of the Quality of Life and Status of Women

This Committee was established to monitor and oversee progress with regard to the improvement of the quality of life and status of women in South Africa, with specific reference to the government's commitments made in Beijing, and with regard to the implementation of the provisions of the Convention on the Elimination of Discrimination against Women (CEDAW).

During November 2001, this Committee tabled a report called 'How best can South Africa address the Horrific Impact of HIV/AIDS on Women and Girls in Parliament'.[1] This report departs from government's stance on anti-retrovirals. Subsequent hearings convened by the Committee focused on how best South Africa could address the impact of HIV and AIDS on women and girls. The Committee noted that rich and middle class South Africans who were HIV positive or had AIDS could choose to access anti-retroviral treatment, they had access to good nutrition and could follow a healthy lifestyle. In contrast however, poor people who were HIV positive or who had AIDS had no such options available to them - 'too often they have limited access to the basics of water, nutrition, and good healthcare, including treatment'.

The Committee recommended that women should exercise their right to choice in relation to their own health, after being informed fully of the benefits and side effects of anti-retroviral treatment. On anti-retrovirals for raped women, the Committee proposed the establishment of an expert committee to examine recommendations for best practice and develop guidelines for the use of anti-retrovirals as post-exposure prophylaxis for rape. On the issue of toxicity the Committee recommended that nurses and health workers be trained to deal with issues relating to the toxicity of drugs.

National Legislation

The Medical Schemes Amendment Act (Act 55 of 2001)[2]

A new amendment Bill to further amend the Medical Schemes Act (Act 131 of 1998) was introduced in 2001.[3,4]

The old 1965 Act was considered to be poorly designed and oriented exclusively to meet the needs of a for-profit health system disinterested in the needs of the majority of South Africans. In particular, it allowed medical schemes to discriminate against groups of people on arbitrary and unfair






grounds. This was driven by the need to make quick profits. While this state of affairs had been considerably altered by the 1998 legislation, the new Amendment Bill was intended to further strengthen the original policy goals. Overall, the Bill aimed to:

- Significantly improve the independence of trustees, and address governance principles
- Create a clear and logical framework surrounding penalties for adverse selection such as waiting periods
- Improve the oversight of and use of re-insurance agreements
- Strengthen and improve complaint procedures
- Eliminate the conditional selling of various financial products with medical scheme membership and improve the enabling legislation dealing with brokers.

An important goal of the current legislation is the maintenance of the 'not-for-profit' status of medical schemes. It had become clear, both before the original Act was passed in 1998 and subsequent to it, that re-insurance has been used to circumvent the not-for-profit provisions of medical schemes. Such agreements had been used to pass reserves of a medical scheme to a third party, such that members lost ownership of these reserves.

In terms of the new Amendment Act, the Registrar of Medical Schemes should review and anticipate problems with these agreements before they are entered into.

The application of waiting periods is limited in cases where transfers are not linked to opportunistic behaviour. However it is broadened where adverse selection is very likely (such as when someone joins the scheme for the first time).

An important area of regulation, relates to provisions dealing with medical scheme brokers. Substantial member movement linked to commission payments (called 'churning') instead of member choice has become a feature of the medical scheme environment. This type of behaviour has added a new layer of unnecessary cost and inefficiency to the medical scheme market. There is a need therefore to develop an entirely new framework for regulating medical scheme brokers, which limits the commissions that can be paid by third parties, such as medical scheme administrators, and ensure that those who receive a service from a broker pay for it. Many of the problems relating to inappropriate re-insurance and poor management arise from conflicts of interest between the trustees of schemes, the principal officer, and parties with whom the scheme enters into contracts. As a consequence, the Act was amended to explicitly exclude all persons who may be subject to such a conflict. Overall, this should improve scheme governance, and contribute to the improved management of schemes. The amendments to the Act also make provision for penalties to be applied in cases where the payments of claims

are delayed without good reason.

There are however outstanding issues for which further legislation in this area may be necessary. Recommendations in this regard include:

- Appropriate measures and guidelines for Managed Care, to ensure that service providers are not encouraged to act unethically to contain costs
- Ensuring that health broker regulation remains a function of the Council for Medical Schemes.

This last mentioned issue was brought into sharp focus by the tabling of the Financial Advisory and Intermediary Services Bill (FAIS Bill).

Financial Advisory and Intermediary Services Bill (FAIS), 2001

During October 2001, the FAIS Bill was tabled and referred to the Portfolio Committee on Finance. This Bill is based on recommendations by the Policy Board for Financial Services and Regulation.

The Finance Portfolio Committee convened hearings on 9 October and thereafter established a sub-committee comprising of committee members to investigate the diverging concerns of the Council for Medical Schemes, the Financial Services Board and other stakeholders.

The FAIS Bill applies to financial service providers; they are defined in terms of the furnishing of advice or the rendering of an intermediary service in respect of a financial product. Within the Bill, the definition of a financial product also includes a health service benefit provided by a medical scheme, and financial service providers that furnish advice or render an intermediary service pertaining to a health service benefit provided by a medical scheme. Given the inclusion of a health benefit as a financial product, the FAIS Bill has significant implications for the Medical Schemes Act.

Administrators and brokers will potentially be faced with a confusing situation. Dual regulation will compromise the ability of the Council for Medical Schemes to properly regulate medical scheme brokers and administrators and will create a clear conflict with the Medical Schemes Act. Further, the proposal to regulate medical scheme brokers would be an encroachment on the area of health policy, which is the designated responsibility of the Health Minister.

The dual regulatory environment creates a conflict in the following areas:

- A code of conduct is already provided for in the Medical Schemes Act. FAIS does not refer to the medical scheme brokers in its code of conduct.
- The Medical Schemes Act does not contemplate the delegation of regulatory powers to representative organisations of the broker, insurance, or medical scheme industry. It is unclear what the relationship between the Medical Schemes Council and broker representative organisations, and the Life Offices Association, who may be given

statutory powers in terms of the FAIS Bill, will be.

By February 2002, the Bill was before the National Assembly Portfolio Committee on Finance and had not been fully processed. The Portfolio Committee on Health placed on record its concerns with the Financial Services Board's recommendations. Further negotiations were underway to establish a middle ground that will serve protect the public against unscrupulous behaviour and protect the objectives of the Medical Schemes Act.

Mental Health Care Bill, 2001[5]

The Mental Health Care Bill departs from the old model of indefinite institutionalisation of individuals to an approach that is more community based and consistent with the Bill of Rights. The Bill is limited primarily to aspects of *mental health care* compared to the broader (1973) Mental Health Act. The Bill, as originally tabled, was amended by the National Assembly Portfolio Committee on Health.[6] The final version of the Bill contains the following provisions:[7]

- It repeals the Mental Health Act, of 1973, which was widely considered to be outdated and, in part, unconstitutional
- It seeks to ensure that appropriate care, treatment and rehabilitation services are made available to people with mental health problems in line with a Primary Health Care approach
- It promotes and safeguards the human rights of people with mental disabilities and balances the rights with those of the public in circumstances where a person may infringe upon their rights with a mental disability.

In particular, the Bills included some of the following design features. A chapter dealing with patient rights has been included. This inclusion is critical as people with mental disabilities are still discriminated against and not protected by law. The Bill also entrenches the main principles of the United General Assembly resolution of 1991, on the Protection of Persons with Mental Illness and the Improvement of Mental Health Care. The Bill introduces a mental health care practitioner category. This allows for greater accessibility to various mental health services. It will also ensure that persons qualified to do so carry out mental health functions. Mental Health Review Boards are introduced to protect the user from unnecessary or arbitrary committal and retention. This involves a shift from a magistrate (which in practice was no more than magisterial ratification) to a Board, which includes a legal person (who may be a magistrate), a mental health care practitioner and a community member (who could be a traditional healer). A 72-hour assessment period prior to involuntary admission at a psychiatric hospital is introduced. This is added because many people recover within this period and the system can avoid many problems and save on administration associated with certification. This is also advantageous to the user. In addition, the period of review for involuntary, assisted, state patients and prisoners who are mentally ill is

shortened.

Various sections of the old Act have been omitted, for example, the section prohibiting the reporting of conditions in psychiatric institutions, which in the past encouraged gross human rights violations. These institutions are now open to public scrutiny. Also excluded are guidelines on how to deal with patients from other states.

Hospital Boards have been taken out of the Bill to avoid duplication with the National Health Bill. Transitional arrangements have been made until such time as the new National Health Bill is passed.

The National Council of Provinces Select Committee on Social Services is expected to pass the Bill during February 2002.

National Health Laboratory Services Amendment Bill, (Bill 56 of 2001)[8]

This Bill is an amendment to the National Health Laboratory Services Act of 2000 that provides a framework for the amalgamation of 234 public sector laboratories and various research facilities.[9] The Amendment Bill provides for employees of the Service who are members of a pension scheme to transfer to a pension scheme to be established by the Service.

The Bill further allows employees who are members of the government Employees Fund to become dormant members of the Fund, remain active members of the Fund, or to become members of a pension scheme to be established by the Service.

Medicines Control Amendment Act (Act 90 of 1997) and Pharmaceutical Manufacturers Association of South Africa and Others Versus The President of The Republic of South Africa and Others

The Medicines Amendment Act, passed in 1997, aimed to introduce three important measures to achieve access to cheaper medicines:[10]

- Generic substitution of off-patent medicines
- Parallel importation of patented medicines
- A transparent medicine pricing system through the establishment of a Pricing Committee.

Generic substitution measures within the Act compel pharmacists to offer a cheaper generic version of the medicine if one exists. Generic substitution does however not apply to medicines under patent. Significantly, the Act leaves the issue of compulsory licenses to be dealt with by the Patents Act.

The most controversial amendment of the Medicines Act relates to parallel importation, which refers to the importation of a cheaper drug from a foreign country. It is based on the principle that once a product is sold, the seller loses all ownership rights over it (exhaustion of rights).

Another element of the Act is the introduction of a Pricing Committee that will set up transparent pricing mechanisms. The Pricing Committee can

recommend that the Minister make regulations on the introduction of a transparent pricing system for all medicines. Drug companies will be allowed to set a single exit price for any medicine, and pharmacies will not be allowed to charge an amount higher than the exit price. Instead, the Pricing Committee may recommend a dispensing fee that pharmacists can charge instead of a mark-up.

After the Act was passed by Parliament, the Pharmaceutical Manufacturers' Association (PMA) and member companies sought an interdict against commencement of the Act until its legal status was clarified. The PMA's main objection to the Act related to the provision of parallel importation, which would allow the importation of medicines. Other issues, which formed the basis of their challenge, were the provisions for the circumvention of statutory patent protections in some circumstances, which the PMA alleged constituted expropriation of intellectual property without compensation, and the increased powers of the Minister *vis-à-vis* the Medicines Control Council.

On 19 April 2001, the PMA and 38 other pharmaceutical companies withdrew their court application against the State and agreed to pay the costs incurred by the State, and the Friend of the Court, the Treatment Action Campaign.

The withdrawal by the giant pharmaceutical companies was seen as a victory worldwide for developing countries and for the ongoing struggle for access to affordable medicines. Global mobilisation was an integral part of the strategy of the government and the Treatment Action Campaign. The court case also saw a resurgence of activism last seen in the eighties. The legal challenge was a lesson for developing countries, agencies and non-governmental organisations on the power of collective mobilisation on issues related to globalisation and poverty.

Withdrawal of the court action

After the withdrawal of the court action, a joint working group was set up between the South African government and the pharmaceutical industry to consider the development and adoption of a code of ethics for the marketing of pharmaceuticals, programmes to improve drug literacy; and improving efficiency and efficacy in the regulatory environment.

Draft regulations relating to the Act were drafted and published for public comment in June 2001.[11] These dealt with, *inter alia*, the process of parallel importation; licensing of professionals other than pharmacists who dispense medicines, the registration of pharmaceutical products purchased on international markets, the future composition of the Medicines Control Council and the composition of the Minister's advisory Pricing Committee.

Certain provisions of the Act, such as the prohibition on sampling, incentives and bonuses by the Industry were perhaps able to be promulgated immediately, such as:

- Setting up of a Pricing Committee to keep the Minister informed on issues relating to the pharmaceutical industry, and to advise on transparent pricing systems for medicines
- The system for generic substitution.

However, to date, no such promulgation notices have been issued, nor have amended regulations been finalised based on the comments received from the public and stakeholders.

Treatment Action Campaign (TAC) Case Against The Minister of Health and The Members of the Executive Council (MECs)

The results of the South African Intrapartum Nevirapine Trials (SAINT) showed that the drug is effective in reducing the risk of intrapartum transmission of HIV. In consultation with the provinces, it was decided to adopt a controlled approach to the introduction of this preventative measure through a programme called Prevention of Mother-to Child-Transmission of HIV (PMTCT).

The Department of Health argued that critical operational issues needed to be explored before deciding to implement on a national scale. There was a need to investigate whether this form of nevirapine use has any toxic side effects or contributes to drug resistance.

National and provincial steering committees were established; national guidelines were finalised; health workers were trained to use rapid HIV test kits; and health workers and NGO staff were trained to counsel mothers.

As a result provinces designated 18 research sites, two each, where nevirapine would be administered within a national research protocol and data would be collected to answer the outstanding questions.

In August 2001, the Treatment Action Campaign, Dr Haroon Saloojee and the Children's Right Centre brought an application against the Minister of Health and eight provincial MECs to force government to make nevirapine available to HIV positive pregnant women (the court papers can be accessed at http://www.tac.org.za/documents/archives.htm).

TAC demanded that:

- Nevirapine be made available to pregnant women with HIV who give birth in the public sector and to their babies, where the medical practitioner deems this to be medically necessary
- Government plans and implements in a reasonable manner an effective national programme to prevent or reduce mother-to-child-transmission of HIV, including the provision of voluntary counselling and testing, and where appropriate, nevirapine or other appropriate medicine, and formula milk for feeding.

The government opposed TAC's application. The case was heard from 27 to 29 November. TAC argued that government had no reasonable timetable for

the expansion of their programme to distribute nevirapine to provinces besides the Western Cape and Gauteng. TAC maintained that government had an obligation to ensure that the poorest provinces were assisted in order to provide nevirapine.

They further asserted that doctors in the public health system should be allowed to decide whether or not to prescribe nevirapine based on its merits.[12]

They argued that government had done nothing to explain why their policy was preventing some doctors in the public health sector from prescribing nevirapine, when they regarded it as in the best interest of a patient, thereby forcing them to act unethically.

The State maintained that insufficient resources limited the expansion of its programme to certain pilot sites only and that the long-term efficacy of nevirapine had yet to be proved.

The basis of government's argument was that:

- Government has implemented health promotion strategies such as the R90 million communication campaign to build public awareness and to prevent the spread of and to mobilise involvement in caring for and protecting the rights of those affected. The Minister of Finance, government maintains is increasing HIV and AIDS spending through the funding of dedicated national AIDS programmes.
- For the first time, the health allocation to provinces will be increased to strengthen hospitals and clinics' capacity to cope more effectively with increased demands for services. Allocation for infectious diseases would be increased substantially as well.
- On escalation of the PMTCT Programme, government maintains that already 18 research and training sites are running for pregnant women providing more than 200 contact points for pregnant women. For 2000, R25 million was set aside nationally for the PMTCT Programme and was augmented by the provinces. Government has emphasised that it is following a more cautious approach, with a strong monitoring component, with safety issues and efficacy being central to this approach.

On 4 December 2001, Minister, Manto Tshabalala-Msimang said: "the public sector cannot afford to provide the drugs, while nevirapine did not guarantee the virus could not be passed from mother to child".[13]

During December 2001, Judge Botha found in favour of the Treatment Action Campaign ruling that it was unconstitutional for government not to have a plan to extend its HIV PMTCT Programme beyond its pilot sites.[14] Section 27 (2) of the Constitution obliges the State to take reasonable measures to achieve the progressive realisation of the right to health care.

Judge Botha ordered that urgent action be taken in the interim to make nevirapine available in all public facilities that have the capacity to run

PMTCT programmes. Also, government has to devise a treatment plan and present it to the court by March 2002.

On 19 December 2001, the Minister of Health declared that government would appeal against Judge Botha's judgement; the appeal seeks to clarify government's constitutional responsibility in terms of the delivery of social services.

The Minister said that: "… this appeal is not an attempt to obstruct the development of the PMTCT Programme. It is aimed at clarifying a constitutional and jurisdictional matter- if left vague- could throw executive policy making into disarray and create confusion about the separation of powers, which is a cornerstone of our democracy."[12]

Draft National Health Bill[15]

On 9 November 2001, the long awaited National Health Bill was gazetted for public comment. The Department of Health indicated that it would table the National Health Bill in Parliament for processing by June 2002.

The passage of the National Health Bill is essential to creating a national legislative framework for the health system. The lack of this national framework has led to provincial health departments initiating their own legislation, which has resulted in a disjointed restructuring process amongst provinces. The introduction of the National Health Bill will require provinces to adapt their legislation to ensure uniformity in the transformation process. Also, the absence of a national legislative framework has created a situation where it has not been compulsory for Members of the Executive Council to adhere to national policies, as decisions of the MINMEC forums are not legally binding.

The National Health Bill is the overarching piece of legislation that enables the establishment of a national health system, which encompasses public, private and non-governmental providers of health services.

It is intended to ensure that the best possible health services are provided to citizens with available resources. The rights and duties of health providers and users are outlined as well.

National health structures and functions of the national department and the performance of functions by the provinces are also outlined. The establishment; composition; duties and powers of the national health authority are also laid out.

The Bill provides for the establishment of provincial functions, provincial health authorities; and very importantly, inspectorates for health facilities.

In addition to this Bill establishing a framework for the District Health System, provincial health legislation must provide for the establishment of a district health system in provinces.

Demarcation of health districts, variations of boundaries, and Municipal






Health Services are provided for in the Bill. According to the Bill provincial health legislation must provide for the preparation of district health plans by District Health Authorities.

The Constitution states that 'Municipal Health Services' and health services are functions of local government and provinces respectively, it does however not define these terms. This has created confusion about the allocation of functions and funding between the spheres. The Health Act of 1977 reinforces this ambiguity by allocating the provision of curative primary health care services to both provinces and local authorities. This has led to functional overlaps and fragmentation in service provision.

In terms of Municipal Health Services, the draft Bill states that municipalities must render Municipal Health Services. These services include: environmental health services, promotive and preventive health services and such curative health services as are currently offered.

In terms of the Bill a province may request a municipality to perform further services, these services must be agreed upon by the MECs for Health, local and provincial government as well as the municipality concerned. Very importantly this request must be accompanied by the necessary funding for the performance of the required services.

Various chapters in the Bill deal with operational plans to improve the quality of service and care in health establishments and academic service complexes. Also, to improve the relationship between public and private institutions various measures are put in place.

To ensure that health research remains relevant to the needs of the country and the prevalent burden of disease the Essential National Health Research Committee is provided for. To ensure that research on humans and animals occurs within a human rights and ethical framework a National Health Ethics Council is provided for which will formulate guidelines and norms and standards for research.

Many health experts are however concerned about the 'watered down' nature of the draft Bill. The Bill has been altered significantly and the Department of Health should anticipate an overwhelming response to the gazetted draft. Also, given the Public Finance Management Act, and its injunction that policies be thoroughly costed, this legislation could become controversial, but necessary nevertheless.

If municipalities are expected to budget over three years, managers must be enabled to plan and budget efficiently and realistically – they will need to be sensitive to the political landscape and the overall needs of the people. Monitoring and evaluation of service delivery at all spheres of government must be stepped up to ensure greater synergy and implementation. National consensus is needed on a clear definition of Municipal Health Services and a national definition of the 'basket of goods' that forms primary health services. The national Department of Health has to develop uniform definitions and

minimum standards of service provision.

The draft National Health Bill has a number of legislative implications. For example provinces will have to adapt their provincial health legislation to ensure uniformity with this Bill. If not already provided for, provincial health legislation must provide for the establishment of district health authorities, the establishment of committees for clinics and community health centres.

The draft Bill has funding implications as various committees need to be established in terms of the Bill e.g. the National Health Ethics Council, the Essential Health Research Committee and a National Health Information System Committee.

In terms of the Bill various Regulations must be issued to achieve the objectives of the Bill. For example Regulations will be prescribed on the minimum requirements for the rendering of services in health institutions, schools and other public places.

Provincial Legislation

Western Cape Health Facility Boards Act, 2001[16]

This Act provides for the establishment, functions, powers and procedures of Health Facilities Boards, and amends and repeals certain laws relating to Hospital Boards.

The Bill was introduced to:

- Facilitate the establishment of representative, and accountable Health Facility Boards as statutory bodies
- Create accountability of health facility management to the community and responsiveness to the needs of patients and their families
- Promote community support for, and involvement in, health facilities and their programmes
- Encourage responsible financial management of health facilities, and effective and efficient use of resources at health facility level
- Develop clearly defined functions and powers, which may be incrementally expanded in the public interests as the capacity of a Board increases.

Traditional Circumcision Bill - Eastern Cape, 2001[17]

This legislation attempts to reduce the number of deaths and unnecessary mutilations as a result of circumcisions performed by traditional healers under unhygienic conditions or traditional healers who have not been properly trained to perform circumcisions.

The Bill provides for the observation of hygienic standards in the performance of traditional circumcision; for the issuing of permission for the performance

of a circumcision operation and the holding of a circumcision school. In terms of the Bill, the MEC must designate one or more medical officers and confer the necessary powers on them to enforce the objectives of the Bill.

The Bill states that no person except a medical practitioner may perform any circumcision in the province without written permission of the medical officer designated for the area in which the circumcision is to be performed. Also, no person in the province may hold any circumcision school or treat any initiate without written permission of the medical officer designated for the area in which the circumcision school is to held or initiate is to be treated. The Bill introduces penalties for any person who fails to comply with conditions imposed by a medical officer. Fines of up to R10 000 or imprisonment of not more than 10 years could be imposed if the law is broken.

The parents or guardians must give written permission if a circumcision is desired for an initiate who is younger than 18 years. The traditional surgeon must be known to the parents or the guardian and must use instruments approved by the parents. Circumcisions must be performed under the supervision of an experienced traditional surgeon.

The designated medical officer is compelled to keep records relating to circumcisions and report to the MEC in the Province. Also, the medical officer, in terms of his/her powers will have access to any occasion or instance where circumcision is performed or an initiate is treated.

Conclusion

Since 1994, 19 pieces of ground-breaking legislation has been processed. In some instances, the legislation proved to be controversial but necessary to achieve improved access, equity and general transformation of the health system. The passage of the National Health Bill envisaged for 2002 will cement government's legislative framework. The national Department of Health has given notice that it intends tabling 11 pieces of legislation in Parliament during 2002.

Since a substantial volume of legislation will be passed, the oversight role of the National Portfolio Committee and the Provincial Standing Committees will be crucial in determining the success of policy implementation and also establishing to what extent legislation has unintended consequences. Where negative consequences of legislation hampers service delivery, these have to be brought back to Parliament for amendment. The policy environment should therefore be examined within a fluid, non-static context with ongoing monitoring, evaluation and amendment. The National Council of Provinces and the Provincial Standing Committees have to ensure that sufficient capacity exists to monitor service delivery. Co-operative working relationships between legislatures and Health Committees at Local government level must be established so that crucial service delivery issues are highlighted. More focus

is needed on the multi-sectoral nature of legislation and the implications thereof.

Also, improved partnerships need to be forged between legislatures and non-governmental organisations and community based organisations to ensure that the voices of marginalised sectors of communities are heard. NGOs and CBOs are failing to lobby policy makers effectively and strategically. This is an issue that needs to be addressed by these respective stakeholders.

References

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