Legislation on the for-profit private health sector in east and southern Africa

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Executive summary

International evidence shows that, if left unregulated, the for-profit health sector may lead to distortions in the quantity, distribution and quality of health services, as well as anti-competitive behaviour. As the for-profit private sector appears to be expanding in east and southern African (ESA) countries, governments need to strengthen regulations to ensure that the for-profit sector does not undermine national health system objectives. This report aims to understand how existing regulation provides for objectives such as the quantity, quality, distribution and price of health care services and to suggest priorities for strengthening legal frameworks. The report is implemented within the Regional Network for Equity in Health (EQUINET) with Wemos Foundation, covering sixteen ESA countries. It draws on a desk-based review of legislation accessed through the internet or from in-country researchers and interviews with in-country experts. Problems accessing information and key informants mean that detailed information could only be obtained on eight countries in the region.

The review shows that the focus of most private-sector legislation in all countries (with the exception of Namibia, South Africa and Zimbabwe) is to control the entry of health professionals and organisations into the market through registration. Most countries do not have adequate legislation on health insurance. Generally, the type and quality of services provided by private practitioners, clinic chains and private hospitals are not well regulated, and patient rights are not well protected, despite the existence of criteria for licensing and inspection. Where health insurers are regulated under general insurance legislation, there are no provisions to deal with the peculiarities of the health care market (such as risk rating and adverse selection), and comprehensive benefit packages are not protected. Even where there is specific health insurance legislation, provisions do not necessarily cover all these areas of concern or protect schemes from having their surplus stripped through unethical practices. Some interventions against anti-competitive behaviour have focused on health insurers without tackling private provision, a major cause of cost escalation.

Several countries are beginning to update and improve their legislation, although, in most cases, this is without the benefit of an overarching policy guideline on the private sector. In some instances, the approach adopted by some countries could be applied usefully in others.

However, enforcement remains an enormous problem. ‘Regulatory capture’ – where those parties who are to be regulated are able to influence the content and enforcement of regulations unduly – is probably still rife. Even where enforcement is active, sanctions will not have an effect if they are set too low, which often seems to be the case.

Finally, prices do not seem to be controlled – directly or indirectly (through managing the market) – to any meaningful extent in any country. This is the biggest gap in health legislation (although it has to be addressed along with quality issues) because it means the private sector is unlikely to become an affordable option for meeting health system objectives.

This review of the legislation suggests that governments and other policy makers need to embark on a programme of action to strengthen regulatory frameworks and instruments in relation to private health care provision and insurance. The capacity to enforce these laws also needs attention. Some activities are necessary regardless of whether mandatory health insurance policies are implemented, but others will be easier to achieve under a mandatory prepayment system.

Some recommended steps in this programme of action are:

- Develop in-country capacity to evaluate legislation affecting the private health sector against public health and other objectives. This capacity should marry public health, legal and financial skills.
- Develop an overarching policy on the private sector to guide legislation and clarify regulatory objectives. Distinguish the roles of different stakeholders clearly, ensuring a clear separation between funders, purchasers and providers. Ensure that ministries of finance and economic development understand the public health objectives of this policy.
- Rationalise the number of regulatory authorities or harmonise their activities and ensure that the legal requirements of multiple pieces of legislation are well understood by both regulators and the industry. While 'self-regulation' – where peers essentially scrutinise one another's behaviour – can be effective where enforcement capacity and codes of conduct are strong, these benefits can be overridden by economic incentives and professional interests.
- Clarify how and where private health professionals and organisations could help to address the needs of disadvantaged populations and create enabling policy and legislation to facilitate this (including mandatory health financing mechanisms).
- Clarify how and where new private health professionals, organisations and products entering the market could distort health care and jeopardise health care objectives, and develop legislation or other incentives to control this entry.
- Develop legislation on the quality of health services (including detailed guidelines for primary care, hospital care and emergency services) and on the conduct of health insurers. This should include greater clarity on the classification of different types of facilities, organisations and insurance plans.
- Develop health-insurance specific legislation that addresses the problems of risk rating, adverse selection and fragmented risk pools.
- Strengthen monitoring systems and create appropriate databases that are adequately maintained. This requires defining the information collection and reporting obligations of the private sector in law, as well as setting penalties for breach of these obligations. It also requires developing the capacity of government to enforce obligations and use and act on the information.
- Develop the capacity to enforce legislation, including adequate and timely inspections and renewal of certificates (setting the period for renewal of certificates at realistic intervals to improve the likelihood of enforcement). In countries with decentralised health systems, investigate opportunities for decentralising enforcement as a way of developing capacity as well as the responsiveness of decision making.
- Review the sanctions for misconduct and set them at appropriate levels. At the same time, eliminate regulatory provisions that discriminate unfairly against the private sector to build the trust of the sector.
- Create greater transparency, inform patients, health insurance beneficiaries and the public at large of their rights, and strengthen the accountability of regulatory authorities, health care providers and health insurers.
- Develop direct and indirect mechanisms for reducing cost escalation, especially within the hospital sector and in relation to the administration of health insurers.
- Investigate and act against anti-competitive behaviour.

Legislation is not the only route for regulating the private sector, and can be very complex and costly to implement. Strengthening of legislation should be accompanied by developing positive and negative incentives (such as alternative reimbursement mechanisms) that also help shift the behaviour of the private health sector.

1. Background

The for-profit private health sector appears to be expanding in east and southern Africa (Doherty 2011). International evidence shows that, if left unregulated, the for-profit sector may lead to distortions in the quantity, distribution and quality of health services, as well as anti-competitive behaviour (Marriott 2009).

Low- and middle-income countries generally have difficulties regulating the for-profit private sector due to limited resources and skills (Soderlund and Tangcharoensathien 2000). Thus, for example, a decade ago a study of private sector regulation in Zimbabwe found that legislation was not being enforced effectively, and providers were engaging in practices such as over-servicing, referring patients to services in which they themselves had a stake and submitting false claims to health insurers (Hongoro and Kumaranayake 2000). Unlicensed doctors were also involved in providing care. A more recent study in the same country found that health insurers had reduced competition through vertical and horizontal integration of services, limited consumers' choices, perpetuated high health care costs, failed to report on their activities adequately, practised tax avoidance and encouraged hospital development in urban rather than rural areas (Shamu, Loewenson et al. 2010).

It is imperative that governments in east and southern Africa (ESA) ensure that, whilst engaging with the for-profit private sector, they also strengthen their regulatory efforts so as not to undermine national health care objectives or distort the health care market. This report is implemented within the Regional Network for Equity in Health (EQUINET) with Wemos Foundation, with support from IDRC Canada. It covers the sixteen ESA countries in EQUINET. The report explores how existing regulation impacts on objectives such as the quantity, quality, distribution and price of health care services, and suggests priorities for strengthening regulatory frameworks. The focus is on that aspect of regulation that prohibits or allows certain behaviour and applies sanctions if these rules are transgressed (i.e. legal controls) rather than on other regulatory instruments that seek to influence private sector behaviour more indirectly (i.e. incentives such as reimbursement mechanisms) (Kumaranayake, Lake et al. 2000).

2. Methods

The report draws on two sources of information. First, a desk-based review was conducted of legislation submitted to the author by researchers in EQUINET working at country level. Some legislation was also found on websites as well as published and unpublished country studies. Second, an attempt was made to interview at least one knowledgeable person from the Ministry of Health (or advising the Ministry of Health) in each country, although this proved difficult.

Because of resource constraints, the review was limited to legislation affecting defined health care providers only (i.e. hospitals, primary care practices and emergency services) and health insurers. The legislation affecting health professionals was only scrutinised insofar as it affects the provision of primary and hospital care (and mainly with a focus on doctors).

The questions used to guide reading of the legislation were:

a) **Is there constitutional protection of the right to health?** This is of interest because it indicates whether government sees access and equity as important principles underlying its health legislation. It also indicates whether the Ministry of Health will be able to draw on constitutional provisions to defend its regulatory decisions.

b) **Is there evidence in health policy and legislation of a general intention to regulate the private sector in line with government's health objectives?** This is important for understanding whether legislation forms part of a coherent policy on the for-profit private sector and is intended as an instrument to achieve social objectives (as opposed to simply economic objectives or to meet the demands of the health care industry, for example).
c) **What regulatory authorities oversee implementation and enforcement of legislation?**
d) This indicates how centralised or co-ordinated regulatory oversight is, and the degree of independence and power of regulators.
e) **What conditions are placed on the licensing and accreditation of health professionals and providers to operate in the private sector?** This indicates whether government places any restriction on the numbers and geographic location of individual health professionals and health care businesses entering the private health sector, or on the conditions under which they enter the private market. It is also one lever for protecting the quality of care.
f) **Similarly, what conditions are placed on the licensing of health insurers?** This question focuses on the degree of oversight to which government is committed, particularly with respect to preventing fragmentation of the market and ensuring the sustainability of risk pools.
g) **How and when are providers and insurers required to report to the regulatory authorities or regulatory authorities entitled to inspect providers?** This gives a sense of the extent to which government has oversight of private provider activities and the ease with which this is able to occur.
h) **How are health professionals prompted to maintain their skills and behave ethically, and what standards and norms apply to health care providers?** These are other levers for protecting the quality of care.
i) **Does government control private health sector prices to any extent?** This is of importance from an affordability and equity point of view.
j) **Are there provisions to promote competition and prevent anti-competitive behaviour?** This is of interest because controlling the quantity, quality, distribution and price of services is difficult under monopolies.
k) **Are there provisions to promote equity and prevent exclusion of certain parts of the population from services?** This is critical to ensuring that good health care is not only the preserve of a wealthy elite.

The provisions of the legislation were summarised in tables based on these questions (see Appendix 1). Further analysis was informed by a framework developed by Kumaranayake et al (2000). This framework allows one to categorise each piece of legislation according to which objective it achieves and at which level it operates. The 'levels' are the individual health professional, the health care organisation (such as a GP practice or private hospital) and different health care markets.

The limitations of this report are that legislation in English could not be accessed within the given time frames from all countries in the region, the legislation accessed may be out of date or incomplete, and the analysis may not have identified all the important features and gaps. Further, it is not known at this stage whether existing legislation has been implemented: although good legislation might exist, it is entirely possible that it is commonly flouted and not enforced, a common situation identified by the international literature (Hongoro and Kumaranayake 2000; Soderlund and Tangcharoensathien 2000; Ravindran and de Pinho 2005; Hort and Annear 2012).

Although considerable effort was put into trying to identify and access knowledgeable people to interview, it proved difficult to find people with overarching legal and public health knowledge of such a broad sector, while some who were identified could not be contacted or could not be interviewed in time for the project deadlines. Language also proved to be a barrier. In total, only eight interviews were conducted.

Consequently, sufficient information was only obtained for eight of the sixteen countries in the region. Although earlier versions of the report were sent to all the contacts the researcher had in each country, only five responses were received. It is therefore likely that the report still contains omissions and inaccuracies. While the findings of the report can only be considered tentative, it is the view of the researcher that the broad trends and recommendations would be largely unchanged even if more detailed information were available.

Other limitations relate to the fact that the review did not look at all the categories of health professionals (including traditional healers) and did not examine the full range of health-related legislation (for example, workers' compensation legislation was not studied) or other legislation that affects business (for example, tax legislation). Public-private partnerships and mandatory health insurance were also not examined as the focus of the report is on that part of the private sector that is regulated at arms' length by government and is not bound through contractual arrangements with the state.

3. Findings

Detailed information on the legislation in each country appears in Appendix 1. For ease of reading, the text below does not provide the full title and date of each piece of legislation, but these do appear in the appendix. The text below focuses on cross-country comparisons.

One point of terminology to note is that, in line with international practice, the term 'voluntary health insurance' is used broadly in this report to denote voluntary prepayment of funds by individuals (and often also employers) into a pooled fund to offset (part of) future health care costs. It refers to voluntary health insurance plans of all types, whether employer-based and restricted to members of the company, or open to anyone.

Voluntary health insurance refers, too, to both non-indemnity and indemnity plans. The distinction between the two is important because this has implications for how health insurance is regulated, the costs and sustainability of health insurance, and the level of risk cross-subsidies in a country. Non-indemnity plans, often known as 'medical aid,' are run on a non-profit, 'mutual' basis where surplus is ploughed back into the scheme (although they are usually run by for-profit administrators who charge a fee). These plans cover a range of health care incidents, reimburse in relation to the costs of care and often reimburse providers directly. For-profit indemnity plans, on the other hand, are offered by short-term and long-term general insurers, and pay beneficiaries a pre-agreed lump sum directly, usually for hospital care. This lump sum is unrelated to the cost of care. Investors require administrators of these plans to provide a return on investment (that is, to extract profit).

For ease of understanding, *Table 1* summarises how the South African national treasury distinguishes between non-indemnity and indemnity health insurance.

Table 1: The difference between indemnity and non-indemnity health insurance in South Africa

Feature	Indemnity insurance	Non-indemnity insurance
Governing legislation	Long-term or Short-term Insurance Acts	Medical Schemes Act and amendments
Regulatory body	Financial Services Board	Medical Schemes Council
Profit-making status	Profit making	Non-profit entities belonging to members (although can be administered by a profit-making company)
Risk rating and exclusion of high-risk individuals or conditions	Allowed	Not allowed
Premiums	For the same cover, vary according to age, health status or income of individual	For the same cover, uniform across ages and health status
Reimbursement of claims	Not directly related to provider costs (lump sums)	Directly related to provider costs
Benefits	Not regulated	Minimum benefits prescribed

Sources: Republic of South Africa 1998; Theron, Erasmus et al. 2010; National Treasury, Republic of South Africa 2012.
Note: In South Africa, indemnity insurance is known as 'health insurance' and non-indemnity insurance as 'a medical scheme'.

3.1 Legal and policy context for the private health sector

Most of the countries studied provide little or indirect constitutional protection of the right to health care (Mulumba, Kabanda et al. 2010). South Africa was the only exception until recently when it was joined by Kenya in making explicit provisions for the right to health services. However, many country constitutions address the social determinants of health in line with the United Nations International Covenant on Economic, Social and Cultural Rights (which is part of the International Bill of Human Rights) and protect some aspects of health care provision. This provides the legal basis for ministries to intervene in the health sector, including the private component.

All public health acts in the region include some general regulation of private actors, although in some countries this is limited to issues such as disease control, environmental health and waste management, ports and mortuaries. Some countries, such as Tanzania, have separate legislation governing public-private partnerships, but this type of regulation is not a focus of this report. Only Botswana, Kenya and Uganda seem to have explicit policies on private health care provision (Uganda Ministry of Health 2010; Botswana Ministry of Health 2012b; Kenya Ministry of Medical Services and Kenya Ministry of Public Health and Sanitation date unknown).

More information on the Ugandan policy appears in *Box 1*. South Africa is an example of country that has made a couple of attempts to formulate an overarching policy in consultation with the private sector, but which has been unable to finalise an agreement because of the conflicting interests of different stakeholders.

Box 1: Uganda's approach to the private sector in its second health policy

Uganda's new health policy (in 2010) looks at the health system as a whole, including the private sector. It is committed to strengthening the supervision and monitoring of the private sector, as well as the functional integration of the public and private sectors. The private sector is seen as complementary to the public sector through helping to extend the geographic range, scope and scale of services. One of the policy objectives is to strengthen the regulatory system and professional councils so that better legislation can be developed. Another is to strengthen enforcement, including inspections. The policy is also committed to strengthening the skills of private providers and managers, improving the quality of private health care, facilitating the involvement of the private sector in planning, attracting private providers to underserved areas, facilitating the development of private sector infrastructure, and collecting adequate information on the private sector.

Source: Uganda Ministry of Health 2010.

Several countries are in the process of planning, introducing or strengthening mandatory prepayment mechanisms for health care, which include mandatory health insurance in some cases. Although not amounting to formal policies on the private sector, these initiatives can be expected to outline the terms on which a publicly funded purchaser is prepared to contract with the private sector, introduce strong incentives for private providers to comply with quality controls and address cost containment to some degree through changed reimbursement mechanisms.

There is a competition policy in at least nine countries in the region that, as discussed later, has had a relatively small impact on health market conditions but may be expected to exert a growing influence in the future, especially in South Africa.

In summary, legislation on the for-profit private sector has historically not been formulated within the context of comprehensive policies on the sector, or benefited from the levers provided by strategic purchasing by organisations funded through mandatory prepayment mechanisms. Neither has legislation against anti-competitive behaviours been deployed successfully in the region. However, the last decade has seen some improvement on all these fronts. Unfortunately, consumer protection legislation in most countries is relatively weak, at least in terms of addressing failings in the health market, and is not expected to have a major influence on the health care market in the region, except possibly in South Africa.

3.2 Regulatory authorities

Generally, several regulatory authorities are involved in private sector regulation in each country. These report to a variety of ministries, including economic development, finance, health and labour. The level of fragmentation to which this can lead is illustrated by the example of the health insurance industry in Tanzania (see *Table 2*).

This not only makes regulation more complex but also muddies the policy environment. The ministries of finance and economic development may see the expansion of the for-profit private health sector as beneficial for economic growth, or the Competition Commission may decry collective bargaining around prices, without appreciating the challenges this poses to the Ministry of Health in its attempts to achieve public health objectives and address 'market failure' in the health sector.

Table 2: Authorities involved in regulating health insurance in Tanzania

Organisation	Regulatory authority	Relevant legislation
National Social Security Fund and its Social Health Insurance Benefits Programme	• Ministry of Labour • Social Security Regulatory Authority (reporting to Ministry of Labour)	• National Social Security Fund Act • Social Security Regulatory Authority Act
National Health Insurance Fund	• Ministry of Health and Social Welfare • Social Security Regulatory Authority (reporting to Ministry of Labour)	• National Health Insurance Fund Act and subsidiary legislation • Social Security Regulatory Authority Act
Private health insurers	• Tanzania Insurance Regulatory Authority (reporting to Ministry of Finance)	• Insurance Act
Community health funds	• Fund Councils (reporting to the Prime Minister's Office section on Regional Administration and Local Government)	
Health maintenance organisations and medical benefits management organisations	• No oversight	

Sources: United Republic of Tanzania 1997,1999, 2008, 2009; Bultman, Kanywanyi et al. 2012.

Zambia faces a particular regulatory challenge as its National Health Services Act, which set up its Central Board of Health to administer providers, was repealed in 2005 (Republic of Zambia 1995). Responsibility for provision then reverted to the Ministry of Health even though the Public Health Act (Republic of Zambia 1995), the only remaining piece of legislation governing the ministry, has not been adjusted accordingly, leaving an administrative vacuum.

All countries have professional councils that control the entry of health professionals into the health care market through registration and oversee professional behaviour. In several countries – Kenya, Zambia, Uganda and Zimbabwe – these councils are also responsible for regulating private health care providers through licensing and accreditation. In other countries, the Ministry of Health is responsible. Unusually, Tanzania has a dedicated Private Hospitals Advisory Board under the Ministry of Health that registers and regulates both hospitals and senior hospital managers.

Only three countries regulate the health insurance industry through a dedicated health insurance authority (namely, Namibia, South Africa and Zimbabwe). In South Africa and Zimbabwe this regulator reports to the Ministry of Health, while, in Namibia, the CEO of the Namibia Financial Institutions Supervisory Authority, which reports to the Minister of Finance, is also the Registrar of Medical Aid Funds, which implies the registrar no longer reports to the Minister of Health. In others, the health insurance industry falls under the general insurance legislation and authority, which in turn fall under the Ministry of Finance. In Botswana and Zambia, some health insurers escape any regulation at all (except that governing the registration of companies or

societies) through loopholes afforded by the definition of health insurance. They thereby escape taxation (through arguing that they are non-profit entities) or extract surpluses that should be ploughed back into the health insurance plan as profit.

Even in South Africa and Zimbabwe, health care insurance products offered by short-term or long-term insurers fall under the general insurance regulator. As shown in *Table 1*, in South Africa the legislation that 'demarcates' this type of indemnity insurance from schemes that fall under the Medical Schemes Act of 1998 (Republic of South Africa 1998), and which are obliged to practise community rating and offer a broadly defined minimum package of benefits, is finally relatively well defined. However, it is not yet completely enacted because of years of conflict between the Council for Medical Schemes and national treasury on the one hand and short- and long-term insurers on the other. The importance of accurate demarcation is to protect the risk pooling and community-rating features of 'mutual' schemes that are important to expand coverage and protect the sustainability of voluntary health insurance.

As mentioned earlier, most countries have Competition Commissions that are empowered to investigate anti-competitive behaviour and unfair business practices, including in the private health sector.

3.3 Regulation of health professionals

As shown in *Table 3*, all countries require registration of health professionals before they can practise in the health sector at all. Of the countries for which information was available, only Botswana, Kenya and Uganda also require health professionals to be licensed to work in the private sector: this licence is only granted after the individual has undertaken a minimum amount of service in the public sector (see *Box 2* for more details on the Kenya licensing system).

Box 2: The licensing system for primary care professionals and facilities in Kenya

The Medical and Dental Practitioners Act of 1978, and accompanying rules for private practice, entitles a board to oversee university training in order to preserve standards, and also license doctors and dentists to work in the public sector, provided they have received appropriate training. It is also responsible for maintaining their standards of practice. An additional (annually renewable) licence is required to work in private practice. The licence is issued in relation to specific premises and cannot be transferred between premises or individuals. There are sanctions for fraudulent licences (e.g. fines, imprisonment, revoking of licence), including for misrepresenting oneself as a qualified health professional: however, there have been problems enforcing these in the past. Finally, nurses and clinical officers are also permitted to work in the private sector, although their legislation has not been reviewed in detail: the main difference is that, before receiving a private practice licence, these categories need to have worked in the public sector for at least ten years, whereas only three years is required for doctors and dentists. All health professionals are required to undergo continuing education.

Sources: Republic of Kenya 1978; Kenyan Medical Practitioners and Dentists Board 2010; Nursing Council of Kenya 2012.

South Africa's requirement that health professionals do community service before they become fully licensed is also a way of controlling their entry into the private sector. Both Kenya and South Africa allow senior doctors working in the public sector (typically in academic settings) to engage in private practice with the permission of the authorities. In South Africa, the perception is that this privilege is widely abused,

especially by specialists working in academic hospitals, and requires much stricter management by hospital and provincial authorities.

Table 3: Regulation of health professionals

Objective		**Botswana**	**Kenya**	**Namibia**	**South Africa**	**Tanzania**	**Uganda**	**Zambia**	**Zimbabwe**
Regulation of entry of inputs into the health care market (i.e. registering of health professionals)		+	+	+	+	+	+	+	+
Regulation of volume of inputs in private health service provision (i.e. licensing of health professionals to practise in the private sector)		+	+	-	+	-	+	-	-
Regulation of distribution (i.e. encouraging privately practising health professionals to work in under-served areas)		-	+	-	(+)	-	-	-	+
Regulation of quality of service provision by privately practising health professionals	Sanctions relating to unprofessional behaviour and practice	+	+	+	+	+	+	+	+
	Requirements for continuing education	no info	+	+	+	no info	+	+	+
Regulation of reimbursement levels for privately practising health professionals		-	+	+	-	-	+	-	+
Regulations to promote fair competition between privately practising health professionals (apart from competition law)		-	-	-	-	-	+	-	+

Note: '+' means that some form of legislation is present; '(+)' means that there are some mechanisms but they are not broadly applied; '-' means that legislation is absent.

There is no legislation directly controlling where health professionals practise in the geographic sense. South Africa tried to implement a 'certificate of need' that would prevent private providers practising in areas where there is an over-supply and reduce 'brain drain' from the public sector, but private providers successfully opposed this through legal action. There is some limited and indirect control as new graduates doing their community service are supposed to be sent to disadvantaged locations (although there is some element of personal choice and people are not supposed to be sent to facilities where there is inadequate supervision).

Legislation governing the quality of care rendered by individual professionals and the standard of their professional behaviour falls almost entirely under the aegis of health professional councils. All countries make provision for disciplinary hearings and sanctions in the form of de-registration, fines and imprisonment. The severity of the sanctions varies from country to country. Until relatively recently continuing professional development was not a requirement in many countries, but increasingly it has become the norm.

South Africa and Uganda require private practitioners to have a licence to stock and sell drugs (requiring specific training and appropriate drug storage facilities), but in Kenya private clinics are required to stock essential drugs.

Except in Kenya, there do not seem to be any direct controls of the fees charged by health professionals (as opposed to the facilities in which they work) or limits on total income. Tariffs mainly seem to be set independently or through negotiation between health insurers and health professional associations and, in addition, patients may have to make co-payments. Kenya is the exception as the legislation allows the Medical Practitioners and Dentists Board to set the fees. With the move to strategic purchasing using mandatory prepayment funding in some countries, it can be expected that reimbursement rates will become formalised, at least for individuals contracted to provide services.

Few countries seem to have specific legislation promoting fair competition between individual health professionals. Uganda is one country that allows nurses and midwives to establish their own practices without supervision of a doctor. While South Africa requires doctors to have a licence if they wish to dispense drugs, the courts are striking down the provision requiring these doctors to practise outside a 5km radius of a pharmacy. Professional councils investigate certain unfair practices, especially when they affect the quality of care. Competition Commissions also have the potential to act on unfair business practices by health professionals. For example, it is expected that the Competition Commission enquiry that is about to get underway in South Africa will investigate whether the treatment and referral practices of doctors are affected by commercial interests in hospitals or the terms of lease agreements for their consulting rooms.

3.4 Regulation of health services and insurers

Health care providers
As shown in *Table 4*, all the countries for which information is available require private hospitals to be licensed. Kenya, Uganda, Zambia and Zimbabwe also require private, primary care facilities to be licensed (although it is only in Kenya and Uganda that health professionals also have to be licensed for private practice).

Uganda also requires the management of private hospitals to be licensed. All countries require inspection of facilities by regulatory authorities, although many lack the capacity to enforce this properly. In all countries, licences can be withdrawn, presumably if quality is poor, amongst other things.

Registration generally appears to be based on fulfilment of minimum requirements for a specified level of inputs such as physical infrastructure, equipment and human resources: process criteria for quality care are not identified. However, Tanzania has published a quality improvement framework, and South Africa is in the process of promulgating detailed quality criteria that will apply across all facilities, both public and private.

Countries having mandatory insurance, such as Kenya and Uganda, have an additional tool to regulate quality, namely, accreditation of facilities contracting to the insurance fund. Even voluntary health insurance can be a tool to improve quality, as providers have to be registered with the plan to qualify for reimbursements and their treatment patterns are monitored, at least in those countries with large insurance industries. Some facilities undergo voluntary accreditation as well.

Table 4: Regulation of hospitals and clinics

Objective		Botswana	Kenya	Namibia	South Africa	Tanzania	Uganda	Zambia	Zimbabwe
Regulation of entry of organisations into the market (i.e. licensing of facilities according to input criteria)	Hospitals	+	+	+	+	+	+	+	+
	Clinics	-	+	-	-	no info	+	+	+
Regulation of number of organisations (i.e. limitation on the number of services in a given area)	Hospitals	-	-	-	(+)	-	-	-	-
	Clinics	-	+	-	-	no info	-	-	(+)
Regulation of distribution (i.e. locating services in under-served areas)	Hospitals	-	-	+	-	-	-	+	+
	Clinics	-	+	-	(+)	no info	-	-	(+)
Regulation of quality of service provision (i.e. standard-setting, quality assurance and reporting)	*Regulation of curricula of training institutions*	+	+	+	+	+	+	+	+
	Setting of norms and standards for quality of care, including processes Hospitals	-	-	-	-	-	-	-	-
	Clinics	-	(+)	-	-	No info	(+)	-	-
	Reporting requirements Hospitals	+	+	(+)	no info	(+)	-	(+)	-
	Clinics	-	+	-	-	no info	+	-	-
Regulation of prices (i.e. setting fees for certain services)	Hospitals	no info	(+)	-	-	+	-	-	+
	Clinics	-	+	-	-	no info	-	-	(+)
Regulations to promote fair competition between organisations	Hospitals	-	+	-	+	+	-	+	-
	Clinics	-	+	-	+	+	-	+	-

Note: '+' means that some form of legislation is present; '(+)' means that there are some mechanisms but they are not broadly applied; '-' means that legislation is absent.

Except South Africa, no country specifically requires ‘certificates of need’ for private hospitals or sophisticated equipment. In South Africa, provincial authorities are supposed to consider a range of requirements, including efficiency and equity, before granting a licence to a private hospital (although, as mentioned earlier, a formal certificate of need, as identified in the National Health Act (Republic of South Africa 2004), has not been promulgated because of its highly controversial status). However, Namibia and Zimbabwe do mention that a licence is dependent on the facility being in the public interest, although this term is never defined. In Zambia, a facility can only be licensed if it does not lead to inefficiency and waste. ‘Certificates of need’ do not seem to be used at the primary care level.

Most countries require some level of reporting from hospitals, although compliance rates can be low. Botswana requires a patient, operations and drug purchase register, which presumably needs to be produced on inspection, but only stipulates that deaths must be reported to the minister within 48 hours. Kenya requires six-monthly reports on which doctors and dentists are working for the hospital and, if they have admitting rights, where their primary care clinics are located. Hospitals are also supposed to submit annual returns to the Health Information System. However, compliance rates in the past have not been good. Namibia only requires subsidised private facilities to submit returns. Tanzania allows the minister to demand information when required, and in Zambia various reports, including quality assurance information, are required before renewal of accreditation. There do not seem to be specific reporting requirements in Uganda and Zimbabwe.

Reporting requirements for clinics seem to be limited or non-existent. In Kenya private clinics are required to stock essential drugs and must keep a record of drugs used, and in Uganda private nurses and midwives have to submit an annual report of the cases they have seen and be ready to make available further records of their cases.

There seems to be little regulation governing hospital prices. In Kenya, daily rates are set only for those facilities accredited for the National Hospital Insurance Fund. However, in Zimbabwe, health insurers do not have to pay providers more than the rate at state facilities for minimum benefits. In addition, hospitals cannot charge fees above a prescribed amount without the approval of the minister to whom they must provide justification of increased costs. Thus, the ministry struck down recent attempts by Zimbabwe’s hospital association to increase tariffs by 20%. Tanzania is another exception as its private hospital regulations lay out a regulated process for determining hospital fees (see *Box 3*).

Box 3: Regulations governing hospital prices in Tanzania

According to the Private Hospitals (Regulation) Act of 1977, the Minister of Health can review hospital fees, either on a national basis or for particular areas. He or she can determine the maximum fees and the manner in which they are calculated, and must keep the interests of both the community and health care provider in mind, as well as the need to ensure the availability of services in rural areas. In making a judgement the minister can receive representations from any groups as well as demand access to data on treatment. A court may not review the minister's decision. Hospitals or practitioners providing services at a greater price than the maximum are guilty of committing an offence, with sanctions of fines and imprisonment. Similar provisions apply to the salaries or other emoluments paid to medical practitioners.

Source: United Republic of Tanzania 1977.

The Competition Commission in South Africa has prohibited providers from colluding when negotiating tariffs with health insurers, but it has also prevented the association of health insurers from collectively setting provider tariffs. This has reduced the power the health insurance industry has to keep provider fees down and, consequently, the upcoming market enquiry by the Commission to investigate how tariffs are – and should be - agreed.

There does not seem to be any direct control of primary care fees except in Kenya where the Private Practice Committee of the Medical and Dental Council, which grants licenses for private practice, can also review fees.

The only legislation that appears to promote fair competition between hospital groups and clinic chains are the competition laws. Mergers and acquisitions, as well as the practice of health insurers referring beneficiaries to providers owned by the same company, have come under investigation by the Commission in South Africa, for example.

The legislation discussed above refers to clinics and hospitals. Little information could be found on legislation governing emergency services. The exception is Zimbabwe where the Paramedic Practices Act requires all ambulance services to be registered, registration being dependent on the services meeting requirements with respect to vehicles, equipment, appropriate personnel and location (Republic of Zimbabwe 1971). Certain standards have to be met, but the act does not lay these out. There do not seem to be any price controls or legislation protecting the industry against anti-competitive behaviour.

Health insurers

As mentioned earlier, dedicated legislation governing the health insurance industry was only found in Namibia, South Africa and Zimbabwe. General insurance legislation governs the health insurance industry in other countries, including non-indemnity health insurance.

As shown in *Table 5*, health insurers have to be registered in all countries, and in South Africa administrators have to be accredited as well. Both employer-based schemes (which restrict membership to their employees and their families) and open schemes (to which anyone can apply) seem to be allowed everywhere and registration is generally on the basis of financial soundness and sustainability, although in Namibia the registrar must also be satisfied the fund is in the public interest. While Botswana has legislation governing general insurers, most health insurers register as voluntary societies under a Societies Act (Botswana 1972): this allows them to escape some of the provisions around financial risk and sustainability, as well as taxation, that otherwise apply to general insurers (interview data).

There does not seem to be any direct limitation on the number of insurers or their location. However, a couple of countries specify the minimum number of beneficiaries a scheme needs to have before it can be licensed, which is an indirect way of controlling the number of insurers. Few countries effectively demarcate indemnity versus non-indemnity insurance, with South Africa having put the most effort into this because of its extensive legislation controlling benefit packages and risk-rating practices for non-indemnity insurance. Thus, insurers that offer lump sums when beneficiaries experience an adverse health event (such as an heart attack) are not allowed to call themselves ‘medical schemes’ and, conversely, any insurer that wishes to offer benefits directly related to the costs of health care need to comply with all the legislation governing medical schemes. Namibia and Zimbabwe also appear to demarcate health insurers but not with legislation that is as detailed as in South Africa.

Table 5: Regulation of insurers

Objective		**Botswana**	**Kenya**	**Namibia**	**South Africa**	**Tanzania**	**Uganda**	**Zambia**	**Zimbabwe**
Regulation of entry of organisations into the market (i.e. licensing and demarcation of insurers)		+	+	+	+	+	+	+	+
Specific legislation for health insurance		-	-	+	+	-	-	-	+
Regulation of number and distribution of organisations (i.e. limitation on the number of services in a given area)		-	-	-	-	-	-	-	-
Regulation of quality of service provision (i.e. comprehensive benefit packages, solvency and reporting requirements)	*Standardised benefit packages*	-	-	-	+	-	-	-	+
	Solvency (specific too health insurance)	-	-	+	+	-	-	-	+
	Reporting (specific to health insurance)	-	-	+	+	-	-	-	+
Regulation of prices (i.e. setting of premiums and administration fees)		-	-	-	-	-	-	-	+
Regulations to promote competition between organisations	*Control of risk rating*	-	-	-	+	-	-	-	-
	Appropriate control of adverse selection (reasonable waiting time)	-	-	-	+	-	-	-	(+)

Note: '+' means that some form of legislation is present; '(+)' means that there are some mechanisms but they are not broadly applied; '-' means that legislation is absent

Only two countries make specifications protecting the comprehensiveness of benefit packages. In Zimbabwe, minimum benefits must be equivalent to the non-specialist services provided by government and state-aided clinics and hospitals, and must make provision for formal referral to government specialists. A listing of the broad categories of services is provided. Low-cost schemes are allowed to provide less than the minimum benefits provided the scheme has been approved. In South Africa, a whole raft of regulations supporting the Medical Schemes Act lays out the minimum benefits that have to be provided by all schemes (Republic of South Africa 1998). A number of clinical guidelines and protocols are also legislated for many of the important conditions, and both schemes and providers are required to comply with these in terms of what they offer patients and how they compensate them (more detail is provided in *Box 4*).

Box 4: Prescribed minimum benefits in South Africa

The Medical Schemes Act of 1998 lays out a set of minimum benefits and its accompanying amendments and regulations, including diagnosis, treatment and care for acute hospital care and chronic conditions, as well as emergency care. Detailed algorithms conditions, especially chronic ones, lay out what treatment approach must be applied by providers and covered by schemes. Schemes must cover the cost of these services in full, provided the beneficiary uses a designated provider (or involuntarily has to use a non-designated service provider). Other protocols and formularies developed by schemes themselves have to be shown to be evidence based. Schemes still have to exert efforts to ensure that these services are delivered efficiently, including using pre-authorisation and drug formularies. A number of provisions relate to controlling the quality of managed care organisations and practices, and their impact on the coverage of benefits. Similarly, capitation agreements have to be in the interests of members.

Source: Republic of South Africa 1998 and accompanying regulations.

Namibia, South Africa and Zimbabwe seem to be the only countries requiring a minimum reserve level of 25% of gross annual contributions, although Namibia's legislation does empower the registrar to oversee the financial stability of schemes and intervene when necessary.

Only Namibia, South Africa and Zimbabwe specify the nature and frequency of specific reporting required of health insurers to the regulatory authorities. Financial information is the common reporting requirement under general insurance legislation, but Namibia includes the need to demonstrate effective and efficient use of funds (*Box 5* provides more detail).

Box 5: Reporting requirements for health insurers in Namibia

The Medical Aid Funds Act of 1995 provides for inspection of the affairs of medical aid funds. Funds are required to submit annual financial statements and reports to the registrar within six months of the close of the financial year. The main concerns appear to be financial and sustainability issues, but there is a requirement that funds demonstrate that they have used funds efficiently and effectively. Funds are required to produce any documentation required by the registrar within an undefined period stipulated by the registrar (and may apply for this period to be extended). The registrar is also empowered to interrogate the accuracy of these documents (e.g. through an auditor or actuary). The registrar must report annually to the minister who tables the report in parliament. Funds also have to report on any amalgamation with another business. Funds are required to provide members with the rules of the fund and annual financial statements.

Source: Republic of Namibia 1995.

The administrators running health insurance plans have little control of the fees charged. Excessively high administrative costs is one way for administrators to extract surpluses from non-profit insurance schemes where surpluses are supposed to be ploughed back into the scheme to benefit the members. Except in South Africa, there is also little control of administrators' reinsurance practices: this is the insurance taken out by administrators to protect the scheme from unusually high claims. In South Africa in the 1990s this was used as another mechanism to extract profits (through excessively high reinsurance taken out with reinsurers belonging to the same company or paying a kickback for the business).

There is also minimal regulation of the brokers who find and sign up new members for insurance plans, usually on commission. Some countries require brokers to be

registered (for example, Kenya, South Africa and Zimbabwe, although in the latter country health insurers tend to deal directly with employers when enrolling new beneficiaries). South Africa also controls brokers' behaviour to some extent by capping their allowed commission and forbidding a scheme to reject a potential new member on the basis that they did not use a broker.

Zimbabwe is unique in experiencing intervention in the health insurance industry by the National Incomes and Pricing Commission that has, on occasion, prevented health insurers from increasing their premiums (Makamure 2008).

Preventing risk rating and adverse selection are strategies for ensuring that health insurers compete on their efficiency rather than on their beneficiaries' health profiles. These strategies therefore are discussed under this paragraph on the promotion of competition between insurers, although they could also be discussed with respect to their impact on equity. South Africa is the only country that has provisions against risk rating, specifically the outlawing of practices such as excluding potential members based on their risk profiles, loading their premiums or excluding them from certain benefits. In all other countries, the legislation says nothing about these practices. In Zimbabwe, in fact, risk rating based on age and health is specifically allowed. The only provisions protecting a beneficiary from being denied entry to a scheme in Namibia and Zimbabwe seem to be around characteristics such as race, gender and marital status.

In all countries, waiting periods before beneficiaries can claim benefits after first registering are allowed, but only South Africa limits the length of this waiting period to three months. While Namibia does not seem to define a waiting period limit, it does ensure that people shifting from one scheme to another may not be subjected to a waiting period if joining the new scheme within three months and having been a member of the previous scheme for at least two years. While Zimbabwe does have a general waiting period of three months, this does not apply to important conditions such as pregnancy and drugs for chronic illness, as well as cancer therapy and haemodialysis (where the waiting period could be up to two years).

3.5 Regulation at the level of the market

As mentioned earlier, at least nine countries in the region have established competition commissions (Bowman Gilfillan Africa Group 2013). Competition legislation is intended to protect the economy against restrictive practices and monopolies, regulate mergers and prohibit unfair trade practices (including misleading advertising, false bargains, collusion etc.). The legislation can also regulate the private health sector, especially with respect to vertical and horizontal integration and collusion on prices, although most countries have not yet begun to use the competition legislation to this effect.

Two exceptions are South Africa and Zimbabwe. In South Africa, a ruling of the Competition Commission a few years ago inadvertently set back effective regulation of the for-profit sector by outlawing collective bargaining around prices, one of the main instruments used by health insurers to prevent the excessive escalation of fees charged by providers. Consequently, each health insurer has to negotiate prices with individual providers on a bilateral basis. Recent amendments to the competition legislation have now allowed the commission to launch a market enquiry, with wide-ranging powers to subpoena stakeholders and demand information on activities (including underlying costs). This is in order to investigate the causes of cost escalation in the private sector, including unfair business practices by private hospitals (such as collusion on prices), health insurance administrators (such as excessive administrative costs) and specialists (who have a financial interest in the hospital to which they refer). The enquiry, which is due to start at the end of 2013 and

run for two years, is expected to lead to more explicit policy on private sector practices as well as strengthen the hand of the ministry in regulating the private sector.

Zimbabwe's Competition Commission has successfully investigated a number of cases relating to mergers, acquisitions and verticalisation (where health insurers become direct providers of services such as hospitals and ambulances). One of the problems has been how the commission finds out about a merger, and accordingly the Competition Act now requires parties to notify the commission of a planned merger before it is implemented (Republic of Zimbabwe 1996). The penalty for failing to comply is up to 10% of both parties' annual turnover. In Namibia, health insurers also have to report any amalgamation with another business although this seems to be less about promoting competition than ensuring the financial sustainability of the health insurer is not jeopardised.

Further, in Zimbabwe, the Medical Services Act prohibits open medical schemes from obliging beneficiaries to use providers owned by them (although this is allowed for closed schemes) (Republic of Zimbabwe 1998). Zimbabwe's National Incomes and Pricing Commission has intervened in the cost of health insurance.

In South Africa, one of the objectives of new regulations clarifying the demarcation between indemnity and non-indemnity health insurance is to protect the medical schemes market from destabilisation due to 'risk skimming.' Risk skimming is the practice of preferentially enrolling low-risk members in an insurance plan and excluding high-risk members, to reduce the costs faced by the insurer. In South Africa, indemnity insurers use cheap plans (with limited benefits) to attract low-risk members away from the strictly regulated non-indemnity market that is not allowed to exclude high-risk members or charge them higher premiums, and which is obliged to offer a standardised minimum package. This leaves non-indemnity insurers with abnormally high risks (and costs) as well as elevated premiums. This reduces the affordability of non-indemnity cover and the sustainability of non-indemnity insurers. It also reduces risk cross-subsidisation in the health insurance market as a whole.

4. Discussion

The focus of most legislation in all of the eight countries studied (with the exception of Namibia, South Africa and Zimbabwe) is on controlling entry of health professionals and provider organisations into the market through registration. Criteria for registration tend to relate to competence (in the case of health professionals) and minimum levels of resources together with financial sustainability (for organisations).

While all countries make provision for inspection of private facilities, usually annually, the extent to which this happens in practice is not clear. Further, criteria for inspection relate mainly to the level of available resources, rather than to process- and outcome-related measures of the quality of care. While professional councils prosecute the more overt instances of malpractice, the quality of care in the private sector is generally not scrutinised in detail, and the rights of patients are not protected effectively. Strikingly, only Zimbabwe has legislation governing ambulance services.

The objective need for, and priority of, private services is not a major consideration in any country although some countries do have a few provisions that seek to influence the number and distribution of health care services. Neither is the impact of new entrants into the market on the overall stability of the market, and the potential of new or existing organisations to distort markets, generally considered. Only in Zimbabwe has competition law addressed anti-competitive practices.

Apart from market entry, most countries have not been able to develop adequate legislation on voluntary health insurance except perhaps South Africa. Where general insurance legislation regulates health insurers, there are no provisions to deal with the peculiarities of the health care market (such as risk rating and adverse selection) and comprehensive benefit packages are not protected. Even where there is specific health insurance legislation, provisions do not necessarily cover all these areas of concern or protect schemes from having their surplus stripped through unethical practices. Some interventions against anti-competitive behaviour have focused on health insurers without tackling private provision, a major cause of cost escalation.

A decade ago, Soderlund and Tangcharoensathien (2000) characterised most low- and middle-income countries as moving only slowly from a state of 'pre-regulation' to a state of 'paper regulation' where legislation exists without the necessary capacity (and sometimes political will) to enforce it adequately. Generally legislation is often old or "emanates from a common legislative template, rather than a contextual understanding of the private health sector in the country concerned" (Soderlund and Tangcharoensathien 2000: 347). This report shows that, since then, several countries have begun to update and improve their legislation (although, in most cases, this still seems to be without the benefit of an overarching policy guideline on the private sector). In some instances, the approach adopted by some countries could be applied usefully in others.

However, enforcement remains an enormous problem and even the new legislation may not yet be sufficiently focused. 'Regulatory capture' – where those parties who are meant to be regulated are able to influence the content and enforcement of regulations unduly – is probably still a problem, especially as in many countries much of the responsibility for regulating providers still lies with health professions councils. South Africa, for example, has seen a number of lengthy and expensive court cases brought by its powerful private sector against introduction of new legislation, some of which the government has lost, as shown in *Box 6*. Regulatory capture is also a problem where the potential for regulators to subsequently get jobs within the regulated industries is high (Soderlund and Tangcharoensathien 2000: 347).

Even where enforcement is active, sanctions will not have an effect if they are set too low. In many countries, fines seem quite low and prison terms seem too short to act as significant brakes on inappropriate behaviour, especially for large businesses.

Finally, prices do not seem to be controlled – directly or indirectly (through managing the market) – to any meaningful extent in any country. This is the biggest gap in the health legislation (although it has to be addressed along with quality issues) because it means that the private sector is unlikely to become an affordable option for meeting health system objectives.

Within this environment of uneven regulation of the private sector, emerging universal coverage policies that promote strategic purchasing with mandatory prepayment funds provide an opportunity to monitor quality more effectively (through accreditation) and influence the distribution and cost of care (through strategic purchasing arrangements). A new generation of legislation against anti-competitive behaviour also offers some potential for protecting the health market against failure. While greater activity by consumer protection organisations and civil society would also be helpful, there seems to be little activity on this front.

Box 6: Results of key court cases brought by the private health sector against the South African government

2011: requirement for service providers to be paid in full by health insurers for prescribed minimum benefits - UPHELD
2010: a government reference price list for providers – OVERTURNED
2008: prevention of commercial health insurance – OVERTURNED
2008: limited dispensing fee for dispensing doctors – NEGOTIATED OUT OF COURT
2004: limited dispensing fee for pharmacists – OVERTURNED
1997: a single exit price for pharmaceuticals to prevent mark-ups by middle-men, especially private hospitals - UPHELD

5. Conclusions

The above review of the legislation suggests that governments and other policy makers need to embark on a programme of action to strengthen regulatory frameworks and instruments in relation to private health care provision and insurance. Some activities are necessary regardless of whether strategic purchasing policies are implemented, but others will be easier to achieve under a mandatory prepayment system.

Some recommended steps in this programme of action are:

- Develop in-country capacity to evaluate legislation affecting the private health sector against public health and other objectives. This capacity should marry public health, legal and financial skills.
- Develop an overarching policy on the private sector to guide legislation and clarify regulatory objectives. Distinguish the roles of different stakeholders clearly, ensuring a clear separation between funders, purchasers and providers. Ensure that ministries of finance and economic development understand the public health objectives of this policy.
- Rationalise the number of regulatory authorities or harmonise their activities and ensure that regulators and the industry well understand the legal requirements of multiple pieces of legislation. While 'self-regulation' – where peers essentially scrutinise one another's behaviour – can be effective where enforcement capacity and codes of conduct are strong, economic incentives and professional interests can override these benefits.
- Clarify how and where private health professionals and organisations could address the needs of disadvantaged populations and create enabling policy and legislation to facilitate this (including strategic purchasing through mandatory health financing mechanisms).
- Clarify how and where new private health professionals, organisations and products entering the market could distort the health care market and jeopardise health care objectives, and develop legislation or other incentives to control this entry.
- Develop legislation on the quality of health services (including detailed guidelines for primary care, hospital care and emergency services) and on the conduct of health insurers. This should include greater clarity on the classification of different types of facilities, organisations and insurance plans.
- Develop health-insurance specific legislation that addresses the problems of risk rating, adverse selection and fragmented benefit packages.
- Strengthen monitoring systems and create appropriate databases that are adequately maintained. This requires defining the information collection and reporting obligations of the private sector in law, as well as setting penalties for

breach of these obligations. It also requires developing the capacity of government to enforce obligations and use and act on the information.

- Develop the capacity to enforce legislation, including adequate and timely inspections and renewal of certificates (setting the period for renewal of certificates at realistic intervals to improve the likelihood of enforcement). In countries with decentralised health systems, investigate opportunities for decentralising enforcement as a way of developing capacity as well as the responsiveness of decision-making.
- Review the sanctions for misconduct and set them at appropriate levels.
- Create greater transparency, inform patients, health insurance beneficiaries and the public at large of their rights, and strengthen the accountability of regulatory authorities, health care providers and health insurers.
- Develop direct and indirect mechanisms for reducing cost escalation, especially within the hospital sector but also in relation to the administration of health insurers.
- Investigate and act against anti-competitive behaviour.

As mentioned at the beginning of this report, legislation is not the only route for regulating the private sector and can be complex and costly to implement. Strengthening legislation should be accompanied by the development of both positive and negative incentives (such as alternative reimbursement mechanisms) that also help to shift the behaviour of the private health sector.

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Appendix 1: Country information

Angola

No relevant information in English was found although the constitution enshrines the right to health, recognises the role of the private sector and requires it to operate within the law (Mulumba, Kabanda et al. 2010; World Bank and International Finance Corporation 2011).

Botswana

In this country fragmented insurance schemes serve different groups, covering 17% of the population and managing just over 10% of total health expenditure (Botswana Ministry of Health 2009; Botswana Ministry of Health 2012b; Munyuki 2013). Private, for-profit hospitals account for 12.5% of expenditure (Botswana Ministry of Health 2012a).

The constitution provides little protection of the right to health (Mulumba, Kabanda et al. 2010). The Public Health Act governs the health sector and is currently under revision (Botswana Ministry of Health 2012b). The new health policy of 2011 includes active involvement of the private sector as one of its guiding principles and intends introducing new legislation and norms to govern the practice of all providers (Botswana Ministry of Health 2012b).

The Ministry of Health currently licenses private hospitals and nursing homes that fulfil minimum standards laid out in the Private Hospitals and Nursing Homes Act and accompanying regulations. These standards are not detailed, leaving much to the discretion of the ministry. The act makes provision for inspection by the Ministry of Health as well as sanctions such as fines, imprisonment and revoking of licences. There does not seem to be similar legislation governing primary care facilities (or whether public professionals may work in the private sector). Neither does there seem to be regulation that controls, in line with national health care objectives, where private facilities are set up, what services they provide and whether dispensing is allowed. The World Bank and International Finance Corporation (2011) assert that the dominant, facility oversight mechanism is inspection for accreditation by the insurance authority as this is necessary for providers to receive reimbursement.

The Health Professions Act governs professionals, requiring them first to register before they can practise and then be licensed to work in private practice. There do not seem to be price controls for private providers.

In 2010, around 17% of the Batswana population was covered by health insurance (Munyuki 2013). Health insurance operators tend to register as voluntary societies under the Societies Act. The provisions of this act do not capture the prudential requirements generally associated with insurance legislation (interview data). In addition, this act allows health insurance operators to declare a surplus, rather than profits, which allows them to escape taxation. It would be more appropriate for medical aid societies to fall under the Insurance Industry Act and be supervised by the Non-Bank Financial Institutions Regulatory Authority, which reports to the Ministry of Finance. However, even under this arrangement the legal provisions would not address many issues specific to health insurance. A further complication is that, should foreign-owned insurance companies provide health insurance in Botswana, they would fall under a different act, the International Insurance Act. At present, however, most medical aid societies are locally owned (Munyuki 2010).

There is a Competition Act (Bowman Gilfillan Africa Group 2013), but there is no information on whether it has been used to address anti-competitive behaviour in the health market.

In effect, therefore, medical aid societies largely self-regulate, and for many years it has been argued that this system should be replaced by a specific regulatory framework for health insurance and health insurers (interview data).

A more detailed summary of the legislation appears below, as well as references for the acts mentioned in the text above.

Summary of private health sector legislation in Botswana

Form of regulation	Relevant legislation and provisions
General legislation governing the health sector	
Constitutional protection of the right to health	Little or no protection of the right to health.
General intention of health policy and legislation to regulate the private sector in line with government's objectives	Public Health Act (Chapter 63:01) of 2002: The act is currently under revision. Active involvement of the private sector is one of the guiding principles of the new health policy published in 2012. The intention is to actively regulate private providers.
Regulatory authorities	Private Hospitals and Nursing Homes Act (Chapter 63:05) of 2001: Ministry of Health. Health Professions Act (Act 17, Chapter 61:02) of 2001: Health Professions Council. Societies Act 23 (Chapter 18:01) of 1983: Registrar of Societies. Non-bank Financial Regulatory Authority Act (Chapter 46:08): Non-bank Financial Institutions Regulatory Authority. Competition Act 17 of 2009 and accompanying regulations: the Botswana Competition Commission assisted by the High Court of Botswana.
Legislation governing health professionals	
Registration of health professionals	Health Professions Act (Act 17, Chapter 61:02) of 2001: Health professionals need to register with council before they can practise.
Maintaining professional skills and professional behaviour	This requirement does not appear in the above act but may be a requirement of the council.
Legislation governing hospital and nursing home providers	
Licensing and accreditation of hospitals and nursing homes	Private Hospitals and Nursing Homes Act (Chapter 63:05) of 2001 and accompanying regulations*:* The act requires fulfilment of certain requirements with respect to types of services provided, levels of resources, quality of care, safety, record keeping, reporting and the presence of a suitably qualified superintendent. The licence specifies the maximum number of patients. The facility cannot be used for any purpose other than that stipulated in the licence. Many of these requirements are subject to the discretion of the ministry. There are provisions for annual inspections. The licence is valid for five years and may be renewed. Sanctions are fines, imprisonment and revoking of licence.
'Certificate of need' governing location of facilities	No information on this could be identified.
Standards and norms	Private Hospitals and Nursing Homes Act (Chapter 63:05) of 2001 and accompanying regulations*:* There is some detail on the type and quality of accommodation required. The only detail the regulations contain on the quality of health care is on operations. More detailed norms are reportedly being planned.
Reporting requirements	Private Hospitals and Nursing Homes Act (Chapter 63:05) of

for facilities	2001 and accompanying regulations*:* The act requires a patient register to be kept. Deaths have to be reported to the minister within 48 hours. The regulations stipulate that patient records must be kept for at least 10 years. An operations register and a record of drug purchase and use must also be kept.
Price controls	No information on this could be identified.
Provisions to promote competition	Competition Act 17 of 2009 and accompanying regulations: general provisions.
Legislation governing private ambulances and emergency medical services	
	No information on this could be identified.
Legislation governing primary care and specialist providers	
Registration and licensing of primary care practitioners and facilities	Health Professions Act (Act 17, Chapter 61:02) of 2001: Health professionals need to be licensed to work in private practice.
Standards and norms	These are apparently being planned.
'Certificate of need' governing location of facilities	No information on this could be identified.
Regulation of dispensing and other clinical support services by primary providers	No information on this could be identified.
Control of private practice by public professionals	No information on this could be identified.
Reporting requirements	No information on this could be identified.
Price controls	No information on this could be identified.
Provisions to promote competition	Competition Act 17 of 2009 and accompanying regulations: general provisions.
Legislation governing health insurers	
Registration and demarcation of different types of health insurance	Societies Act 23 (Chapter 18:01) of 1983: Requires the registration of medical aid societies but does not require demarcation.
Promotion of competition	Competition Act 17 of 2009 and accompanying regulations: The regulatory authority is the Botswana Competition Commission assisted by the High Court of Botswana.
Control of risk rating and adverse selection	This does not exist.
Standardised benefit packages	This does not exist.
Price controls	This does not exist.
Reporting requirements	Insurance Industry Act (21 of 1987) for domestic and International Insurance Act (5 of 2005) for foreign insurers: These only exist with respect to the financial requirements for general insurance.
Solvency	Insurance Industry Act (21 of 1987) for domestic and International Insurance Act (5 of 2005) for foreign insurers: These only exist with respect to the financial requirements for general insurance.
Provisions to promote competition	Competition Act 17 of 2009 and accompanying regulations: General provisions.

Note: This table may contain gaps and inaccuracies. The table only addresses legislation governing health care professionals (with a focus on doctors), health care providers (with a focus on private hospitals) and health insurers. The pharmaceutical industry is not addressed.

Electronic sources for acts: Botswana Attorneys General Chambers 2013.
Other sources: Botswana Ministry of Health 2009; Mulumba, Kabanda et al. 2010; Munyuki 2010; World Bank and International Finance Corporation 2011; Botswana Ministry of Health 2012a; Botswana Ministry of Health 2012b; Bowman Gilfillan Africa Group 2013; Munyuki 2013.

Democratic Republic of Congo

No relevant information in English was found.

Kenya

The new constitution that came into effect in 2010 provides protection of the right to health for the first time (Mulumba, Kabanda et al. 2010; Kenya Ministry of Medical Services and Kenya Ministry of Public Health and Sanitation date unknown). In addition, the country is undergoing extensive devolution to local governments. The Public Health Act of 2002 gives the Ministry of Health the right to regulate the private sector, but delegates extensive responsibility for implementing this regulation to the professional boards and to the Ministry of Local Government. This act is due to be replaced by a General Health Law that is in the early stages of development and will reflect the constitutional changes.

Government currently licenses both hospital and primary care facilities that fulfil minimum standards laid out in the Medical Practitioners and Dentists Act and the accompanying Medical Practitioners and Dentists (Private Practice) Rules. The same acts also require practitioners to be licensed before they are allowed to work in private practice, while the Local Government Act requires public professionals to gain permission from their health authority and the minister before engaging in private practice. These overlapping mandates for licensing and inspection cause some confusion regarding which institution has prime responsibility (World Bank and International Finance Corporation 2011). Further, facilities have to be accredited under the National Hospital Insurance Fund Act to be reimbursed by the fund.

The requirements of these acts deal mainly with resource levels and qualifications, and do not refer to standards of quality of care and requirements for reporting. It appears that the board sets and reviews the fees charged by practitioners and facilities. The acts provide for inspection as well as sanctions such as fines, imprisonment and revoking of licences.

A decade ago a study identified several problems enforcing these provisions (Muthaka, Kimani et al. 2004). Private clinics expanded rapidly and the government had difficulty checking the entry of unqualified practitioners into this market due to resource and capacity constraints in the Ministry of Health, Central Board of Health, Medical Practitioners and Dentists Board, Clinical Officers Council, Nursing Council of Kenya, Pharmacy and Poisons Board and the Ministry of Local Government. Many private facilities, including clinical and radiological laboratories, operated without having sought approval and many health professionals misrepresented their qualifications or practice without having achieved the required qualification. Pharmacists were increasingly involved in diagnosis and treatment, but the legislation treated them as private businesses rather than health providers, which meant that regulation of their behaviour was weak. Many clinics were in residential premises, which is against the law, and there were problems arising from private practice by publicly employed officials. There were also accusations that professional boards were often reluctant to act against professionals that had transgressed, even when malpractice was reported. All of these problems would have compromised the quality of care (see *Box A*). The situation has apparently changed but it is not clear to what extent.

There is some incentive for practitioners to work in rural areas as the law allows them to register two facilities in these areas as opposed to the usual one. Licensing also requires private laboratories and radiological services to serve the surrounding population and facilities. The fact that practitioners are usually only allowed to run one

practice may be an attempt to control the supply of private facilities and increase competition.

There does not seem to be specific legislation governing private health insurers, which seem to fall under the general conditions of the Insurance Act (as do medical insurance brokers). This act does lay out solvency and reporting requirements but says nothing about contribution levels, risk rating, exclusions, benefit packages and the like. There is a new Competition Act No. 12 of 2010 that came into force in 2011 and established the Competition Authority, but accompanying regulations that give better effect to the act do not yet seem to have been written (Bowman Gilfillan Africa Group 2013).

In summary, Kenya does not have an official overarching policy on the private sector, but existing legislation does attempt to control the supply, cost and quality of different providers through compulsory licensing. As in all countries, there are challenges to the enforcement of regulations, and specific legislation governing the behaviour of private health insurers is lacking.

Recent proposals put forward by health sector stakeholders towards a committee investigating implementation of the new constitution have highlighted the importance of creating an overall framework for government's relationship with the private health sector and the integration of this approach into all health policies and legislation (Kenya Ministry of Medical Services and Kenya Ministry of Public Health and Sanitation date unknown).

A more detailed summary of the legislation appears below, as well as references for the acts mentioned in the text above.

Box A: The consequence of poor regulation of the private sector in Kenya in the past

- Mushrooming of unregistered clinics and laboratories
- Doctors operating illegally more than one clinic
- Facilities operating without meeting the legal requirements
- Unregistered persons providing health care, including 'quacks'
- Poor physical infrastructure
- Poor equipment or inappropriate technology
- Medical malpractices and negligence
- Low-health standards
- Corruption during licensing and inspection
- Poor inspection
- Use of unapproved premises for provision of medical services
- No requirement for health professionals to update their skills
- No laws to protect patients against negligent staff

Adapted from: Muthaka, Kimani et al. 2004.

Summary of private health sector legislation in Kenya

Form of regulation	Relevant legislation and provisions
General legislation governing the health sector	
Constitutional protection of the right to health	The previous constitution did not protect the right to health (except for children through the Children Act 8 of 2001) but the recent version of 2010 does, including the right to emergency treatment.
General intention of health policy and legislation to regulate the private sector in line with government's objectives	Public Health Act (Chapter 242): This gives the ministry the authority to regulate the private sector and to carry out inspections. If other acts conflict with its provisions, its provisions prevail. The act empowers local authorities to provide hospitals and carry out inspections. Currently there are recommendations to improve the constitutionality of health services, including creating an overall framework for government's relationship with the private sector and

	the integration of this approach into all health policy and legislation.
Regulatory authorities	Public Health Act (Chapter 242): Central Board of Health (plus Ministry of Health and Local Authorities). Medical Practitioners and Dentists Act (Chapter 253) of 1978: The Medical and Dental Practitioners Board (plus Ministry of Health). Local Government Act: Local Authorities (plus Ministry of Local Government). Insurance Act: The Insurance Regulatory Authority.
Legislation governing health professionals	
Registration of health professionals	Medical Practitioners and Dentists Act (Chapter 253) of 1978; Medical Practitioners and Dentists (Private Practice) Rules of 2000; Nurses Act (Chapter 257); Clinical Officers Training Registration and Licensing Act: The boards govern the entry of appropriately trained graduates into the professions through licensing that allows them to work, in the first instance, in the public sector only. There are sanctions for fraudulent licences (e.g. fines, imprisonment, revoking of licence), including for misrepresenting oneself as a qualified health professional. Tort law (for prosecuting medically negligent health professional), which is part of Common Law, is not well developed.
Maintaining professional skills and professional behaviour	Medical Practitioners and Dentists Act (Chapter 253) of 1978; Medical Practitioners and Dentists (Private Practice) Rules of 2000: The acts entitle the boards to oversee university training in order to preserve standards, and are responsible for maintaining standards of practice. Continuing professional development is a requirement for all health professionals.
Legislation governing hospital and nursing home providers	
Licensing and accreditation of hospitals and nursing homes	Medical Practitioners and Dentists (Private Medical Institutions) Rules of 2000; National Hospital Insurance Fund (Accreditation) Regulations of 2003: The first act requires annual registration of all private facilities, along with registration of private practitioners (see below), by the Medical Practitioners and Dentists Board. Entry criteria are minimal, focusing mainly on the level of resources availability and the presence of a suitably qualified superintendent, rather than the quality of care. Facilities must also be accredited (or 'declared hospitals') under the National Hospital Insurance Fund Act in order to be eligible for reimbursement, providing they meet minimum criteria: it is not clear whether these criteria are more stringent.
'Certificate of need' governing location of facilities	Does not seem to exist.
Standards and norms	Medical Practitioners and Dentists (Private Medical Institutions) Rules of 2000; National Hospital Insurance Fund (Accreditation) Regulations of 2003: No detail was accessed.
Reporting requirements for facilities	Medical Practitioners and Dentists Act (Chapter 253) of 1978; Medical Practitioners and Dentists (Private Medical Institutions) Rules of 2000: Hospitals must report every six months on which doctors and dentists are working for them and, if they have admitting rights, the place of their primary care clinics. They must also ensure that these health professionals do not practise outside their area of competence. There are supposed to be annual returns to the Health Information System but there is only a two-thirds response rate, plus there are problems with classification and coding hampers interpretation.
Price controls	National Hospital Insurance Fund (Accreditation) Regulations, 2003: Daily rates are set by the board for facilities accredited for the fund, according to the type of facility and services.
Provisions to promote competition	Competition Act No. 12 of 2010: The Minister of Finance may develop regulations under this act to give better effect to these provisions but these have not yet been forthcoming.
Legislation governing private ambulances and emergency medical services	
	No information on this could be identified.

Legislation governing primary care providers	
Registration and licensing of primary care practitioners and facilities	Medical Practitioners and Dentists Act (Chapter 253) of 1978; Medical Practitioners and Dentists (Private Practice) Rules of 2000: An additional (annually renewable) licence is required for a doctor to work in private practice. Nurses and clinical officers are also permitted to work in the private sector, although their legislation has not been reviewed in detail: the main difference is that, before receiving a private practice licence, these categories need to have worked in the public sector for at least ten years, whereas only three years is required for doctors and dentists. The licence is issued in relation to specific premises, and a facility licence is required. Licences cannot be transferred between individuals or premises. There are sanctions for fraudulent licences (e.g. fines, imprisonment, revoking of licence).
Standards and norms	Medical Practitioners and Dentists Act (Chapter 253) of 1978; Medical Practitioners and Dentists (Private Practice) Rules of 2000: Basic norms and standards are laid out, especially with respect to the resources that must be supplied.
'Certificate of need' governing location of facilities	Medical Practitioners and Dentists (Private Practice) Rules of 2000: Practitioners are allowed to run up to two clinics but these have to be within 20km of each other. There is no 'certificate of need' requirement for equipment.
Regulation of dispensing and other clinical support services by primary providers	Medical Practitioners and Dentists (Private Practice) Rules of 2000: Private clinics are required to stock essential drugs and keep adequate reports. Some clinical and radiological laboratory services are allowed under licence, depending on the presence of a suitably qualified person. Clinical and radiological laboratories are required to serve the surrounding community.
Control of private practice by public professionals	Local government Act (Chapter 265) of 1963. Section 138. Restriction on engaging in private practice etc.: Medical officers and public health officers may not engage in private practice without the consent of the health authority and minister. This is confined to senior doctors. In practice, rules are not always followed, however.
Reporting requirements	Medical Practitioners and Dentists (Private Practice) Rules of 2000: Practices must keep a record of drugs used and must also report deaths and notifiable diseases. Only about 50% of clinics report as required.
Price controls	Medical and Dental Practitioners Act (Chapter 253) of 1978; Medical Practitioners and Dentists (Private Practice) Rules of 2000: No fees may be charged unless the practitioner has a private licence. The private practice committee set up to grant licences can review the fees. A board sets the fees for general practitioners, specialists and clinical and radiological laboratories.
Provisions to promote competition	Medical and Dental Practitioners Act (Chapter 253) of 1978; Medical Practitioners and Dentists (Private Practice) Rules of 2000; Competition Act 12 of 2010: Doctors may only run one private clinic (unless they are in a rural area, in which case they may run two). However, there is no limit on the number of hospitals the owners may run. It is not clear whether the competition law affects primary care practitioners.
Legislation governing health insurers	
Registration and demarcation of different types of health insurance	No specific legislation was found for voluntary private health insurers that seem to be covered under general insurance legislation, namely, Insurance Act of 1987 (Chapter 487) and revisions and accompanying regulations.
Control of risk rating and adverse selection	Private voluntary insurers are covered by general insurance legislation so there are no specific provisions against risk rating.
Standardised benefit packages	There is no legislation on this governing voluntary health insurance.
Price controls	Brokers need to be registered under the Insurance Act.
Reporting	These were not accessed.

requirements	
Solvency	This is controlled through the general Insurance Act of 1987 (Chapter 487) and is not necessarily sufficient for health insurance purposes.
Provisions to promote competition	Competition Act No. 12 of 2010: The Minister of Finance may develop regulations under this act to give better effect to these provisions but these have not yet been forthcoming.

Note: This table may contain gaps and inaccuracies. The table only addresses legislation governing health care professionals (with a focus on doctors), health care providers (with a focus on private hospitals) and health insurers. The pharmaceutical industry is not addressed.

Sources of acts and other information: Kububa 2004; Muthaka, Kimani et al. 2004; Kasimbazi, Mulumba et al. 2008; Kububa 2009; Mulumba, Kabanda et al. 2010; World Bank and International Finance Corporation 2011; Bowman Gilfillan Africa Group 2013; National Council for Law Reporting 2013; Kenya Ministry of Medical Services and Kenya Ministry of Public Health and Sanitation date unknown; Kenya Ministry of Public Health and Sanitation and Kenya Ministry of Medical Services date unknown.

Lesotho

No legislation for this country was accessed. The constitution apparently recognises the right to health, and the protection of health is noted as a principle guiding government (Mulumba, Kabanda et al. 2010). A new Public Health Act is apparently under development. The country engages actively in public private partnerships, but inspection of private facilities is apparently problematic due to overlapping mandates between different authorities (such as the Ministry of Health, municipality and district health office), leading to confusion around who holds final responsibility for inspections (World Bank and International Finance Corporation 2011).

Madagascar

No relevant information in English was found but the constitution does provide for the right to health (Mulumba, Kabanda et al. 2010). Also, there is a Competition Law (No. 2005-020 of 17 October 2005) and an implementing decree (No. 2008-771 of 28 July 2008), but the Competition Council is not yet fully functional (Bowman Gilfillan Africa Group 2013). Inspection of private sector facilities is reportedly sporadic (World Bank and International Finance Corporation 2011).

Malawi

Little information was found for this country except that the constitution does provide for the right to health (Mulumba, Kabanda et al. 2010). The Public Health Act (Chapter 34:01) of 1948 does not refer to the regulation of private providers and insurers. However, there is a Competition and Fair Trading Act (No. 43 of 1998) that is enforced by the Competition and Fair Trading Commission (Bowman Gilfillan Africa Group 2013).

Mauritius

No health legislation could be accessed although this country's constitution does enshrine the right to health, there is active dialogue and information exchange between the public and private sectors, and legislation governing the private health sector is apparently relatively well developed (Mulumba, Kabanda et al. 2010; World Bank and International Finance Corporation 2011). Also, there is the Competition Act of 2007 that set up the Competition Commission (Bowman Gilfillan Africa Group 2013). One problem noted by the World Bank and International Finance Corporation (2011) is that there is no requirement for private practices to be registered as these are classified merely as consultation rooms, thereby escaping the provisions of legislation governing the registration of private clinics.

Mozambique

No English-language legislation could be accessed on the private sector; however, the constitution enshrines the right to health and medical services within a national health system and requires the private sector to operate within the law.

Namibia

This is one of the few countries that has dedicated legislation governing health insurers. The registrar now falls under the umbrella body for financial institutions, which implies that he/she is answerable to the Minister of Finance. These regulations appear to be mainly concerned with financial sustainability and do not specify benefit packages and measures against risk rating.

Private hospitals need to be licensed, and some broad standards are mentioned in the legislation although these focus mainly on inputs. There is a requirement that licensing should ensure private provision is in the public interest although this is not defined. Primary care facilities do not seem to be governed by any legislation.
A more detailed summary of the legislation appears below, as well as references for the acts mentioned in the text above.

Summary of private health sector legislation in Namibia

Form of regulation	Relevant legislation and provisions
General legislation governing the health sector	
Constitutional protection of the right to health	There is no express provision for the right to health but other provisions protect welfare and the right to life.
General intention of health policy and legislation to regulate the private sector in line with government's objectives	No information was accessed.
Regulatory authorities	Medical and Dental Act (Act 10 of 2010): Medical and Dental Council. Medical Aid Funds Act (Act 23 of 1995): Ministry of Health appoints a Registrar of Medical Aid Funds. The registrar is entitled to investigate funds' business practices and rules and demand that they be altered if they jeopardise financial stability. Funds are entitled to appeal against the registrar's decisions to the Ministry of Health. Inspection of Financial Institutions Act (Act 38 of 1984) and Namibia Financial Institutions Supervisory Authority Act (Act 3 of 2001) (these are under review): Ministry of Finance oversees the Namibia Financial Institutions Supervisory Authority (since 2001, the CEO of this authority is also the Registrar of Medical Aid Funds and other authorities overseeing financial institutions, which implies that they may no longer be directly answerable to the Minister of Health). Namibian Association of Medical Aid Funds (for all registered funds and managed by seven representatives of these funds): The association has authority to investigate inappropriate practices by its members and impose penalties. These may be appealed at the High Court. The Competition Act 2 of 2003: the Competition Commission.
Legislation governing health professionals	
Registration of health professionals	Medical and Dental Act (No. 10 of 2004): The act entitles the council to oversee university training in order to preserve standards, and also license doctors and dentists to work as health professionals (and as specialists), provided they have received appropriate training and receive continuing professional development. It is also responsible for maintaining their standards of practice and behaviour. Similar acts exist for other health professionals, but these were not reviewed.
Maintaining	Medical and Dental Act (No. 10 of 2004): The council oversees

professional skills and professional behaviour	university training to preserve standards and is also empowered to require continuing education. It is also empowered to scrutinise practice and inspect premises. It can act against unprofessional behaviour.
Legislation governing hospital and nursing home providers	
Licensing and accreditation of hospitals and nursing homes	Hospitals and Health Facilities Act (Act 36 of 1994); Hospitals and Health Facilities Amendment Act (No. 1 of 1998): Letting of government rooms for private purposes is allowed with the agreement of the minister. Private hospitals and facilities may be licensed if they comply with physical infrastructure and human resource requirements, and it is deemed in the public interest to do so. A licence may be withdrawn if the hospital is run inappropriately, fails to comply with provisions or it is not in the public interest.
'Certificate of need' governing location of facilities	This does not seem to exist. One of the conditions of granting a licence is that it is in the public interest, a provision that could possibly be used to influence the location of private facilities.
Standards and norms	Hospitals and Health Facilities Act (Act 36 of 1994): The act contains broad statements about adequate physical infrastructure, enough staff and appropriate running of the business. It could not be ascertained if there are more detailed regulations on the quality of care.
Reporting requirements for facilities	Hospitals and Health Facilities Amendment Act (No. 1 of 1998): A subsidised private facility must submit annual reports and audited financial statements.
Price controls	These do not seem to exist.
Provisions to promote competition	The act empowers the minister to subsidise a private hospital or facility, in consultation with the Minister of Finance and out of finances appropriated by law for that purpose.
Legislation governing private ambulances and emergency medical services	
	No information on this could be identified.
Legislation governing primary care and specialist providers	
Registration and licensing of primary care practitioners and facilities	It does not seem that there is legislation governing primary care facilities.
Standards and norms	
'Certificate of need' governing location of facilities	
Regulation of dispensing and other clinical support services by primary providers	
Control of private practice by public professionals	
Reporting requirements	
Price controls	
Provisions to promote competition	
Legislation governing health insurers	
Registration and demarcation of different types of health insurance	Medical Aid Funds Act (Act 23 of 1995): Funds are required to register within two months of commencing business. The registrar must be satisfied that the fund is in the public interest and that it will be run according to sound business practices, especially with respect to financial stability. The registrar is granted the same powers towards an unregistered fund as to a registered fund if the former is deemed to be carrying out the business of a fund. The act excludes funds established in terms of an insurance policy, as well as schemes

	established by government. The registrar may cancel the registration of a fund should it contravene the act's rules or engage in unsound practices.
Control of risk rating and adverse selection	Medical Aid Funds Act (Act 23 of 1995): No one can be obliged to become a member simply by becoming an employee, or can be excluded because married to a member. Someone transferring to another fund because of a change of employer, or because no longer a dependent, cannot be subjected to a waiting period or have new restrictions placed on benefits due to his/her state of health (provided that he/she has been a member of a fund continuously for the previous two years and has applied for admission to a new fund within three months of leaving the previous scheme). The same applies for pensioners, widows/widowers and dependents who switch funds to which they (or their partner/parent) had belonged because of their employer. No one can be a member of more than one fund.
Standardised benefit packages	There do not seem to be any legal requirements for the type and amount of benefits, although these do have to continue after employment terminates due to age/retirement, illness or disability. Benefits also have to continue for a dependent on the death of a member until becoming eligible to become a member, or becoming a dependent on another scheme.
Price controls	There do not seem to be any.
Reporting requirements	Medical Aid Funds Act (Act 23 of 1995): The act provides for inspection of the affairs of medical aid funds. Funds are required to submit annual financial statements and reports to the registrar within six months of the close of the financial year. It appears that financial and sustainability issues are the main concern, but there is a requirement that funds demonstrate that they have used funds efficiently and effectively. Funds are required to produce any documentation required by the registrar within an undefined period stipulated by the registrar (and may apply for this period to be extended). The registrar is also empowered to interrogate the accuracy of these documents (e.g. through an auditor or actuary). The registrar must report annually to the minister who tables the report in parliament. Funds also have to report on any amalgamation with another business. Funds are required to provide members with the rules of the fund and annual financial statements.
Solvency	Medical Aid Funds Act (Act 23 of 1995): The registrar is empowered to require funds to change their business practices and rules in order to improve financial stability. The registrar may also apply to a court to have a fund placed under management should it not appear financially sound. Voluntary or automatic liquidation of a fund may occur according to its pre-established rules, although the registrar must oversee this process. The Namibia Financial Institutions Supervisory Authority uses 25% of gross contributions as its benchmark for funds.
Provisions to promote competition	The Competition Act 2 of 2003: Funds have to report on any amalgamation with another business. There is a provision that amalgamation must not harm the interests of members and the registrar must be convinced that it does not harm the fund's ability to remain financially viable and carry out its responsibilities.

Note: This table may contain gaps and inaccuracies. The table only addresses legislation governing health care professionals (with a focus on doctors), health care providers (with a focus on private hospitals) and health insurers. The pharmaceutical industry is not addressed.

Sources of information on acts: country contacts; Bowman Gilfillan Africa Group 2013.

South Africa

South Africa has a large and sophisticated private sector. Private non-indemnity health insurance (known as 'medical schemes' in South Africa) accounts for around 42% of total health expenditure although these schemes only cover 16% of the population. The fact that the majority of health professionals, excluding enrolled nurses, have been attracted by higher salaries and bettering working conditions to work in the private sector poses one of the biggest challenges to strengthening the public health system on which the majority of the popuation relies. Consequently, South Africa has a highly inequitable, two-tier health system.

The Health Professions Council, Nursing Council and Pharmacy Council play an active role in overseeing the quality of university training, developing scopes of practice, registering health professionals and maintaining standards of professional behaviour. Continuing professional education is a requirement. Registration is strongly enforced because health insurers are legally only allowed to reimburse registered doctors. The councils rely on formal complaints to pick up cases of negligence or malpractice and, for the most part, the maintenance of quality care in the private sector relies up self-regulation by health professionals.

There is limited legislation governing private facilities. New hospitals have to be licensed and comply with the Department of Health's building and equipment regulations. While the National Health Act makes provision for a 'certificate of need', this is controversial and has never been proclaimed: provincial departments of health apply some principles of need in their licensing decisions, but these do not in effect control the supply of hospital beds, and are applied unevenly across the country (interview data). Licensing is followed by annual re-inspection that is reportedly well coordinated, fair and transparent (World Bank and International Finance Corporation 2011). A factor contributing to the presence of an up-to-date registry of public facilities is that health insurers are legally only allowed to reimburse those that are registered.

The only other piece of relevant legislation prohibits the stocking and sale of drugs by private practitioners unless licensed (with licensing requiring evidence of specific training in dispensing, and adequate drug storage facilities). There is no legislation govering primary care facilities or ambulances and emergency services (although paramedics are governed by the Health Professions Council). Neither is there any monitoring of the quality of care provided by private providers except through voluntary accreditation through the independent Council for Health Service Accreditation in South Africa.

In 2011 the Department of Health published the first set of standards monitoring the quality of care. These apply across all facilities, public and private, and at primary and hospital level. A bill that will establish an Office of Health Standards Compliance within the Department of Health to enforce these standards is nearing enactment. In future, facilities will be required to meet the minimum standards before they can be accredited, while more sophisticated standards will be used to encourage facilities to continuously improve their quality.

Over the years there have been attempts by several bodies to regulate or at least influence the tariffs charged by providers. In the past, the Ministry of Health has published a National Reference Price List, the association of doctors has published guideline tarifs, the association of health insurers has published the rates at which it is prepared to pay providers and, recently, the Health Professions Council has attempted to publish rates over charges it deems to be unfair (but has had to withdraw them following outrage on the part of providers). In 2004 the Competition Commission ruled that groups of stakeholders setting rates (such as the Assocation

of Health Insurers) amounts to price fixing and is illegal. Consequently, health insurers have to negotiate rates with providers on a bilateral basis.

Following a period of deregulation in the 1990s, the Medical Schemes Act and a raft of supporting regulations introduced since 2000 extensively regulate non-indemnity health insurers. A well-capacitated statutory body, the Council for Medical Schemes, implements this legislation. The regulations focus on ensuring a minimum benefit package together with treatment protocols and guidelines, prohibiting risk rating and preventing unethical practices around stripping the surplus from the non-profit schemes (through inappropriate reinsurance practices and overly high administrative costs). Measures protecting solvency are also in force. An independent regulatory authority, the Council for Medical Schemes, enforces the act.

Despite these advances, the medical schemes environment is highly fragmented, offering more than 400 plans covering on average only 20,000 beneficiaries each. The administrative costs associated with the medical schemes industry are also high: the reasons for this are contested, but critics argue that for-profit administrators, managed care companies and brokers are charging unnecessarily high fees. The governance of open schemes is weak as the trustees and management of schemes are seldom sufficiently skilled to oversee or even monitor the performance of administrators adequately (interview data).

As in other countries, the national treasury regulates indemnity-related health insurance. Unlike in most other countries, the demarcation between this form of insurance and non-indemnity insurance has been relatively well defined through medical schemes legislation and a demarcation agreement with government signed by long-term insurers in 2004 (Still 2012). In 2012, the national treasury published new regulations refining this demarcation for public comment. The intention was to regulate practices by the short-term insurance industry that have encroached on the terrain of medical schemes and threatened the cross-subsidisation of risk on which the concept of medical schemes relies. The differences between medical schemes and other health insurance are summarised in *Box B*.

Box B: Difference between indemnity and non-indemnity health insurance in South Africa

Feature	**Indemnity insurance (health insurance)**	**Non-indemnity insurance (medical schemes)**
Governing legislation	Long-term or short-term Insurance acts	Medical Schemes Act
Regulatory body	Financial Services Board	Medical Schemes Council
Profit-making status	Profit-making	Non-profit entities belonging to members (although can be administered by a profit-making company)
Risk-rating and exclusion of high-risk individuals or conditions	Allowed	Not allowed
Premiums	For the same cover, vary according to age, health status or income of individual	For the same cover, uniform across ages and health status
Reimbursement of claims	Not directly related to provider costs (lump sums)	Directly related to provider costs

Sources: Theron, Erasmus et al. 2010; National Treasury (Republic of South Africa) 2012.

In late 2013, the Competition Commission is launching a 'market enquiry' specifically targeted at health care providers (especially hospitals) and health insurers. Through an amendment of the commission's governing act, the inquiry has the authority to subpoena stakeholders and request the submission of data, as well as to impose hefty fines on firms that engage in price fixing, collusive tendering, market allocation and other practices. The purpose of the enquiry is to understand whether anti-competitive behaviours are contributing to continuing cost escalation. It is expected that the findings of the commission will lead to wide-ranging changes in policy, especially with respect to negotiated tariffs for private providers (which will eliminate co-payments), more efficient provider reimbursement mechanisms and incentives for greater transparency around private sector costs (interview data).

Another development in the legislative environment is also expected to have repercussions for the private health sector, namely, the Consumer Protection Act 68 of 2008 that came into effect in 2011. Not only do some of the provisions of the act conflict with the regulations governing medical schemes (specifically with respect to strategies to prevent adverse selection, such as waiting periods and late joiner penalties), but they empower consumers to challenge unethical and unfair practices more actively (Still 2012).

A proposed national health insurance policy, which includes the contracting of private providers, especially at primary care level, will certainly influence formal relationships between the Ministry of Health and the private sector. Strategic purchasing (such as capitation payments) and accreditation are expected to become strong levers for cost control in the private sector. For this and other reasons, implementation of national health insurance has become a priority, and detailed efforts in the early 2000s to develop a comprehensive policy on the private sector, and broker a comprehensive agreement between the two sectors, are on the back burner,[1] at least until the Competition Commission concludes its enquiry at the end of 2015 (interview data). A 'social compact' has however been signed between the Minister of Health and some elements of the private sector. This compact is supposed to involved twice-yearly meetings between the minister and the CEOs of the 23 participating pharmaceutical, private hospital and medical scheme administration companies, as well as the creation of a Public Health Enhancement Fund that will fund certain aspects of health personnel training through donations by the private sector.

A more detailed summary of the legislation appears below, as well as sources for the acts and other information mentioned in the text above.

Summary of private health sector legislation in South Africa

Form of regulation	Relevant legislation and provisions
General legislation governing the health sector	
Constitutional protection of the right to health	The constitution has a strong provision for the right to health, especially for children, but also, in terms of 'basic health services' for the rest of the population.
General intention of health policy and legislation to regulate the private sector in line with government's objectives	National Health Act (No. 61 of 2003): This recognises the right of everyone to health care within a decentralised, quasi-federal health system and proposes a unified health system encompassing public and private services. It empowers the Ministry of Health to co-ordinate the relationships between the two sectors and develop guidelines for standards and monitoring. Beyond this, there is no official, comprehensive policy on the private health sector although there were in-depth consultations

[1] These included in-depth consultations between the public and private sectors around the public-private mix and the publication of a draft Charter for the Public and Private Health Sectors. Neither of these processes resulted in a formal policy or agreement between the two sectors because of the differing interests of the different stakeholders (interview data).

	around public-private partnerships in the 1990s, and a medicines pricing policy has been implemented through legislation. However, a recent Green Paper on National Health Insurance lays out an approach to involving the private sector under a mandatory financing system (this envisages accredited primary care providers, some limited role for some hospital services and greater contracting of private practitioners in public services, and sees private health insurers as limited to providing top-up cover). The outcome of a market enquiry commissioned by the Competition Commission is expected to inform policy on the private health sector.
Regulatory authorities	National Health Act (No. 61 of 2003) and its proposed amendment of 2011: The Ministry of Health, including the newly created Office of Health Standards Compliance. Medical, Dental and Supplementary Health Services Amendment (Act 1 of 1998): Established the Health Professions Council and its 12 constituent boards. Nursing Act (33 of 2005): Established the South African Nursing Council. Medical Schemes Act 131 of 1998: The Council for Medical Schemes was established under this act and is a strong, statutory body that is located outside the Ministry of Health and responsible for regulating all non-indemnity health insurers. Under the Council for Medical Schemes Levy Act 58 of 2000, the council is able to impose levies on schemes to finance its activities, Competition Act of 1998 and amendments: The Competition Commission reports to the Minister of Economic Development.
Legislation governing health professionals	
Registration of health professionals	Health Professions Amendment Act 29 of 2007; Nursing Act 33 of 2005: The act entitles the councils to oversee university training in order to preserve standards, describe scopes of practice, register health professionals provided they have received appropriate training and receive continuing professional development, and maintain professional standards of practice and behaviour.
Maintaining professional skills and professional behaviour	See above.
Legislation governing hospital and nursing home providers	
Licensing and accreditation of hospitals and nursing homes	Regulations Governing Private Hospitals and Unattached Operating Theatre Units. Published under Government Notice No. R. 158 of 1 February 1980 as Regulations to the Health Act 1977 No. 63 of 1977: These regulations require new hospitals to apply for a once-off licence. Detailed requirements are listed in the regulations, focusing on infrastructure and equipment.
'Certificate of need' governing location of facilities	National Health Act (No. 61 of 2003): The act proposes that a certificate of need should be held by each health institution. Granting this could depend on several factors, including the impact on equity and efficiency (and the prevention of distortion in the health market). The certificate could be for a maximum of 20 years. However, a formal certificate of need has not yet been proclaimed under the act. Nonetheless, provincial departments of health, who have responsibility for hospital licensing, do effectively apply principles of need when issuing a licence, although these principles differ between provinces, an there is no active control of the supply of private hospital beds.
Standards and norms	National Health Act (No. 61 of 2003): All facilities are supposed to comply with quality requirements but common standards for the public and private sectors were only laid out in 2011 by the Ministry of Health publication, 'Core Standards for Health Establishments in South Africa'. An amendment to the act that

	will create an Office of Health Standards Compliance in the National Department of Health, and allow the standards to be implemented, has not yet been enacted. Once enacted, this will be the first time that quality will be monitored in private facilities. Regulations Governing Private Hospitals and Unattached Operating Theatre Units. Published under Government Notice No. R. 158 of 1 February 1980 as Regulations to the Health Act 1977 No. 63 of 1977: These include standards for physical infrastructure and equipment that are pre-requisites for licensing, but do not regulate the process of care.
Reporting requirements for facilities	There are no requirements for private hospitals to report to the Department of Health or submit any information.
Price controls	Hospital tariffs are not regulated. Health insurers negotiate tariffs with hospitals on a bilateral basis. In the past, the association of health insurers published rates at which they would reimburse hospital care, but in 2004 this was outlawed by the Competition Commission which saw it as amounting to price fixing. In the past, the Department of Health published an annual reference price list that quoted much lower rates but was not obligatory. This list was struck down recently by a court order on procedural grounds (the department had not consulted fully with all the tiers of government). The department is awaiting the outcome of the Competition Commission's market enquiry that it hopes will open the way, once again, to negotiated tariffs between providers and insurers, and empower the Minister of Health to legislate tariffs should these two sets of stakeholders not be able to reach an agreement.
Provisions to promote competition	Competition Act of 1998 and amendments: The Competition Commission is able to act against anti-competitive behaviour, and a few years ago ruled against private hospital chains negotiating annual tariffs with the association of health insurers, describing this as a form of collective bargaining that amounted to price fixing. It is hoped that the upcoming private health market enquiry by the commission will re-instate some form of collective bargaining based on an improved understanding of market failure in the health sector.
Legislation governing private ambulances and emergency medical services	
	There is no formal legislation governing ambulances, although the Health Professions Council controls paramedics. The Department of Health does have some unofficial norms for vehicles, but these are not necessarily up-to-date or comprehensive. Recently a tender for aero-medical services awarded by the national treasury was scrapped because it turned out the specifications did not comply with international standards for such services.
Legislation governing primary care providers	
Registration and licensing of primary care practitioners and facilities	There is no legislation governing primary facilities, and there is no licensing requirement for these facilities.
Standards and norms	National Health Act (No. 61 of 2003): All facilities are supposed to comply with quality requirements, but common standards for the public and private sectors were only laid out in 2011 by the Ministry of Health publication, 'Core Standards for Health Establishments in South Africa'. An amendment to the act that will create an Office of Health Standards Compliance in the National Department of Health, and allow the standards to be implemented, has not yet been enacted. Once enacted, this will be the first time that quality will be monitored in private facilities.
'Certificate of need' governing location of facilities	There is no certificate of need controlling the distribution of primary care facilities although the National Health Act does make provision for a certificate of need. This has however not yet been proclaimed.

Regulation of dispensing and other clinical support services by primary providers	Medicines and Related Substances Control Act (Act no. 101 of 1965), as amended, plus accompanying regulations of 2001: Under these regulations, private doctors have to be licensed by the Ministry of Health in order to stock and dispense drugs. They are required to undergo a course and demonstrate appropriate facilities for storage of drugs. The Constitutional Court overruled a Ministry of Health requirement that a self-dispensing doctor may not dispense within a 5km radius of a pharmacy on the basis that it protected pharmacies from competition by doctors.
Control of private practice by public professionals	Under the Department of Public Services Administration's policy of 'Remunerative work outside the public sector (RWOPS)' doctors may conduct private practice outside public facilities and official working hours with permission. Provincial department's of health are empowered to negotiate the precise terms of this permission, leading to variation around the country. The system is perceived to be widely abused, and medical scheme claims reflect this, especially for academic specialists. There are calls to revise this policy and impose stricter sanctions on doctors abusing the system. One province, the Western Cape, has reportedly been able to manage RWOPS effectively through creating greater transparency: participating health professionals are required to report in detail regarding both their public and private sector activities, allowing managers an overview of their total workload and thus cutting down on opportunities to cheat.
Reporting requirements	There are no reporting requirements.
Price controls	Health professionals' fees are not regulated. In the past, medical and dental associations published guideline professional tariffs that, over the years, became increasingly higher than the reimbursement rates published by the association of health insurers. In addition, the Ministry of Health published a national reference price list that was often higher than what health insurers were prepared to pay. In 2004, the Competition Commission outlawed publishing rates, seeing it as amounting to price fixing. Currently health insurers negotiate tariffs with providers on a bi-lateral basis. Recently the Health Professions Council published rates to guide their response to allegations by members of the public that they had been overcharged, claiming that this was part of their mandate under the Health Professions Act. These rates were withdrawn following outrage on the part of doctors who felt they were not calculated fairly. In addition, they felt that the health insurers would see the rates as guidelines rather than maximum rates. If national health insurance is implemented, it is likely that active purchasing arrangements, such as capitation payments, will come into being.
Provisions to promote competition	Competition Act of 1998 and amendments: The Competition Commission has never investigated anti-competitive behaviour by general practitioners and specialists, but the upcoming market enquiry may address this, especially with regard to specialists' relationships with the private hospitals in which they have consulting rooms.
Legislation governing health insurers	
Registration and demarcation of different types of health insurance	Medical Schemes Act No. 131 of 1998 and amendments and a series of regulations: This legislation allows for the non-indemnity health insurance industry to be regulated in line with national health objectives, including registration of health insurers and other controls on their activities. Schemes have to be registered and their administrators accredited. The act also requires brokers to be accredited, controls their behaviour and forbids a scheme to refuse membership to anyone because they have not used a broker.

	Indemnity insurance is regulated separately under the short- and long-term insurance acts. There is ongoing work by national treasury and the Council for Medical Schemes to delineate the differences between non-indemnity and indemnity insurance more clearly through draft regulations. When agreement between the regulators of each (the Council for Medical Schemes and Financial Services Board) cannot reach agreement, the National Department of Health is empowered to adjudicate.
Control of risk rating and adverse selection	Medical Schemes Act No. 131 of 1998 and amendments and a series of regulations: This legislation outlawing risk rating requires that premiums for the same plan cannot be differentiated based on individual health risk. However, there are some remaining mechanisms that undermine community rating, such as the fragmentation of plans (there are over 400 plans offered by 110 schemes, resulting in an average of only 20,000 members per plan), as well as targeted marketing of certain plans to certain risk groups.
Standardised benefit packages	Medical Schemes Act No. 131 of 1998 and accompanying regulations and amendments: A set of minimum benefits is laid out by the act and its regulations, including diagnosis, treatment and care for acute hospital care and some chronic conditions, as well as emergency care. There are detailed algorithms for certain conditions, especially chronic ones, which lay out the treatment approach that schemes must reimburse in full. Schemes are authorised to require that, to be reimbursed, beneficiaries must make use of a designated provider. The legislation also requires that other protocols and formularies used by schemes must be shown to be evidence based. Schemes have to exert efforts to ensure that these services are delivered efficiently, including using pre-authorisation and drug formularies A number of provisions relate to controlling the quality of managed care organisations and practices and their impact on the coverage of benefits. Similarly, capitation agreements have to be in the interests of members.
Price controls	There are no price controls with respect to health insurance premiums or administrative costs. Financial Advisory and Intermediary Services Act of 2001: This guards against unfair behaviour by brokers and regulates commission.
Reporting requirements	Medical Schemes Act No. 131 of 1998 and accompanying regulations and amendments: Annual financial reports must be submitted to the registrar who is entitled to request any other documentation he requires. Reimbursement of trustees of schemes must be reported.
Solvency	Medical Schemes Act No. 131 of 1998 and accompanying regulations: Reserves must not be less than 25%.
Provisions to promote competition	Competition Act of 1998 and amendments: The Competition Commission's market enquiry is also expected to investigate the reasons behind the high administrative costs faced by medical schemes.

Note: This table may contain gaps and inaccuracies. The table only addresses legislation governing health care professionals (with a focus on doctors), health care providers (with a focus on private hospitals) and health insurers. The pharmaceutical industry is not addressed.

Sources of information: interview data; Mulumba, Kabanda et al. 2010; ; National Department of Health 2011a; Still 2012; van Rensburg and Engelbrecht 2012 (2nd ed.); Bester 2013; Malan 2013.
A more detailed discussion of the entire set of acts and regulations affecting the private health sector can be found in Still (2012).

Swaziland

Constitutionally there are no express provisions for the right to health, but some other provisions protect health (Mulumba, Kabanda et al. 2010).

It was not possible to access copies of the Public Health Bill and the Medical and Dental Council Bill.

No specific legislation governs health insurers. However, Swaziland has a new institution called the Financial Service Regulatory Authority, which is empowered by the Retirement Funds Act of 2005, the Insurance Act of 2005 and the Financial Institutions Act of 2005. The latest organisations to be included under this institution's authority are financial co-operatives, which include health insurers and medical aid (interview data; Swaziland Financial Services Regulatory Authority 2013).

Further, work is in progress to develop social security legislation that will include regulations governing national health insurance, which will certainly affect the regulatory framework for the private sector (interview data).

Tanzania

In the 1970s Tanzania banned commercial health care. In the 1980s it developed a more tolerant attitude towards the private sector and is now considered a regional pioneer in developing a comprehensive policy on the private sector (Callahan 2012). The Tanzanian Government's website and strategic plan acknowledge and describe the role of the private health sector and indicate that the government's objective is to find the right mix between public and private services (World Bank and International Finance Corporation 2011; Tanzania National Website 2012). There is a public-private partnerships policy, and a desk within the Ministry of Health, but this has limited capacity (Janovsky and Travis 2010).

There is a clear intention in the legislation to regulate the private sector. This is seen in the Public Private Partnerships Act as well as the Private Hospitals (Regulation) Act and the Private Health Laboratories Regulation Act. The latter two acts require private facilities to be registered and give the minister extensive competencies to formulate standards (and the government has published the 'Tanzania Quality Improvement Framework in Health Care 2011-2016', although it seems that this has not yet been used as a basis for accreditation of private facilities (Bultman, Kanywanyi et al. 2012)). The acts also give the minister the authority to regulate both fees and remuneration levels of private practitioners working in these facilities. This provides the ministry with a powerful lever to affect the cost and quality of private health services.

Unlike in several other countries, the legislation governing health professionals does not seem to be involved in licensing of private practices and facilities. Facilities are licensed by four different bodies and there are plans to bring these together under an umbrella body (Janovsky and Travis 2010). Facilities are required to provide detailed monthly reports to the national health management information system but compliance rates are low, mainly because facilities find these requirements extremely onerous (World Bank and International Finance Corporation 2011).

Health insurers are regulated under general insurance law, which means that there are no provisions for controlling the factors that contribute to market failure in the

health sector (such as risk rating, price inflation etc.). However, there are some efforts to establish a health insurance regulatory body.

There is a Fair Competition Commission and Tribunal.

A more detailed summary of the legislation appears below, as well as references for the acts mentioned in the text above.

Summary of private health sector legislation in Tanzania

Form of regulation	Relevant legislation and provisions
General legislation governing the health sector	
Constitutional protection of the right to health	There is no express provision for the right to health, but some other provisions protect health.
General intention of health policy and legislation to regulate the private sector in line with government's objectives	Public Health Act 1 of 2009; Public Private Partnerships Act No. 18 of 2010 and Public Private Partnership Regulations of 2011: In 1977 commercial health care was banned. However, in the 1980s a more tolerant approach to the private health sector developed. The website of the Government of Tanzania now states that developing an appropriate mix of public and private services is now part of the Tanzanian health policy. Still, the Public Health Act of 2009 does not refer to the private primary and hospital providers or insurers. However, the Public Private Partnerships Act states that it is to give effect to a policy on these partnerships and seeks to promote private sector participation in the provision of public services through investment capital, managerial skills and technology.
Regulatory authorities	Medical Practitioners and Dentists Act and amendments of 1996 and 1998; Nurses and Midwives Registration Act of 1997; Health Laboratory Technologists Registration Act of 1997: Professional councils Private Hospitals (Regulation) Amendment Act of 1991: Private Hospitals Advisory Board registers and regulates private hospitals and the people running these hospitals. Sanctions in the form of fines and imprisonment are applicable. Presumably this authority has more capacity than the registrar who held this responsibility under the 1997 version of the act. Private Health Laboratories Regulation Act of 1977: The Private Health Laboratories Board regulates private and government laboratories and registers reagents and laboratory equipment. Insurance Act of 2009: Tanzanian Insurance Regulatory Authority (reporting to the Ministry of Finance) under which, in the absence of specific legislation governing health insurers, health insurers and brokers appear to fall. There are some efforts to establish a health insurance regulatory body to regulate premiums, standard benefit packages etc.
Legislation governing health professionals	
Registration of health professionals	Medical Practitioners and Dentists Act and amendments of 1996 and 1998; Nurses and Midwives Registration Act of 1997; Health Laboratory Technologists Registration Act of 1997: Doctors, dentists and nurses are required to register.
Maintaining professional skills and professional behaviour	This is presumably the preserve of the professional councils, but the original acts could not be accessed.
Legislation governing hospital and nursing home providers	
Licensing and accreditation of hospitals and nursing homes	Private Hospitals (Regulation) Act No. 6 of 1977 and the Private Hospitals (Regulation) Amendment Act 26 of 1991; Private Health Laboratories Regulation Act of 1977: Every private hospital has to be registered, whether or not it is run by the same organisation. The act restricts management to approved organisations and

	controls fees to patients as well as reimbursement of practitioners. The suitability of the premises and the capacity of the senior manager are conditions for registration. Similar requirements exist for health laboratories, but less detail is provided in the act.
'Certificate of need' governing location of facilities	This is not a consideration for registration.
Standards and norms	Private Hospitals (Regulation) Act of 1977; Private Health Laboratories Regulation Act of 1977: These are not laid out, but registration can be withdrawn if premises and the quality of medical care are not adequate. The acts give the minister the power to enact regulations that control the accommodation, types of staff and skills, equipment, reagents and food provided by private hospitals.
Reporting requirements for facilities	Private Hospitals (Regulation) Act of 1977: The minister can demand financial/business reports (including income) as well as other information he deems necessary. Records also have to be kept of fees and salaries/emoluments paid. Monthly reports are required and are quite onerous.
Price controls	Private Hospitals (Regulation) Act of 1977: The minister can review hospital fees, either on a national basis or for particular areas. He can determine the maximum fees and the manner in which they are calculated, and must keep both the interests of the community in mind as well as the provider and ensure the availability of services in rural areas. In making his judgement he can receive representations from any groups as well as demand access to data on treatment. A court may not review the minister's decision. Hospitals or practitioners providing services at a greater price than the maximum are guilty of committing an offence, with sanctions of fines and imprisonment. Similar provisions apply to the salaries or other emoluments paid to medical practitioners. Tanzania Food, Drugs and Cosmetics Act 2003: This also affects hospital prices by mandating the minister through regulations to prescribe the prices of medicines, medical supplies and equipment.
Provisions to promote competition	Fair Competition Act (No. 8 of 2003) and the Merchandise Marks Act (No. 20 of 1963): These established a Fair Competition Commission and Tribunal.
Legislation governing private ambulances and emergency medical services	
	There is no specific legislation, but there are apparently guidelines.
Legislation governing primary care providers	
Registration and licensing of primary care practitioners and facilities	Private Hospitals (Regulation) Act of 1977 and the Private Hospitals (Regulation) Amendment Act of 1991: Private medical practice is regulated under this act. Nurses and Midwifery Act: This apparently regulates maternity homes, but could not be accessed.
Standards and norms	No information on this could be identified.
'Certificate of need' governing location of facilities	No information on this could be identified.
Regulation of dispensing and other clinical support services by primary providers	No information on this could be identified.
Control of private practice by public professionals	Public sector health workers are allowed to work in private practice after working hours. This is regulated by the act governing health professionals and the Public Service Act of 2002.

Reporting requirements	The Public Health Act and its attendant regulations and guidelines require each facility to report to a certain administrative level, the minimum being the local government authority. Reports then flow upwards until they reach the Ministry of Health.
Price controls	It appears that the price controls described above regarding hospitals also apply to doctors where they also work in hospitals.
Provisions to promote competition	Fair Competition Act (No. 8 of 2003) and the Merchandise Marks Act (No. 20 of 1963): These established a Fair Competition Commission and Tribunal.
Legislation governing health insurers	
Registration and demarcation of different types of health insurance	Insurance Act of 2009: Registration is done by the Tanzanian Insurance Regulatory Authority. Health insurers simply have to register and comply with the general provisions of the general insurance act: there is no specific accreditation of health insurers. Health maintenance organisations (which have their own prepayment systems) are not covered by this or any other act. The National Health Insurance Fund and Community Health Fund each have their own specific acts.
Control of risk rating and adverse selection	There is no specific legislation.
Standardised benefit packages	Benefit packages are not regulated by the act.
Price controls	There is no specific legislation.
Reporting requirements	The laws of general insurance apply here and are not necessarily sufficient for health insurance.
Solvency	The laws of general insurance apply here and are not necessarily sufficient for health insurance.
Provisions to promote competition	Fair Competition Act (No. 8 of 2003) and the Merchandise Marks Act (No. 20 of 1963): These established a Fair Competition Commission and Tribunal.

Note: This table may contain gaps and inaccuracies. The table only addresses legislation governing health care professionals (with a focus on doctors), health care providers (with a focus on private hospitals) and health insurers. The pharmaceutical industry is not addressed.

Sources of information: country contacts; Janovsky and Travis 2010; Mulumba, Kabanda et al. 2010; World Bank and International Finance Corporation 2011; Bultman, Kanywanyi et al. 2012; Callahan 2012; Tanzania National Website 2012.

Uganda

Uganda launched a new health policy that takes a comprehensive view of the health sector, both public and private. The private sector is mentioned throughout the document and is seen as complementary to the public sector in that it helps to extend the geographic range, scope and scale of services. The government is committed to improved supervision and monitoring of the private sector and to building the skills of this sector (although it is not clear whether this refers to both non-profit and for-profit components). In 1994 a position for a public-private partnerships officer was created in the Ministry of Health, and this is currently being developed into a fully fledged unit backed by a formal policy on public-private partnerships and jointly funded by the public and private sectors (interview data; Musila 2013). One role of the new unit will be to develop an accurate database on the private sector and its performance. Already some practices benefit from government subsidies to offset overheads and support for the provision of services such as antiretrovirals, immunisation and TB care (interview data). Government also seconds staff on its payroll to assist at some private facilities. Further, private sector representatives are also involved in some policy-making processes and committees.

The Public Health Act was enacted in 1935, however, and therefore does not reflect these developments. The act is currently being revised. Legislation on health professionals requires them to be registered as well as licensed for private practice: licences are only granted upon completion of three to ten years working in the public sector, depending on the type of professional. Health facilities also have to be registered annually. Drug dispensing by private professionals is not allowed without special permission. Unlike many other countries, nurse and midwives are allowed to establish practices independently, without the supervision of a doctor. The professional councils are responsible for maintaining standards of professional practice and behaviour and act against health professionals contravening the regulations. An interesting element of the Nurses and Midwives Act is that private nurses have to submit annual reports on their activities and make their records available when requested. Hospitals do not report to the professional council but do report to the central Ministry of Health (interview data).

No legislation on private health insurance could be found. This means that there are no provisions for controlling the factors that contribute to market failure in the health sector (such as risk rating, price inflation etc.). Work is in progress to develop specific legislation.

As the private sector is not yet very strong, the need has not yet been felt to apply legislation against anti-competitive behaviour, especially as there are relatively few facilities that are purely private (interview data). One respondent noted that: “of course we have had things like patients not being offered what they had expected, or being kept in [hospital] much more than what is necessary, or being treated with what is not required, so the small things are still there” but that collusion is not yet evident (interview data).

One of the main challenges facing the Ugandan Government with respect to private sector legislation is the lack of a critical mass of people within the Ministry of Health who understand the private sector (Musila 2013). Further, the capacity of the councils is also limited, as is the capacity of local authorities who have delegated powers to conduct inspections. This means that it has not been possible for inspectors to reach every facility for inspection, while there is also some confusion regarding to whom local inspectors are accountable and who will provide them with support when they find it necessary to close facilities (interview data; Janovsky and Travis 2010). Currently the Health Professions Council is working with the private sector to improve its inspection tools with a view to speeding up the process and encouraging self-assessment locally so that practices are prompted to improve themselves (interview data). Additional inspectors have also been recruited to improve the extent of inspection. It is anticipated that the job of inspection will also be made easier by the fact that the number of practices has been reduced considerably following raising of standards and requirements (so that, for example, clinics have to be supervised directly by a doctor).

The accreditation process is also a priority for improvement in preparation for national health insurance, especially so that the public can be made aware of service options (interview data). It is also planned to improve health management information systems, including creating a geographic information system. Lastly, the legal capacity of councils needs to be upgraded in order to speed up the process of responding to complaints, and the Medical and Dental Practitioners’ Act needs to be updated to take account of developments in technology and medical practice. Part of this process will be to unify all the councils under an umbrella body, while all acts governing professional councils are being reviewed to make them stronger (interview data).

A more detailed summary of the legislation appears below, as well as references for the acts mentioned in the text above.

Summary of private health sector legislation in Uganda

Form of regulation	Relevant legislation and provisions
General legislation governing the health sector	
Constitutional protection of the right to health	There is no express provision for the right to health but some other provisions protect health.
General intention of health policy and legislation to regulate the private sector in line with government's objectives	Second National Health Policy; Public Health Act of 1935 (Chapter 281): This new health policy looks at the health system as a whole, including the private sector. It is committed to strengthening the supervision and monitoring of the private sector, as well as the functional integration of the public and private sectors. The private sector is seen as complementary to the public sector through helping to extend the geographic range, scope and scale of services. Some of the policy objectives are to strengthen the regulatory system and professional councils so that better legislation can be developed and to strengthen enforcement, including inspections. The policy is also committed to strengthening the skills of private providers and managers, improving the quality of private health care, facilitating the involvement of the private sector in planning, attracting private providers to underserved areas, facilitating the development of private sector infrastructure and collecting adequate information on the private sector. However, The Public Health Act is an old act and does not refer to the private sector. It is currently being revised.
Regulatory authorities	Public Health Act of 1935: The Ministry of Health Medical and Dental Practitioners Act of 1996 (Chapter 272): The Medical and Dental Practitioners Council is in charge of upholding standards of practice and ethics, maintaining standards of training (including continuing education), advising government on matters related to the health professions and educating providers and the public about patient rights. Nurses and Midwives Act of 1996 (Chapter 274): The Nurses and Midwives Council.
Legislation governing health professionals	
Registration of health professionals	Medical and Dental Practitioners Act of 1996 (Chapter 272); Nurses and Midwives Act of 1996 (Chapter 274): health professionals have to be registered.
Maintaining professional skills and professional behaviour	Medical and Dental Practitioners Act of 1998 (Chapter 272); Nurses and Midwives Act of 1996 (Chapter 274): The councils are responsible for ensuring professional behaviour is maintained. Continuing education is obligatory for all categories. Sanctions of fines or imprisonment are noted under the Nurses and Midwives Act. The councils can inquire into allegations of misconduct.
Legislation governing hospital and nursing home providers	
Licensing and accreditation of hospitals and nursing homes	Medical and Dental Practitioners Act of 1996 (Chapter 272); Nurses and Midwives Act of 1996 (Chapter 274): Under the Medical and Dental Practitioners Act, private health units must apply for a licence which is granted provided the unit operates under a licensed doctor or dentist and complies with certain standards. The act provides for annual inspection. The sanctions for contravening the act are available in the act. Nurses and midwives also have to apply for a licence to run a nurse health unit or maternity home, and are able to do so independently and without the supervision of a doctor. The council conducts inspections. The licence is annually renewable.
'Certificate of need' governing location of	There do not seem to be any such provisions although the new health policy suggests more oversight in the future.

facilities	
Standards and norms	Standards are available but are being modified.
Reporting requirements for facilities	Nurses and Midwives Act of 1996 (Chapter 274): Nurses and midwives licensed to practise in the private sector have to submit an annual report of all their cases to the council. They also have to make available all the records of their cases.
Price controls	There do not seem to be any.
Provisions to promote competition	There do not seem to be any
Legislation governing private ambulances and emergency medical services	
	New legislation is being developed.
Legislation governing primary care providers	
Registration and licensing of primary care practitioners and facilities	Medical and Dental Practitioners Act of 1998 (Chapter 272); Nurses and Midwives Act of 1996 (Chapter 274): Doctors and dentists must have a private practice licence to work in private practice: the licence is annually renewable. The act makes provision for annual inspection. The sanctions for contravening the act are not noted. Midwives can only work in private practice five years after training during which time they must work in the public sector. The period for nurses is 10 years.
Standards and norms	There do not seem to be any such provisions, although the new health policy suggests more oversight in the future.
'Certificate of need' governing location of facilities	There do not seem to be any such provisions, although the new health policy suggests more oversight in the future.
Regulation of dispensing and other clinical support services by primary providers	Medical and Dental Practitioners Act of 1996 (Chapter 272); Nurses and Midwives Act of 1996 (Chapter 274): Doctors, dentists, nurses and midwives need a licence to stockpile and sell drugs. Guidelines are currently being improved.
Control of private practice by public professionals	There do not seem to be any provisions for this.
Reporting requirements	Nurses and Midwives Act of 1996 (Chapter 274): Nurses and midwives licensed to practise in the private sector have to submit an annual report of all their cases to the council. They also have to make available all the records of their cases.
Price controls	There do not seem to be any, but the various professional associations are discussing the issue.
Provisions to promote competition	There do not seem to be any.
Legislation governing health insurers	
Registration and demarcation of different types of health insurance	No information was accessed.
Control of risk rating and adverse selection	No information was accessed.
Standardised benefit packages	No information was accessed.
Price controls	No information was accessed.
Reporting requirements	No information was accessed.
Solvency	No information was accessed.
Provisions to promote competition	No information was accessed.

Note: This table may contain gaps and inaccuracies. The table only addresses legislation governing health care professionals (with a focus on doctors), health care providers (with a focus on private hospitals) and health insurers. The pharmaceutical industry is not addressed.

Sources of information: country contacts and interview data; Janovsky and Travis 2010; Mulumba, Kabanda et al. 2010; Musila 2013.

Zambia

There is no overarching national health policy on the private sector. However, liberalisation of the economy in the 1990s has meant that there is a positive attitude to private sector involvement, although the private sector is still quite small and concentrated in Lusaka and the Copper Belt (interview data). Reflecting this, there was a concrete public-private partnerships policy, and a task force on this topic was active for a while, although implementation has been slow, partly because of a changing political environment and turnover of senior policy makers (World Bank and International Finance Corporation 2011).

The old National Health Services Act was repealed in 2005 so the responsibility for the management of facilities has reverted from the Central Board of Health to the Ministry of Health. The old act has not yet been replaced with more updated legislation (although there is talk of a new National Health Services Bill) which leaves a legislative vacuum with respect to administrative requirements as the Public Health Act does not contain provisions on these (United Nations Development Programme 2011; Howse, Kalila et al. 2012 [in press]).

The weight of regulation of the private sector falls on the Health Professions Council as it has a wide mandate to register, license and accredit both individual professionals and public, non-profit and for-profit health facilities (excluding those owned by mining companies (United Nations Development Programme 2011)). Existing legislation indicates that standards for various characteristics (such as facilities and staff) are the basis for licensing and that the minister has the right to develop detailed standards. These standards have been developed by the Health Professions Regulatory Authority, an umbrella organisation under which fall councils for all the different health professions. Accreditation can be withheld if it would lead to waste and inefficiency although this is not defined, and there is reportedly no attempt to guide the distribution of facilities in practice (interview data). Annual inspection and re-licensing of private facilities may work quite well in some places although *"*obviously there are challenges in the sense as to whether the Council is able to police the entire country" (interview data). United Nations Development Programme (2011: 63) concluded that generally the statutory boards engaged in health sector regulation "lagged behind in institutional development compared to the institutions they are required to regulate".

Zambia is an example of a country where scopes of practice, as defined by the councils, have not kept pace with changing health system needs, especially given the shortage of human resources across the country. For example, Zambia requires a full-time physician to supervise private sector nurses, making it impossible for nurses to set up their own clinics or midwife units independently, a particular problem in areas where there are no doctors (Feeley, O'Hanlon et al. 2009). As one key respondent explained, in the early years of this century a nursing home bill, which would have allowed nurses to practise independently, was ready to go to Parliament:

The GNC worked hard on lobbying, advocating and preparing the draft legislation. However, at the last minute it appears the medical doctors had it shot down. And since then, it has died a natural death or perhaps it's in hibernation.

This illustrates the political difficulties associated with transforming legislation, given the large number of powerful stakeholders affected.

There also appears to be a problem with collating information from private providers for the national health management information systems because, although the Ministry of Health does have data collection forms for providers to complete, private

providers do not seem to be aware of them or are unsure how they should be submitted (interview data; World Bank and International Finance Corporation 2011).

There is no specific legislation regulating health insurers. Four health insurers are currently registered by the Pensions and Insurance Commission under legislation for long-term insurers: these are long-term insurance companies that comply with the relatively strict prudential requirements governing the insurance industry in general, and offer health insurance amongst other insurance products (interview data).

Many other companies offering only health insurance (and not other insurance products) remain unregistered, except under the Companies Act (No. 24 of 1995), which applies to the long-term insurers as well. Likewise, hospitals that negotiate to provide services, or a discount on services, for the employees of a specific employer are often not registered under insurance law (interview data). The Companies Act does not contain any prudential provisions that would normally apply to the insurance industry, such as the maintenance of reserves, the demonstration of risk-management capabilities and disclosure of key financial information (Theron, Erasmus et al. 2010). Several fly-by-night health insurers have failed to honour claims in the past, or have dissolved, because of poor financial management (interview data).

Many unregistered companies argue that they offer 'medical aid' as opposed to 'health insurance' (a distinction that is described under the South African country profile) although in practice there is considerable overlap in the type of products offered by both registered and unregistered insurers, with almost all providing non-indemnity cover (Theron, Erasmus et al. 2010). Part of this problem is due to the vagueness of legislation and the willingness of the Ministry of Health to allow unregistered companies to continue to operate (although the Pension and Insurance Commission regards unregistered health insurers as operating illegally). However, there are also incentives for companies to remain unregistered as they are able to avoid taxation of profits by arguing that they simply manage societies' funds, ploughing back surpluses into the society (interview data).

Neither registered nor unregistered health insurers are subject to any provisions controlling the factors that contribute to market failure in the health sector (such as risk rating, price inflation etc.). As one key respondent put it:
The problem arises because health insurance is quite a unique product. For instance, even in terms of the financing and actuarial issues, and in terms of contracting with the providers. Because of that relationship you find it is a little bit different from ordinary insurers.

Theron, Erasmus et al. (2010: i) conclude that:
…much of the current market dynamics is shaped by an unlevel playing field between regulated insurance companies, on the one hand, and "medical schemes" and private hospitals providing health insurance (but choosing to stay outside the regulatory regime), on the other hand.

Currently there are proposals to group health insurers into a separate category under the Pension and Insurance Commission and create specific legislation to ensure financial soundness, the protection of reserves, minimum benefit packages, accreditation criteria for providers and more transparency around the setting of premiums, amongst other things (interview data). One respondent noted that it is important to unify accounting and actuarial skills with health economics and public health skills in order to design appropriate regulation mechanisms.

Recent proposals for social health insurance for formal sector employees may also affect the health insurance and private provision environment and inevitably require more integral involvement of the Ministry of Health in developing legislation (interview data). However, one key informant noted that:

We are not agreed that we should have this [social health insurance] bill and, if we are to have it, what the key legislative issues should be. Some advocate issues of institutional reform. Others on the financial side ... I suppose some consensus will be reached if the MoH do not lose steam.

There is a competition policy and accompanying legislation. The regulatory authority is the Competition and Consumer Protective Commission. However, the activities of the commission have "been marred by lack of a distinct policy on these issues. As a consequence, government support to competition and consumer issues has not been focused enough" (Zambia Competition and Consumer Protection Commission 2013). One key respondent felt that the private sector has evolved relatively recently and is still so small that anti-competitive behaviour has not yet emerged (interview data). For example, there are only four health insurers registered under the Pension and Insurance Commission. However, Theron, Erasmus et al. (2010) identify the need to improve consumer protection, especially with respect to the marketing of health insurance products.

A recent United Nations report on Zambia suggests that policy-related priorities in the health sector are to: accelerate development of the National Health Services Bill, accelerate development of new legislation on the private health sector, emphasize the regulation of private facilities, establish an independent health care regulatory authority reporting directly to Parliament, and create a system of re-registration of practitioners focusing on professional development (Luchsinger 2011). One key respondent interviewed for this study made the point that it is important to put in place regulatory frameworks "to control the behaviour of all these players [in the private sector]" before abusive practices become established. Much improved health management information systems within private health insurers are also required, as well as mechanisms for insurers and providers to negotiate prices collectively (Theron, Erasmus et al. 2010).

A more detailed summary of the legislation appears below, as well as sources for the acts mentioned in the text above.

Summary of private health sector legislation in Zambia

Form of regulation	Relevant legislation and provisions
General legislation governing the health sector	
Constitutional protection of the right to health	There is little or no constitutional protection of the right to health.
General intention of health policy and legislation to regulate the private sector in line with government's objectives	Public Health Act of 1930 (plus a number of amendments) and the National Health Services Act (repealed by Act 17 of 2005): This legislation does not say anything specific on the private sector, and there is no overarching national health policy on the private sector. However, there is a public-private partnerships policy, and a task force on this topic was active for a while, although implementation has been slow. The National Health Services Act has been repealed and not yet been replaced with more updated legislation, although there is talk of a National Health Services Bill.
Regulatory authorities	Public Health Act of 1930 (plus a number of amendments): Ministry of Health National Health Services Act (repealed by Act 17 of 2005): The Central Board of Health (which has now been dissolved). The

	National Health Services Act established and laid out the roles of the Central Board of Health that managed the executive boards of public facilities and was able to advise the minister on the role of the private sector. However, these boards have been dissolved with the repeal of the act. The ministry now has these functions although the Public Health Act no longer lays out the administrative functions. Health Professions Act (No. 24 of 2009): The Health Professions Council appears to have the most influence over the private sector because it is responsible for registration of health professionals, licensing of facilities and accreditation of services. General insurance legislation: The Pensions and Insurance Commission. Competition and Consumer Protection Act (No. 24 of 2010) and general regulations (2011): The Competition and Consumer Protection Commission
Legislation governing health professionals	
Registration of health professionals	Health Professions Act (No. 24 of 2009) and the Nurses and Midwives Act (No. 31 of 1997): The former provides for the registration of all health workers except for nurses (which are registered by the latter act). Both acts require the respective councils to approve the training programmes. Contravention of the requirements leads to the withdrawal of registration/approval or a fine or imprisonment.
Maintaining professional skills and professional behaviour	Health Professions Act (No. 24 of 2009) and the Nurses and Midwives Act (No. 31 of 1997): The councils are responsible for ensuring professional behaviour is maintained, responding to complaints and holding disciplinary enquiries. There do not seem to be requirements for continuing professional education. The councils can inquire into allegations of misconduct.
Legislation governing hospital and nursing home providers	
Licensing and accreditation of hospitals and nursing homes	Health Professions Act (No. 24 of 2009): The act requires different sizes and functions of facilities to be licensed provided they meet physical, staffing, equipment and organisational standards (although these are not included in the act itself). The facility must be inspected before granting of the licence and at least every two years thereafter. Fines and imprisonment are intended for those who break the terms of the licence and inspection. Licensed facilities can apply for accreditation of their services: inspection powers are also granted to the council for this.
'Certificate of need' governing location of facilities	Health Professions Act (No. 24 of 2009): Accreditation can be withheld if accreditation would result in waste or inefficiency in the health care system, but the geographic distribution of private facilities is not actively controlled.
Standards and norms	Health Professions Act (No. 24 of 2009): This act empowers the minister to develop requirements for accreditation, which include staffing, facilities, equipment, procedures, record-keeping, data collection, staff training and compliance with treatment protocols and clinical guidelines.
Reporting requirements for facilities	Health Professions Act (No. 24 of 2009): The council may require reports, including quality assurance information, before renewing accreditation.
Price controls	There are no price controls.
Provisions to promote competition	Competition and Consumer Protection Act (No. 24 of 2010) and general regulations (2011).
Legislation governing private ambulances and emergency medical services	
	No information on this could be identified.
Legislation governing primary care providers	
Registration and licensing of primary care	Health Professions Act (No. 24 of 2009): The act requires different sizes and functions of facilities to be licensed provided

practitioners and facilities	they meet physical, staffing, equipment and organisational standards (although these are not included in the act itself). The facility must be inspected before granting of the licence and at least every two years thereafter. Fines and imprisonment are intended for those who break the terms of the licence and inspection.
Standards and norms	Health Professions Act (No. 24 of 2009): This act empowers the minister to develop requirements for accreditation, which include staffing, facilities, equipment, procedures, record-keeping, data collection, staff training and compliance with treatment protocols and clinical guidelines.
'Certificate of need' governing location of facilities	Health Professions Act (No. 24 of 2009): Accreditation can be withheld if accreditation would result in waste or inefficiency in the health care system, but the geographic distribution of facilities is reportedly not controlled.
Regulation of dispensing and other clinical support services by primary providers	There does not appear to be any legislation.
Control of private practice by public professionals	There is no legislation against doctors working in both the public and private sectors. Nor are there guidelines around how they should refer between their public and private practices or around reimbursement levels.
Reporting requirements	Health Professions Act (No. 24 of 2009): The council may require reports, including quality assurance information, before renewing accreditation.
Price controls	There are no price controls.
Provisions to promote competition	Competition and Consumer Protection Act (No. 24 of 2010) and general regulations (2011).
Legislation governing health insurers	
Registration and demarcation of different types of health insurance	There is no specific legislation governing health insurers that, in the case of long-term insurance companies, are registered by the Pensions and Insurance Commission under insurance legislation and, in the case of companies that only offer health insurance, only under the Companies Act.
Control of risk rating and adverse selection	There is no legislation on this.
Standardised benefit packages	There is no legislation on this.
Price controls	There are no price controls.
Reporting requirements	There is no specific legislation on this, apart from what is required of long-term insurance companies under insurance legislation.
Solvency	There is no specific legislation on this, apart from what is required of long-term insurance companies under general insurance legislation.
Provisions to promote competition	Competition and Consumer Protection Act (No. 24 of 2010) and general regulations (2011).

Note: This table may contain gaps and inaccuracies. The table only addresses legislation governing health care professionals (with a focus on doctors), health care providers (with a focus on private hospitals) and health insurers. The pharmaceutical industry is not addressed.

Sources for acts and other information: country contacts; Feeley and O'Hanlon 2007; Feeley, O'Hanlon et al. 2009; Mulumba, Kabanda et al. 2010; Theron, Erasmus et al. 2010; Luchsinger 2011; World Bank and International Finance Corporation 2011; United Nations Development Programme 2011; Howse, Kalila et al. 2012 (in press); Zambia Competition and Consumer Protection Commission 2013.

Zimbabwe

There is no formal policy on the private sector although professional councils are supposed to help promote the health of the population and the minister is supposed to consider national needs when deciding whether to grant permission for new private hospitals to be built.

The Health Professions Act and the Paramedic Practices Act have wide responsibilities, ranging from registering and licensing individuals, health institutions and emergency services, to overseeing the quality of training. Registration and licensing is dependent on compliance with some basic standards, although the acts do no lay these out in much detail. The regulator is the Health Professions Regulatory Authority, an umbrella body under which fall several councils. Annual inspection of private facilities does apparently occur, although this is not necessarily thorough in all cases (interview data).

Zimbabwe has one of the higher levels in Africa of health expenditure financed through voluntary private health insurance, covering around a million individuals (interview data; Sekhri and Savedoff 2005). Health insurers, known as medical aid societies, have to be registered under the Medical Services Act and accompanying regulations, which include stipulations around solvency requirements, minimum benefit packages and waiting times before new members can receive benefits, but do not protect members against risk rating. The bulk of societies are employer-based, but some are 'open' schemes, open to any applicants.

In addition to medical aid societies, there are indemnity-type health insurance products registered under general insurance legislation. In addition, the poor economic climate of recent times has prompted some medical aid societies to offer savings plans (interview data). Neither of these options provides risk or income cross-subsidies.

Further, there are some for-profit insurance providers that register under the general insurance legislation, even though they provide medical aid-type products (often together with other forms of insurance): these insurers are often not part of the tariff agreements negotiated with providers by the Association for Health Funders of Zimbabwe (Osika, Altman et al. 2011). Evading registration under the Medical Services Act, although not as rampant as in the past, remains illegal because, as one key respondent put it:
The medical aid regulations in Zimbabwe, they say that everyone who is in the business of collecting contributions or who would want to honour claims, or is in the type of business which is likely to lead people to believe they have joined a medical aid, ... has to be registered [under the Medical Services Act].

A Competition Act came into force in 1998 and, in the wider economy, has been used to regulate anti-competitive agreements and mergers (both vertical and horizontal), the abuse of monopolies and unfair business practices, including some consumer protection around prices (Kububa 2009). The Competition Amendment Act of 2001 made notification of an intended merger by the business partners compulsory so that the commission would no longer be caught unawares (Kububa 2004). The commission has taken a number of significant actions against anti-competitive practices in the private health sector, including mergers, acquisitions, cross-ownership of medical aid societies and direct provision of hospital and emergency care by medical aid societies. A particular practice that it is currently trying to stamp out is 'open' medical aid societies - which are owned by commercial companies - obliging their members to use providers owned by the same company (interview

data). Eliminating this practice is difficult as medical aid societies can use indirect incentives, such as placing providers that they own close to their membership base.

Some of the more recent legislation described above was enacted to address the problems typical of the 1990s. A study published in 2000 concluded that there was self-referral by doctors (where doctors refer to other services in which they have a financial stake), over-servicing of patients and false billing of health insurers. Unlicensed doctors often practised without sanction. These problems were ascribed to: multiple agencies enforcing laws and regulations; a weak and under-resourced main regulatory body (the Health Professions Council) which was not truly independent; weaknesses in the design of legislation; a lack of mechanisms to control prices; and lack of knowledge on the part of patients of their rights (Hongoro and Kumaranayake 2000).

Unfortunately, the growth of medical aid societies in the first decade of this century has not had the intended effect of bringing down prices. Fees are supposed to be set through negotiations between medical aid societies and providers, with the Minister of Health stepping in to legislate fees where agreement cannot be reached, as is currently the case. A study published in 2010 found that this has not been able to address the cost spiral, partly due to persistent vertical integration, despite some Medical Services Act amendments that seek to reduce this by prohibiting open schemes from obliging members to use providers forming part of their stable (Shamu, Loewenson et al. 2010). As one key respondent put it:

It has been a sort of a vicious cycle.... If providers increase their costs of care, medical aid societies would want to cover this by increasing their contributions. Once the contributions have increased, then the providers would then increase their costs to absorb all that has been contributed.

Further, medical aid coverage is apparently declining due to the economic climate, with some medical aid societies failing to make promised reimbursements (interview data). Benefit packages are segmented according to different levels of cover and income groups, and have become outdated since the escalation of HIV/AIDS and other chronic diseases (interview data). Consumer choice and information is also not good, while some societies default on their obligations to report to government and hold annual advisory council meetings (Shamu, Loewenson et al. 2010).

The Medical Aid Societies Statutory Instrument (sub-section 4) allows a medical aid society to invest its funds in any manner provided by its constitution or rules. This has prompted medical aid societies to modify their constitutions to give them wide-ranging authority to invest in non-core enterprises and circumvent other Ministry of Health regulations, specifically with respect to the extraction of profit from medical aid societies (interview data).

Shamu, Loewenson et al. (2010) found that enforcement of the legislation is still problematic due to human resource shortages in the Ministry of Health, ambiguities in the law, lack of databases on medical aid societies and insufficient monitoring, and lack of consumer awareness and advocacy. A policy proposal is currently on the table to develop an independent regulatory authority for medical aid societies in order to address the problem of limited capacity for oversight within the Ministry of Health (interview data). In the meantime, a joint advisory council has been established to deal with issues related to medical aid societies. The Minister of Health chairs this council, which includes representatives of medical aid societies, providers, regulatory authorities, employers and employees, amongst others. The council attempts to solve problems through dialogue between the different parties and is currently involved in

trying to find a way forward after the recent impasse between medical aids and providers around tariffs, including through benchmarking tariffs in other countries.

A more detailed summary of the legislation appears below, as well as sources for the acts mentioned in the text above.

Summary of private health sector legislation in Zimbabwe

Form of regulation	Relevant legislation and provisions
General legislation governing the health sector	
Constitutional protection of the right to health	There is little or no protection of the right to health. However, the draft of the new constitution includes the right to health.
General intention of health policy and legislation to regulate the private sector in line with government's objectives	Neither the Public Health Act of 1925/1996 (Chapter 15:09) nor the Health Service Act of 2005 (Chapter 15:16) refers to the role of the private sector. Health Professions Act (Chapter 27:19) does note that professional councils are intended to assist in the promotion of the health of the population.
Regulatory authorities	Public Health Act of 1925/1996 (Chapter 15:09): Public Health Advisory Board advising the minister and local authorities. Health Professions Act (Chapter 27:19) of 2001: Councils for all the different professions, including nurses (it is not clear where paramedics fall although they may be included under allied health professionals); professional boards may also be established by the councils to assist in improving the standards of training and behaviour. The health professions councils control the entry of health professionals into the health sector, register institutions, monitor the quality of professional practice and training institutions (including through inspection), and provide continuing education. The Health Professions Act also registers and controls health institutions and the services they provide, and empowers councils to conduct inspections. Medical Services (Medical Aid Societies) Regulations, 2000 (SI 330/2000 amended by SI 35 of 2004: The Medical Aid Societies Advisory Council (with closed and open scheme representatives) and the Joint Advisory Council (with scheme and professional grouping representatives). Insurance Act of 1998 (Chapter 24:07): The Commissioner of Insurance. Competition Act of 1996: Industry and Trade Competition Commission prevents and controls restrictive practices and monopoly situations, regulates mergers, and prohibits unfair trade practices (including misleading advertising, false bargains, collusion, predatory pricing etc.). It can carry out investigations and inspections as well as monitor prices when requested by the Minister of Industry and Commerce. National Incomes and Pricing Commission Act of 2007: the National Incomes and Pricing Commission develops pricing models with a view to balancing the welfare of the Zimbabwean population with the viability of producers.
Legislation governing health professionals	
Registration of health professionals	Health Professions Act (Chapter 27:19) of 2001 and Paramedic Practices Act (Chapter 27: 11): The acts provide for the registration of all professionals.
Maintaining professional skills and professional behaviour	Health Professions Act (Chapter 27:19) of 2001: The councils are responsible for ensuring professional behaviour is maintained, responding to complaints and holding disciplinary enquiries. There are requirements for continuing professional education, and training courses are monitored and evaluated. Registered practitioners are not allowed to practise without a licence, which is awarded based on good standing and competence. The councils can inquire into allegations of misconduct.

Legislation governing hospital and nursing home providers	
Licensing and accreditation of hospitals and nursing homes	Medical Services Act of 1998 (Chapter 15:13), amended by Act 22 of 2001, and the Health Professions Act (Chapter 27:19) of 2001: The Medical Services Act states that a private hospital can only be established with the permission of the minister who will consider whether there is a national need for the hospital (taking into account the services to be provided and the location). Under the Health Professions Act, a health institution has to be registered to operate. The awarding of this certificate is based on appropriate physical infrastructure, equipment and staff, according to standards supposedly laid out by the councils. The registration also has to be in the public or national interest. Penalties of fines or imprisonment are imposed for working without registration of the institution or a practice licence.
'Certificate of need' governing location of facilities	Medical Services Act of 1998 (Chapter 15:13), amended by Act 22 of 2001, and the Health Professions Act (Chapter 27:19) of 2001: There is an explicit requirement in the Medical Services Act for 'need' to be a determining factor in the granting of permission for a new private hospital, although this is not well defined. Under the Health Professions Act, registration has to be 'in the public interest', which could possibly be interpreted similarly.
Standards and norms	Specific standards and norms could not be accessed.
Reporting requirements for facilities	There do not seem to be any reporting requirements. There is a general lack of private hospital statistics in the national health information system database.
Price controls	Medical Services Act of 1998 (Chapter 15:13), amended by Act 22 of 2001: Health insurers and private hospitals are supposed to negotiate fees, with the Minister of Health stepping in to legislate fees should there be no agreement. Hospitals cannot charge fees above the prescribed amount without the approval of the minister to whom they must apply giving justifications for increased costs.
Provisions to promote competition	Competition Act of 1996 (Chapter 14:28): The Competition Commission prevents and controls restrictive practices and monopoly situations, regulates mergers, and prohibits unfair trade practices (including misleading advertising, false bargains, collusion, predatory pricing etc.). It can carry out investigations and inspections as well as monitor prices when requested by the Minister of Industry and Commerce.
Legislation governing private ambulances and emergency medical services	
Licensing and accreditation	Paramedic Practices Act (Chapter 27: 11): All ambulance services have to be registered, and registration is dependent on meeting requirements on the vehicle, equipment, appropriate personnel and location.
'Certificate of need' governing location of services	Paramedic Practices Act (Chapter 27: 11): Location is one criterion for registration.
Standards and norms	Paramedic Practices Act (Chapter 27: 11): The act says that certain standards have to be met but does not lay them out.
Reporting requirements for services	Paramedic Practices Act (Chapter 27: 11): There do not seem to be any reporting requirements.
Price controls	Paramedic Practices Act (Chapter 27: 11): There do not seem to be any price controls.
Provisions to promote competition	Competition Act of 1996 (Chapter 14:28): (see above)
Legislation governing primary care providers	
Registration and licensing of primary care practitioners and facilities	Health Professions Act (Chapter 27:19) of 2001: Practitioners have to be licensed to practise and their health institution has to be registered in order to operate. The awarding of the practice certificate is based on good standing and competence, while the registration is based on appropriate physical infrastructure, equipment and staff, according to standards supposedly laid out by the councils. The registration also has to be in the

	public or national interest. Penalties of fines or imprisonment are imposed for working without registration, a practice licence and registration of the institution.
Standards and norms	These could not be accessed.
'Certificate of need' governing location of facilities	Health Professions Act (Chapter 27:19) of 2001: There does not seem to be an explicit requirement for 'need' to be a determining factor in the granting of registration although the phrase 'in the public interest' could possibly be interpreted as such.
Regulation of dispensing and other clinical support services by primary providers	There do not seem to be any specific norms and standards.
Control of private practice by public professionals	There does not seem to be legislation controlling this.
Reporting requirements	There do not seem to be any reporting requirements
Price controls	Although there is mention in the Medical Services Act that hospitals may not charge fees above prescribed amounts, this does not seem to cover private practitioners.
Provisions to promote competition	The Competition Act of 1996 (Chapter 14:28): (see above).
Legislation governing health insurers	
Registration and demarcation of different types of health insurance	Medical Services Act of 1998 (Chapter 15:13); Medical Services (Medical Aid Societies) Regulations, 2000 (SI 330/2000 amended by SI 35 of 2004); Insurance Act 27 of 1987 (amended in 1998 and 2001); The Insurance Act of 1998 (Chapter 24:07): Medical aid societies have to be registered annually. Both restricted and open societies are allowed. The decision to register appears to be based on financial sustainability. The secretary may develop codes of practice for medical aid societies, providers and brokers in relation to one another and the public. There does seem to be a demarcation between the business of a medical aid society (which is mutual insurance) and general insurance in the Insurance Act.
Control of risk rating and adverse selection	Medical Services (Medical Aid Societies) Regulations, 2000 (SI 330/2000 amended by SI 35 of 2004): Members are protected from discrimination for factors such as race, gender and marital status, but this does not include differentials in health status and age - premiums may be adjusted according to health and age and income of the main member. The general waiting time is three months but times up to two years can be stipulated for certain conditions, including the common ones of pregnancy and drugs for chronic illness, as well as cancer therapy and haemodialysis. People who were members of another scheme for at least two years are exempted from a waiting period if they join another scheme within three months. Retired members of restricted schemes may continue membership beyond retirement, depending on the rules of the scheme. Providers cannot refuse to treat any patient covered by a scheme, require advance payment or charge more than the fees decided by the association of medical aid societies and the Zimbabwe Medical Association (or by the minister if the former are unable to reach agreement). The secretary can investigate unfair practices and write an order against the scheme, which is obliged to act on the order.
Standardised benefit packages	Medical Services (Medical Aid Societies) Regulations, 2000 (SI 330/2000 amended by SI 35 of 2004): Minimum benefits must be equivalent to the non-specialist services provided by government/state-aided clinics and hospitals, and must make provision for formal referral to government specialists: a listing of the very broad categories of services is provided in a

	schedule in the 2000 regulations. Low-cost schemes are allowed to provide less than the minimum benefits provided the secretary has approved the scheme. The minister is empowered to legislate a uniform minimum benefit package and contributions.
Price controls	Medical Services (Medical Aid Societies) Regulations, 2000 (SI 330/2000 amended by SI 35 of 2004); The Insurance Act of 1998 (Chapter 24:07); The National Incomes and Pricing Commission of 2007: The National Incomes and Pricing Commission has, on occasion, prevented medical aid societies from charging higher premiums. Government is not normally involved in setting provider fees as these are negotiated between societies and providers. This is sometimes done directly by the relevant parties. However, the Association of Health Funders of Zimbabwe handles negotiations on behalf of most employer-based schemes. For the minimum benefits, societies do not have to pay providers more than the rate at state facilities. Reimbursements have to be within 60 days. Brokers fall under The Insurance Act and have to be registered, although they do not appear to work in the health insurance industry as health insurers deal directly with employers, which saves on administrative costs but hampers competition and consumer choice.
Reporting requirements	Medical Services (Medical Aid Societies) Regulations, 2000 (SI 330/2000 amended by SI 35 of 2004): Annual financial reports must be copied to the secretary.
Solvency	Medical Services (Medical Aid Societies) Regulations, 2000 (SI 330/2000 amended by SI 35 of 2004): Open schemes may not have less than 2,000 members. Reserves may not be less than 25% of gross annual contributions. A scheme's liquid funds must not be less than its liabilities, or the total claims settled in the preceding month. Investments by the scheme in a health-related company allowing that company to enjoy the same tax exemptions must be notified to the secretary within a year.
Provisions to promote competition	Medical Services (Medical Aid Societies) Regulations, 2000 (SI 330/2000 amended by SI 35 of 2004); Competition Act of 1996(Chapter 14:28): The Medical Schemes Act does not allow open schemes to oblige members to use providers owned or partly owned by them. However, this is allowed for closed schemes that are entitled to own facilities but which must also reimburse members who have to use other providers because the services of retained providers were not available or the costs of other providers are equivalent. See earlier for information about the Competition Act: in addition, the act requires parties to notify the Competition Commission of a planned merger before it is implemented. The penalty for failing to comply is up to 10% of the parties' annual turnover.

Note: This table may contain gaps and inaccuracies. The table only addresses legislation governing health care professionals (with a focus on doctors), health care providers (with a focus on private hospitals) and health insurers. The pharmaceutical industry is not addressed.

Sources for acts and other information: country contacts; Hongoro and Kumaranayake 2000; Kububa 2004; Health Economics Unit 2009; Kububa 2009; Shamu, Loewenson et al. 2010; Osika, Altman et al. 2011; Bowman Gilfillan Africa Group 2013; Murombedzi 2013)