



**THE SOUTH AFRICAN MEDICAL ASSOCIATION**

**SUBMISSION  
TO  
MINISTER OF HEALTH,  
NATIONAL DEPARTMENT OF HEALTH**

**COMMENTS IN RESPECT OF WHITE PAPER  
FOR  
NATIONAL HEALTH INSURANCE  
FOR  
SOUTH AFRICA  
TOWARDS UNIVERSAL COVERAGE**

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## **Pre-Amble**

This document has been compiled in response to Government's public consultation on the White Paper for National Health Insurance (NHI) for South Africa, which was published on 11 December 2015. It represents the official view of the South African Medical Association ("the SAMA" or "the Association") and its members.

## **The Functions and Role of the South African Medical Association**

### Role in the Healthcare Sector

The South African Medical Association is a professional association for public and private sector medical practitioners and is registered as an independent, non-profit company. The SAMA is also registered as a trade union for its public sector members.

Membership to the SAMA is voluntary, and with over 17 000 public and private sector doctors currently registered as members (December 2015), the SAMA is the single largest representative organisation of doctors in South Africa.

### Relationship with its members

The SAMA's responsibility is to act as a voice for its members, representing the interests of doctors at local, regional and national levels, and to ensure that the professional expertise of the medical profession is noted in national debates that shape the future of healthcare in South Africa.

### The SAMA's Role in Policy Development

SAMA supports all legislative and policy measures aimed at accentuating the protection and promotion of public health. Furthermore, the SAMA supports all measures designed at promoting access to healthcare, whether through public or private providers, across the country. The SAMA is also engaged with ensuring that a sustainable healthcare industry is supported. Since it is our conviction that healthcare practitioners are the foundation of healthcare system, our membership is ideally placed to make meaningful submissions on the NHI White Paper.

## **The SAMA's Position on the National Health Insurance**

SAMA commends the National Department of Health (NDOH) for championing the health system reform process in South Africa, and for finally releasing the White Paper on NHI. The delayed release of the White Paper posed a threat to national dialogue, increased anxiety and created a negative impression of the NDOH. Nevertheless, the release of the White Paper for public comment is a massive step in the right direction for the improved access to healthcare for all South Africans.

As medical professionals, we are patient-centred in our view of any health system reform, as the practice of medicine demands that the patient's health and wellbeing is of foremost importance. When the idea of NHI was promoted in South Africa, the SAMA voiced its official support for the principle of universal healthcare, a worldwide trend that should address many health inequities in the South African healthcare system.

If implemented properly, NHI should afford South Africans their right to access to the best quality healthcare irrespective of their socio-economic status, leading to better health outcomes and better quality of life for the majority. At the same time, a re-engineered health system would create a safe and enabling environment for health workers to deliver their best care with unhindered morale, having an excellent structural platform for delivery.

These enablers should encourage more of our doctors to stay in South Africa, thus stemming the on-going exodus of health professionals.

Recognizing that no health system can stand without health professionals, it is clear that NHI will be doomed to fail if the health workforce is not satisfied with the NHI processes and proposals.

## **The Procedure**

In compiling this official response on the NHI White Paper, we consulted our members in their various categories. In addition to a member survey that was undertaken in

25 May 2016

December 2015, the various structures of SAMA were consulted on a continuous basis.

These structures are: the Board of Directors, the Private Doctors Committees (both general practitioners and specialists), Public doctor groupings, Junior Doctors, Human Rights Law and Ethics Committee, as well as the Health Policy Committee.

A number of the SAMA doctors inside, and outside of NHI pilot districts, provided their valuable insights and experiences of NHI in this pilot phase. All member views were considered and form the basis of this document.

### **Structure of the Submission**

This submission is structured according to chapters. We considered **eleven topical issues** as raised by our members, to be, from our standpoint, the core matters that deserve serious attention and are determinants of the success or failure of NHI. Each chapter provides concrete recommendations to Government or any relevant stakeholders. We endeavoured as much as possible to base our recommendations on scientifically proven facts and information, in the spirit of evidence-based health policy development, while taking into consideration the views and expectations of our members.

Although the document is long, it is structured in such a way that chapters can be **allocated to various NHI work streams**. We have tried to be accommodating the potential readers by using common writing styles. E.g. the rest of the documents conforms to the health sciences academic writing types, whilst chapter 1, 10 and 11 conforms to the most recognised academic writing for law schools, hence different referencing mechanisms

## EXECUTIVE SUMMARY

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This SAMA submission on the NHI White Paper consists of ten Chapters representing, in SAMA's view, critical issues that need serious consideration for a successful reform of the health system in South Africa. In this submission focus is placed on issues affecting the patient, as well as providers charged with caring for the patient, without both of whom there would be no health system to talk about.

While our submission rigorously examines key challenges to be overcome in implementing NHI, it does not ignore the sterling efforts and achievements by the Government and the National Department of Health in addressing healthcare challenges facing the nation.

In particular, Government's keenness on wide stakeholder/public consultation on NHI is applauded, exemplified by the on-going stakeholder meetings as well as the gesture of extending the initial deadline for White Paper submissions. Other broader, progressive health system reform initiatives by Government congruent to the NHI rollout process are significant milestones for the nation, such as the ideal clinics initiative, and the promotion of a new medical school in Limpopo. This is highly respected.

### Chapter 1: COMPULSORY MEMBERSHIP OF THE NHI

Chapter 1 addresses the constitutionality of mandatory prepayment to raise revenue for NHI by citizens (and permanent residents), as proposed under the NHI. The question addressed is: does mandatory participation infringe on the rights of citizens? According to the White Paper, *"NHI funding will be mobilised through mandatory prepayment. Individuals will not be allowed opt out of making the mandatory prepayment towards NHI, though they may choose not to utilise the benefits covered by the NHI Fund"*.

The chapter describes two fundamental rights pertinent to the query, namely the right to freedom of choice, and the right to have access to healthcare. Drawing on key

documents viz. the Constitution of the Republic of South Africa Act 108 of 1996, the National Health Insurance White Paper, as well as a document by the World Health Organization (WHO), the chapter concludes that NHI mandatory prepayment will not, *prima facie*, infringe on these constitutional rights. Possible exceptions in this regard are explored in Chapter 10.

The NHI is likely to enhance certain rights, i.e. the right to access healthcare services, as the NHI ensures that citizens are able to access healthcare, irrespective of their socio-economic status and ability to pay.

## Chapter 2: QUALITY OF CARE

Chapter 2 provides an examination of the quality of care gaps and opportunities in the South African healthcare system and scrutinizes quality-related proposals (and omissions) in the White Paper. The poor quality of care, particularly in the public sector, is highlighted with facts, making a case for urgent redress by Government.

The less-publicised quality deficiencies in the private health sector are also unveiled. The chapter notes the enormous damage, and loss (i.e. poor population health outcomes, high mortality, etc.), on the citizens brought by poor quality of care practices across all system layers, sectors and facets (e.g. poor quality in: services, training, staff, clinical processes of care, data collection and dissemination, primary to quaternary levels of care, etc.). Michael Porter's concept of 'value-based care' is emphasized.

Using the basis of the Donabedian Framework that evaluates quality at three levels, namely: Structure, Processes, and Outcomes, the chapter identifies the heavy lean of government initiatives (including the mandate of the Office of Health Standards and Compliance - OHSC) on **structural** improvements/performance of facilities to the (almost) exclusion of processes of care and outcomes measurement. The independence of the OHSC is also thrown into question.

The key recommendations made in the chapter are: desperate attempts to boost personnel numbers (e.g. mid-level workers) should not compromise quality; there must be standardised quality metrics in both sectors, with comprehensive and monitored reporting; the OHSC must be **truly** independent and must monitor **all** three

Donabedian dimensions. **Process** indicators of care in particular are easier/faster (than e.g. mortality data) to measure and must be prioritised for priority health conditions; there must be enforcement of quality measurement in both health sectors. Quality of Cuban-trained graduates must be scrutinised. Government must influence shift of competition in the market towards competing on outcomes rather than on patient volumes and facility outlook; critical functions must not be decentralised to grassroots levels.

### Chapter 3: HUMAN RESOURCES FOR HEALTH

SAMA is a doctor representative organisation, and as such, issues of 'human resources' are of broad interest to the body. SAMA acknowledges and appreciates the efforts of the Health Minister to consult the medical profession on the NHI.

'Health workforce', as one of the WHO-identified key building blocks of any health system, is indispensable in NHI. Chapter 3 articulates the collective voice of the various SAMA doctor categories (Junior doctors, Public sector doctors, General Practitioners, Specialists, etc.) on key issues in the White Paper with a bearing on the medical profession and health workers in general.

Chapter 3 uses data and statistics to highlight the serious human resource gap in the country, attributing the problem to, inter-alia, **misdistribution** between public and private health sectors. The continuous 'bleeding' of professionals is lamented.

Five migration patterns of South Africa doctors are noted, namely: 1. Public to private; 2. Rural to urban; 3. South Africa to overseas; 4. from the medical profession to other professions; 5. from overseas back to South Africa. Caution is made about Government's 'additive' approaches to enhance the number of health professionals (e.g. Cuban training program, more undergraduate training in bachelor of medicine and surgery intake), without addressing absorptive capacity of the system and effective **retention** interventions. This will perpetuate brain drain while medical output quality and quality of service delivery becomes compromised.

Rural retention is specially emphasized. Evidence of the enormous retention potential of non-financial incentives as a complement of financial incentives is used to urge

government to implement such incentives as: good working conditions, rural infrastructure development, rural CPD activities, and rural rotation of specialists, among others. The outcome of Government's GP **contracting in** expedition (only about 300 doctors contracted) is symptomatic of a major problem, and the government needs to properly engage health professionals and commit to ironing out any sticking points.

We specifically note that **contracting out** is the preferred model for the majority of independent doctors, yet the model has not been piloted. Also, irrespective of NHI, the current inadequate remuneration (basic salary and overtime) for doctors is a major sticking point and an automatic push factor, which will affect available human resources for NHI.

The chapter's key recommendations are that:

- Retention be strengthened especially in rural areas,
- NHI must be doctor-led,
- Multi-sectorial collaboration is needed to create retentive conditions ("pull factors") for health professionals,
- It is cheaper, and appropriate, to import trainers and train locally rather than training doctors in Cuba,
- Government must restrain itself from freezing posts in the public sector,
- Medical school intake should reflect national demographics,
- Voluntary accreditation of private practitioners should be considered, and,
- The scope of practice for Clinical Associates must be finalised.

#### **Chapter 4: NHI PILOTING AND PHC RE-ENGINEERING**

The chapter recapitulates the NHI pilot program and its achievement to date, informed by the White Paper and government's series of 12 month progress reports. Progressive achievements of the pilot exercise are acknowledged, such as the successful Human Papilloma Virus school program and the good pace of establishing District Clinical Specialist Teams.

The reports, covering pilot districts and some non-pilot districts, as well as wider developmental projects aligned to NHI, show that primary facilities scored more poorly

than hospitals when assessed for infrastructural development/status. In this section SAMA provides a case for inclusion of private sector in delivering of health care.

SAMA raises three critical issues in relation to the NHI piloting exercise:

- I. On what grounds are certain claims of 'improvement' (as stated in the White Paper and reports) due to NHI-related initiatives in pilot districts based? For such claims to be valid there should have been an identified baseline health status of the population against which to measure any achievements. To SAMA's knowledge, no such baseline was established, nor was any such made publicly available. Can we truly say NHI will assist in achieving a life expectancy of 70, improve access to health care, and turn the potential diabetes tsunami?
- II. Engagement of doctors for NHI has been anomalous. **Contracting in** of GPs was refuted by doctors when the model was presented a few year back but it went ahead irrespective, hence the sluggish pace of contracting under that model. Only few doctors signed the contract. **Contracting out**, which is another option of choice, has not been piloted. We recommend that this model be piloted. Also, there is paucity of information on GP involvement. GPs are not part of the district health services despite ability to contribute significantly. Government must tap into this resource to broaden access to a doctor for many South Africans.
- III. Section 335 of the NHI White Paper proposes that the NHI Fund in consultation with the Minister will determine its own pricing and reimbursement mechanisms. This presents as unfair, unconstitutional, and dictatorial. Lack of consultation will place the Government or its entity at risk of legal challenge. Determination of capitation fees and timeliness of payments must be scientific and reasonable enough not to affect provider morale and the care delivery process.

## Chapter 5: NHI FINANCING

Chapter 5 analyses cost projections for NHI, in response to chapter 5 of the NHI White Paper, and identifies potential problems and possible solutions. Specific attention is also devoted to current inefficiencies in the health system. SAMA appreciates the rationale for universal health coverage, which is a vital need for South Africans. However, for such an enormous undertaking to be successful, it would require an

additional investment into the national health budget vote. SAMA laments the preponderance of groundless financial/economic assumptions and claims in the White Paper. Also, the recent assertion by the Health Minister in line with the NHI White Paper that “NHI costing is impossible” and should not be an object of attention is troubling as effective NHI policy planning cannot be devoid of proper costing.

The WHO has a variety of costing tools applicable in different country settings, which SAMA urges the government to consider. If government positions itself as the **single buyer** for NHI services as per the White Paper, at what cost levels does it intend to procure the goods and services? SAMA raises the following key concerns:

**Need for definition of package of care:** SAMA emphasizes that the package of care needs to be defined first before embarking on a costing exercise. The discussion on cost can only take place once a determination on what will be capitated is made, and where we are going to be contracting on global fees, as well as remuneration models to be used. What would be most workable is to paint and model various scenarios and then have them costed. Projections should then be based on the preferred model.

**Proper cost estimates for NHI:** Our assessment that the costing information provided in the White Paper is based on unrealistic assumptions. In the face of South Africa’s current economic growth rate of less than 1%, the White Paper’s assumption of a 3.5% annual growth rate is overly ambitious, and higher than real term projections by several reputable international institutions, including National Treasury, the International Monetary Fund (IMF), the World Bank, Investec, and The Economist, among others. Since economic growth is a determinant of the tax base, proper estimations are urged.

We also underscore that the reluctance on proper costing by government is the root of problems in the health sector such as interrupted supply of medical supplies, salaries, and budget allocations that lag behind population growth rates including migrant populations.

A number of Provincial Health Departments have been placed under administration due to poor financial management practices, among other reasons. Additionally, to obtain some form of financing through National Treasury, the Minister will have to table financial estimate, which we believe should be informed by appropriate and scientific costing methodologies.

Proper, objective and scientific costing, based on a defined package, must be done, with the use of experts in addition to economists, such as epidemiologists to properly estimate the burden of diseases. Adequate costing for anticipated services and essential medication for chronic patients in particular is emphasized, since chronic patients are among those that bear the brunt in the event of erratic service availability due to inadequate funding. Comprehensive costing of the agreed package based on an 'ideal clinic' environment must be done.

**Inefficiencies in the system:** Using current costs as the basis for projections, as proposed in the White Paper, is a problem when inefficiency is considered. The WHO warns against 'locking today's inefficiencies into future estimates'. This warning is applicable in the South African health system which is riddled with substantial inefficiencies, in the public sector specifically. For example, unauthorised, irregular and fruitless expenditure for 2014/15 was about 4% of the entire national health budget. At the time of producing this report, the Auditor General reports for the PFMA 2014/2015 for the Free State and KwaZulu-Natal provinces, have not yet been made available publicly.

**Tapping into medical scheme reserves:** Currently medical scheme reserves are estimated to be R46 billion. The question is: suppose there is going to be natural attrition from medical scheme cover towards NHI services, which is most likely, contingent upon competitive quality in the NHI system, what happens to those scheme members' contributions already made towards reserves of a medical scheme? In planning the future role of Medical Schemes the Ministry is encouraged to look at the disbursement of this funds in a way that would have maximal impact to the citizens..

**Comprehensive piloting:** In order to attain estimates with a higher reliability factor, SAMA proposes that the number of NHI pilot sites be increased to 20 (approximately 40% of the number of districts in South Africa). The NHI sites should be selected in such a manner that results in clustering, i.e. that NHI sites are adjacent to each other. This should be done in order to include referral facilities up to and including tertiary facilities, so that referral patterns are piloted, and also so that the complete suite of NHI factors is piloted. Further, we propose that the newly established pilot districts be operational for at least five years in order to ensure that trends in costs and utilisation can be measured.

## Chapter 6: UNIVERSAL HEALTH COVERAGE FOR MENTAL HEALTH

Chapter 6 singles out mental health to emphasise and lobby for prioritization of this disease in universal coverage, since this disease has been neglected in the health system despite having a high burden, and in spite of the available robust national Mental Health Policy Framework.

SAMA appreciates the White Paper statements (albeit broad) on mental health in paragraphs 96, 131, 169, 199, and 341 of the White Paper. This chapter uses evidence to strengthen the case for allocation of more focus and resources towards this disorder, which has an annual prevalence of about 17% in South Africa and is exacerbated by effects of HIV/AIDS.

Lifetime prevalence of common mental health disorders was in the region of 33% in 2009. The chapter highlights the enormous **stigma and discrimination** suffered by those with the disorder at the hands of the health system and society, and also pinpoints that mental disorders are a risk factor for communicable and non-communicable diseases. The chapter also reports that the challenge is not confined to the state sector, but also plagues the private sector, for example PMBs only cover two chronic mental conditions, are hospital-centric, and often demand out of pocket payment.

As mental disorders are associated with certain socio-economic environments that many South Africans are exposed to (poverty, violence, drug abuse, family discord, workplace stress, etc.), SAMA commends the national departments of Health and Education for implementing the Integrated School Health Programme in the needy quintile 1 and 2 schools. Early interventions at critical childhood developmental stages are likely to have positive impacts and have been appropriately prioritized.

The chapter describes critical issues, namely barriers to accessing mental health services, poor financial prioritisation of mental health, as well as requisite human resources for the discipline. The recommendations in this section make a case for integration of comprehensive mental health into PHC, deinstitutionalisation of mental health, effective anti-discriminatory strategies, the use of mental health coordinators and specialist mental health professionals at primary level, improved access to

medicine through patent law reforms and other interventions, and strengthening monitoring and evaluation. In order to redress the inequities experienced by mental health patients, the NDOH in its NHI pilot districts must implement the mental health package as envisioned in the National Mental Health Policy.

## Chapter 7: MONOPSONY AND LABOUR MARKETS

Monopsony is an example of imperfect competition whereby one buyer of healthcare services exists among many suppliers of services. Monopsony is often referred to as a buyer's monopoly. This chapter uses available literature to analyse the pros and cons of the monopsony model envisioned for the NHI whereby the NHI Fund will leverage its monopsony purchasing powers as a single purchaser of health services supplied by multiple providers.

One attractive feature of monopsony is the allure of efficiency (economies of scale) and thus potential reduction of prices or goods and services, leading to broader access to healthcare services. The downside is that the monopsonist buyer (NHI Fund) is poor at negotiating quality. The monopsonist also dictates terms to suppliers (healthcare providers), thus potentially leading to low reimbursement levels for doctors. Under monopsony, salaries are, in theory, determined by government's **willingness** to pay, government's **ability** to pay, and the size of supply (number of medical employees). Unionisation by doctors would be critically imperative to enhance suppliers' negotiating power for tariffs.

The chapter identifies that review of competition laws is necessary to allow health professionals to negotiate tariffs. To ensure transparent price determination, establishment of a **Pricing Commission** is recommended, as well as institution of cost studies and evaluation of existing coding systems. Short of competitive salary (reimbursement) levels, and conducive working conditions, brain drain is inevitable.

## Chapter 8: MORAL HAZARD

Chapter 8 describes the dilemma of potential moral hazard within NHI. The White Paper identifies the risk of moral hazard (paragraph 137) from both the user and providers' side, and recognizes some of the possible mitigating interventions against moral hazard (paragraphs 138 and 325). The meaning of moral hazard is explained.

This chapter evaluates the merits of such interventions against international literature and best practices. From the NHI beneficiary's side, patients are incentivised to overuse NHI services or take health risky behaviours (such as smoking) knowing that they are not paying directly for the costs. From the suppliers' side, health professionals are likely to over-service for their own interests. (However, underservicing is more likely under a capitation system). Both types of moral hazard drive up costs.

To reduce hospital and professional moral hazard, SAMA supports the use of treatment guidelines and protocols, which must be evidence-based and cost effective.

To reduce user side moral hazard, two standard mechanisms are propounded:

- **Co-payments** – In congruence to the White Paper, SAMA does not support this as it may reduce access to care and may entrench inequalities.
- **Gate-keeping** (paragraph 128) – SAMA supports this intervention with the GP as the central figure. However, the envisioned bypass fees (paragraph 148) must be properly defined. What proportion does the patient pay? Fees must be set in such a way that inequities are not promoted i.e. high socio-economic strata continually accessing unnecessary specialised care because of ability to pay.

## Chapter 9: CORRUPTION

In considering NHI as a new funding system for South Africa, SAMA members identified corruption as a serious risk for successful and sustainable NHI. The NHI White Paper acknowledges the threat of corruption, noting that the NHI Fund itself may succumb to the temptations of corruption (paragraph 375). Chapter 9 turns the spotlight on corruption, recognizing it as the vicious cankerworm that is eating away our health system and is posing a serious threat to the achievement of health outcomes.

General corruption and corruption in the health sector is a global problem; there is increasing concern worldwide about the adverse effects of corruption on the developmental agenda in terms of attainment of Millennium Development Goals (now Sustainable Development Goals). In Africa, big scandals involving officials and leaders in both government and private circles have been reported. South Africa is no exception, where grant corruption is reported in common media and by advocacy

groups such as Corruption Watch. Recent international data categorises South Africa among countries perceived to have serious corruption, ranked 61 out of 170 countries and with a corruption score of 44 (100 being perfect and 0 being completely corrupt). A unique aspect in the South African context is the question of trustworthiness of government. It is recognised that trust must be earned. This chapter strongly points out that the apparent societal (South African) suspicion on (and diminishing confidence in) political leaders and/or government institutions has relevance in the search for right solutions.

Corruption is not just about money. Systemic corruption rampant in our health sector and the South African health sector in general, takes many forms: contemptible so-called 'tenderpreneurship', cronyism, kickbacks, theft of time (absenteeism), bribery, medical scheme fraud, and theft of medicine, among other things. Besides being severely costly to the system, corrupt behaviour is unacceptable and puts anyone who practices it – health workers included – at odds with ethical expectations of good professional practice.

By way of recommendation, this chapter emphasizes the need to strengthen transparency and control, as well as prosecution. Absenteeism of state employees can be addressed by measures like better working conditions including better management of RWOPS, establishment of a **Commission of Inquiry** to interrogate state sector absenteeism, and better remuneration including performance bonuses for clinicians.

## **Chapter 10: LEGAL PERSPECTIVE ON THE WHITE PAPER**

This chapter gives a comprehensive view on the predominant legislative and regulatory aspects relating to the NHI implementation, providing legal guidance and highlighting potential legal pitfalls that must be avoided in foreseeable changes to legislation necessitated by NHI implementation. Identifying over a dozen directly health-related Acts and regulations, as well as a flurry of non-health statutes (e.g. the Income Tax Act and Patents Act) that must be carefully considered, reviewed and aligned in the course of NHI implementation, this chapter underscores that strict adherence to the principles entrenched in the Rule of Law, and reinforced by the South

African Constitution, will be essential for the success of the NHI. The National Health Department and the NHI system will be expected to comply with all these legislations.

Some examples of legal precedent included in this chapter highlight a number of critical issues that could arise under the NHI, for example:

- Limitations imposed on the State's constitutional obligation to provide healthcare services as a result of budget constraints;
- The risk of health regulators acting outside their statutory mandate in contravention of the Promotion of Administrative Justice Act; and
- The need for appropriate balance between the interests of the public to have access to affordable health care, and the interests of suppliers or providers and their viable livelihood.

With regards to the Office of Health Standards Compliance (OHSC), a three-year-old statutory body, SAMA regrets the absence of final Norms and Standards Regulations to give the entity full powers, especially against the background of evidence (following inspections) of serious non-compliance by health facilities. SAMA supports the principle that both the OHSC and the Ombudsman should remain totally independent from undue influence by the State.

In relation to the Medical Schemes Act, this Chapter interrogates Section 8.10 of the White Paper ("The future role of medical schemes") and raises two major issues:

- I. The White Paper is disconcertingly vague on the specifics in relation to the NHI versus the future of medical insurance and medical schemes. With specific reference to 'Demarcation Regulations' drafted in terms of the Long Term Insurance Act of 1998, SAMA submits that medical schemes (regulated by the Medical Schemes Act), and insurance products (regulated by the Short and Long-term Insurance Acts) for a variety of health services should still find regulated application under the NHI until such time as a proper public sector health service system can carry the weight of adequate health services without the need for these additional insurance products.

- II. The White Paper's suggestion that, on full implementation of the NHI, the only cover to be provided by medical schemes will be complementary and not duplication is too drastic and should be reconsidered, in the absence of assurances that the NHI services will be available and of acceptable quality.

The Medicines and Related Substances Amendment Act 2015 creates the South African Health Products Regulatory Authority (SAHPRA), which SAMA hopes will manage to accelerate the medicine registration process to such an extent that quality-approved generics can rapidly enter the health system, while maintaining quality standards. SAMA supports efficient and effective regulatory control of the very large complementary medicine industry to be incorporated in, or cross-referred to, in the eventual NHI Act, based on a risk-based approach under the auspices of SAHPRA.

With regards to Prescribed Minimum Benefits (PMBs), the Minister of Health's intention to change Regulation 8 alongside the NHI implementation is noted, but SAMA has to caution that any capping of the current "payment in full" obligation of medical schemes without effective alternatives firmly in place will be detrimental to patients who cannot afford co-payments and who will have only the current public sector facilities to rely on, with, for example, frequent stock-outs of life-saving antiretroviral medication. Any foreseen regulatory changes in this regard will have to be approached with the utmost caution. The Ministry must remain careful that in their efforts to improve health care, they do not deliberately reduce the health status of medical aid beneficiaries to achieve their equalisation with the rest of the population.

A number of paragraphs in the White Paper allude to access and affordability of health services and goods, including medicine, e.g. paragraph 392 thereof. SAMA supports the right afforded to government to regulate the price of medicines – in both public and private sectors – provided that such regulation is effected within practical and reasonable parameters, and in an open and transparent manner, with due regard to economic viability.

This chapter also highlights and recommends initiatives (such as SAHPRA's membership to the International Consortium of Medicines Regulatory Authorities) that enhance international harmonization of medicine laws. SAMA fully supports all such

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essential interventions that can ensure provision and availability of essential and other medicines to South Africans. SAMA, regrettably noting that patents are not properly scrutinised in the South African system, and that the patent system undermines access to medicines, recommends drastic review of the Patent Act and the removal of patent protection from the Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The government's proposed use of external reference pricing (ERP) benchmarking against countries such as Australia, Canada, and New Zealand etc. is noted. It is SAMA's contention that, for the Department of Health to effectively implement external reference pricing as part of medicine price regulation in South Africa, it would have to require data of true negotiated prices rather than shadow prices, and that its legislation framework for the use of external reference pricing will have to be sound, including criteria of choice for reference countries.

In respect of price regulation, it is noted that, although individual price item regulation may produce savings to health systems, it is not guaranteed that the overall cost of rendering health services would be reduced by price regulation without considering health outcomes, the availability of services and the utilisation and costs of resources in other parts of the social security system.

On value added tax (VAT) as a revenue stream for the NHI, it is SAMA's recommendation that VAT on essential medicines be scrapped to broaden access to these medicines, as was done in Ukraine. It is recommended that the components used for the manufacture of medicine locally be exempted from import duties.

Product liability legislation is investigated with reference to the Consumer Protection Act and its influence on SAHPRA and it is pointed out that regulatory development supporting the NHI will have to keep track with pharmaceutical and healthcare innovations.

The possible influence of the soon-to-be-promulgated Protection of Personal Information Act on the national e-Health strategy and the Normative Standards for eHealth is cautioned against.

The White Paper gives scope for the **contracting** of private healthcare providers for the NHI. SAMA notes the limited number of GPs who have to date signed the contracts, due to the unreasonable contracting model (“contracting in”) and contracting rates offered. SAMA strongly contends that any capitation model in terms of a regulatory price regime set by the NHI (also with reference to paragraph 335 where the White Paper expressly states that the Minister and the NHI Fund will determine **its own** pricing and reimbursement systems) will have to be economically viable for practitioners (GPs) to be enticed to enter into contracts based on such regime.

The chapter concludes that it will be essential for the NHI to be harmonised with the necessary legal changes that must give effect to the successful implementation thereof. Gradual changes will provide stability and the effective provision of the resources needed to enable effective transitional arrangements until the system is fully operational. Legal changes should be phased in by providing different operation dates for various sections of new or amended legislation, allowing sufficient time to plan for additional responsibilities, functions and resources needed to give effect to the legislation.

## Chapter 11: GOVERNANCE PERSPECTIVE ON THE WHITE PAPER

Good governance is imperative for a successful NHI in South Africa. Governance within the NHI health system ought to mirror generally accepted global governance principles. SAMA lauds the White Paper's acknowledgment of the important role of good governance in the achievement of its goals, in view of the fact that Thailand's success with universal healthcare is *inter alia* attributed to the good governance achieved through its development of institutional capacity. Beginning with providing a comprehensive WHO definition of 'governance' that encompasses six aspects this Chapter elucidates the role of governance in NHI and highlights specific governance issues and challenges prevalent in South Africa.

The White Paper provides envisaged commitments on governance structures and promises the improvement of management and governance of health facilities at PHC and hospital levels by strengthening these "in terms of structure, powers, delegation, financial management and accountability".

Regrettably NHI is being implemented in an environment riddled with serious governance challenges especially in the public sector, namely: corruption; poor management at various levels (aggravated by a lack of accountability), a notable lack of implementation of existing policies, regulations and guidelines, and a lack of proper evaluation and monitoring. SAMA is concerned about the NHI's capacity to meet these challenges.

SAMA highlights that certain NHI-related entities which are supposed to have autonomous decision making powers, must be protected by legislation. These include: the OHSC, the NHI Fund, and the National Health Commission. SAMA is also concerned that decentralisation to district level was first proposed in the 1997 White Paper on transformation of health services. Almost 20 years after this proposal, decentralisation to district level has not been implemented. It is very important that the NDOH reviews why decentralisation to districts has not yet happened. If success of NHI depends on decentralisation, barriers to such must be addressed urgently.

SAMA also strongly supports the establishment of an independent Medical Practitioner Council, especially in light of the acute deficiencies identified in respect to the HPCSA.

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This chapter also makes recommendations on key governance aspects that impact on NHI, including: public-private partnerships, human resource requirements to improve governance, political influence on governance, and Intergovernmental relationships.

# 1. COMPULSORY MEMBERSHIP FOR THE NHI

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## 1.1 Introduction

The White Paper on the National Health Insurance (NHI) makes it mandatory for all citizens to join the NHI system. The question raised is whether this would be constitutional as it limits the rights to freedom of association and health care.

## 1.2 Research and findings

In addressing this query, key documents were consulted and are cited further in the document. The documents include: the Constitution of the Republic of South Africa Act 108 of 1996; the National Health Insurance White Paper; as well as a document by the World Health Organization (WHO).

### 1.2.1 *Mandatory participation:*

Under the proposed NHI, a single, compulsory medical scheme will be created. All South African citizens and permanent residents will be covered by the NHI, while a special fund will be set up for refugees. However, asylum seekers will only be able to access emergency health care.

The universal health cover that is envisaged by the NHI has been successfully implemented in various countries, such as Brazil, the United Kingdom, America and Thailand. The World Health Organization has urged more countries to implement universal health care coverage. [1]

a)

### 1.2.2 *Freedom of choice:*

Section 18 of the South African Constitution [2] establishes the right to freedom of association, which all South African citizens have. SAMA notes that the idea of compulsory membership to the NHI may, in certain instances, infringe on this right.

The NHI does not, at least prior to its finalisation, prevent people from joining private medical aid schemes for supplementary health services (paragraph 399). However, under the NHI, medical aid schemes are to offer only complementary services, which the NHI will exclude once the system is fully implemented (paragraph 401). Foreseeable legal challenges in regard to the latter scenario are addressed under Chapter 10 hereof.

### **1.2.3 Right to access health care:**

The right to health care is entrenched in section 27 of the Constitution, it reads:

*“(1) everyone has the right to have access to –  
(a) Health care services, including reproductive health care;  
(3) No one may be refused emergency medical treatment.”*

The NHI aims to provide affordable health care services to all South African citizens. It will offer services based on peoples’ health needs and not their socio-economic status. In this regard, it will be consistent with the constitutional right of providing access to health care services. Further, all South Africans will have access to essential health care services from state and private health care providers contracted to under the NHI.

**b)**

### **1.2.4 Infringement of rights:**

For the purposes of this report, it is crucial to consider whether any of the above rights would be infringed by the implementation of the NHI. The Constitution makes provision for the limitation of rights, as no right is absolute. Section 36 provides:

#### **“36. Limitation of rights**

*(1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open*

*and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including –*

- (a) The nature of the right;*
  - (b) The importance of the purpose of the limitation*
  - (c) The nature and extent of the limitation;*
  - (d) The relation between the limitation and its purpose; and*
  - (e) Less restrictive means to achieve the purpose.*
- (2) except as provided in subsection (1) or in any other provision of the Constitution, no law may limit any right entrenched in the Bill of Rights.”*

The NHI's goals of universal health care cannot be said to be infringing on any of these rights. Even if this was the case, any such infringement would be tested against section 36.

### **1.3 Conclusion**

In conclusion, mandatory participation in the NHI ensures that citizens are able to afford health care, irrespective of their socio-economic status. This is of utmost significance in a country such as South Africa, where most people cannot afford basic amenities. Constitutionally speaking, the NHI will not, *prima facie*, infringe on any constitutional rights as long as it does not prevent people from joining private medical aid schemes that will be able to cover supplementary services. If only complimentary cover is allowed as set out in paragraph 401 of the White Paper, such a situation will be susceptible to a constitutional challenge, to be weighed under section 36 of the constitution.

### **References**

1. World Health Organisation. Universal Health Coverage.[cited 2016 March 18].Available from: [http://www.who.int/universal\\_health\\_coverage/en/](http://www.who.int/universal_health_coverage/en/)
2. Constitution of the Republic of South Africa Act 108 of 1996.

## 2. QUALITY OF CARE

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### 2.1 Introduction and background

The impacts of health care investments in South Africa, a developing country, are typically measured by inputs (e.g. budgets), and general health outcomes. Missing from the health agenda are measures of quality that reflect whether health systems are meeting their objectives, public resources are being used appropriately, and whether the priorities of government are being implemented [1]. Good governance is central to raising good quality health care delivery. Crucial to high quality are **standards, information, incentives and accountability**.

Quality healthcare ought to be the lynchpin of NHI. According to the WHO, ‘the main objective of Universal Health Care (UHC) is for the **quality** of health services to be good enough to improve the health of those receiving services [2].

South Africa as a nation has constitutional obligations to deliver socio-economic rights to its citizens. SAMA fully supports the provision of UHC, a phenomenon sweeping across the globe, and is in agreement with the globally-embraced non-negotiable need for quality health care, especially in an era where healthcare costs are spiralling and patients deserve better value of health services provided.

The White Paper fully acknowledges the serious quality shortcomings spanning across public and private sectors. Despite some pockets of excellence, the challenges of poor health care quality, and related contributing factors latent in the South African health system, are profound. These threaten the trustworthiness of the system and international image and. The problem of poor quality in South Africa is fairly well diagnosed and almost over-debated, but little or no corrective action has been taken.

South Africa now needs proper, comprehensive and timely responsive measures by responsible government and health authorities. Given the clear failed past attempts to improve quality in the South African system, the realization of quality goals now demands a **comprehensive redesign** of the health system.

We note that the NHI fund will be responsible for performance measurement and reimbursement linked to performance measures. In view of the current unsatisfactory state of affairs in South Africa regarding health care quality practices, a lot can be

learnt from other international bodies. For example, the Care Quality Commission, the **independent** regulator of health and social care in England, monitors, inspects and regulate services such as GP practices, walk-in centres, out-of-hours services, NHS trusts, and independent hospitals, with a rating of performance and ample publication of findings. The Care Quality Commission uses its power to take action on the non-compliant, including imposing penalties, warnings, and restrictive conditions on the provider's registration/scope, close supervision, as well as prosecution [3].

In our Submission we take a patient-centred view and make recommendations for quality of care measurement, monitoring and transparent information dissemination. It is our view that quality measurement be conducted by an independent body. (More details on this are available in the Regulatory Framework chapter).

## 2.2 Problem Statement

SAMA is extremely troubled by the current poor levels of quality, in all its dimensions, experienced by health service users, and the poor patient outcomes especially in the public health sector of South Africa, but also in the private sector.

**Of particular importance, SAMA bemoans the lack of proper, coordinated tracking, recording and publishing of objective quality evidence/data in the health system at national level, which renders evaluation of any improvement in health outcomes difficult.**

One example of inappropriate approach to quality measurement is the implementation of NHI piloting that was done without, to the SAMA's knowledge, a baseline of health quality outcomes upon which to base claims of quality improvements attributed to NHI piloting. Without proper monitoring and enforcement of quality of care, universal coverage may result in false successes and claims, as well as unintended equitable distribution of poor quality of care and lack of impact on health outcomes.

SAMA fully supports the notion of value-based health care propounded by Michael Porter, which emphasizes patient centeredness and achievement of better patient health outcomes [4]. As such, the SAMA is cognisant of its role in contributing cooperatively with other key health stakeholders, to the creation, measurement, reporting and improvement of quality in the entire health system , including quality in clinical processes, among health professionals and health leaders, as well as quality

of infrastructure and care environment that are linked to positive health outcomes. This, of course, is dependent on government's willingness to engage stakeholders in the national quality effort in a collective and meaningful manner.

SAMA's commitment to quality health care and continuous quality improvement is discernible. In addition to direct engagements with the National Department of Health (specifically the Office of Health Standards and Compliance) in the past few years, the SAMA established a SAMA sub-group on Quality of Care to unpack quality-related issues to inform the SAMA submission on the Green Paper, during the NHI Green Paper round of consultations. The submission highlighted serious quality shortfalls within the South African health system, most of which needed immediate attention. The SAMA also emphasised evidence-based medicine as one vehicle for the achievement of quality health care.

In his numerous speeches on NHI, the Minister of Health, Dr Aaron Motsoaledi, underlines **quality health care** as the central element in NHI or UHC in these words:

*"The NHI is not about abolishing private healthcare, but about making quality healthcare more affordable".*

The centrality of quality of care can also be found in Dr Motsoaledi's recent response to a question about what he considered to be the one, great challenge he faces in trying to introduce an equitable health system in the public sector in South Africa:

*"There are many, but I would say quality of care and human resources are the toughest challenges when it comes to establishing NHI."*[5].

South Africa's poor achievement of some of the health-related millennium development goals (MDGs) by the target year of 2015 distressingly exemplifies the enormous quality challenge gripping South Africa. One of the most common outcome measures is the infant mortality rate (IMR), which is considered a sensitive marker of a country's development. South Africa's IMR, when compared to other countries, is still high at 34 deaths per 1000 in 2015 [6].

With the mission of "Empowering doctors for bring health to the nation", SAMA recognises the focused commitments on improvement of quality of health services in the NHI White Paper and agrees that the pursuit of quality health care is a responsibility of both the public and private health sectors. SAMA is, however, not

convinced that the current structure and mandate of the newly established Office of Health Standards and Compliance (OHSC), the national quality and accreditation watchdog, is designed to fully evaluate and control quality in all its measurable dimensions and in both sectors. This will be elaborated on further in the document.

### 2.3 Healthcare quality dimensions and principles

It is indisputable that quality must be engrained in the entire value chain of healthcare delivery to give South Africans their constitutional rights to high standard healthcare and a better quality of life. The current poor quality of care, especially in the public sector, blocks the route to citizens' constitutional right to health care. The challenge in South Africa has been the lack of a common and adequate framework to measure quality.

Measurement depends on the development of suitable empirical and normative standards [7]; this has been elusive in South Africa. Lately the Department of Health developed the National Core Standards for Health Establishments in South Africa, as a vehicle for quality assurance. These core standards cover seven domains namely:

- Patient Rights
- Patient safety
- Clinical Governance and Care
- Clinical Support Services
- Public Health
- Leadership and Corporate Governance
- Operational Management, as well as Facilities and Infrastructure

SAMA contends that, while appreciating the availability of the above national quality measurement frameworks and other quality efforts, the framework is narrow, not covering all the WHO-defined dimensions of quality as defined below.

Secondly, judging from past performance, these government tools and frameworks are 'good' on paper but poorly implemented. For example:

- I. Comprehensively and systematically **evaluating** effectiveness of healthcare services based on process and outcomes indicators.

- II. Reporting findings on quality performance, for public consumption (i.e. reports intended for citizens not professionals).

### **8.1.1. Dimensions of Quality**

Quality must be defined, pursued, measured, and improved upon. In order to properly evaluate the quality proposals set out in the NHI White Paper, and to gauge the quality scenario in South Africa, a brief look at definitions of quality is needed.

The USA's Institute of Medicine (IOM) defines quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." [8].

The WHO's working definition of quality is based on six areas or dimensions of quality that a health system should seek to make improvements in. These are [9]:

- I. *Effectiveness*: delivering health care that is adherent to an evidence base and results in improved health outcomes for individuals and communities, based on need;
- II. *Efficiency*: delivering health care in a manner which maximizes resource use and avoids waste;
- III. *Accessibility*: delivering health care that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical need;
- IV. *Acceptability/patient-centeredness*: delivering health care which takes into account the preferences and aspirations of individual service users and the cultures of their communities;
- V. *Equity*: delivering health care which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location, or socio-economic status;
- VI. *Safety*: delivering health care which minimizes risks and harm to service users.

The NHI White Paper's recognition of some of the above quality dimensions, and what needs to be done to improve quality, is a significant step in the right direction for the nation's health. These assurances notwithstanding, what has proven to be a critical issue has been the extent to which government can control and practically enforce each of the quality aspects? An example is the high inefficiency besetting the public and private health sectors, as well as safety and security in hospitals; the unwarranted

status quo persists - what has the government done in the past to control costs and wastage in the system, and to ensure safety?

### 8.1.2. The Donabedian Framework on Quality [9]

Propounded by the father of quality assurance, Avedis Donabedian in the 1960s, the Donabedian Framework is one of the common theoretical frameworks for examining health services and evaluating quality in health care settings. According to the model, information about quality of care can be drawn from three categories: structure, process, and outcomes. As depicted in the diagram below, Donabedian's framework is a linear, step-wise model involving linearly dependent relationships between each of the three components. For quality-improvement efforts, performance indicators can be set for each of the components. The triad is described below:



- **Structure:** refers to the physical and organizational aspects of health care settings (e.g. physical facilities, equipment, personnel, culture, management, incentives, operational systems).  
At a health system level in South Africa, structural issues in NHI include things such as the NHI Fund, hospitals at all levels of care, the OHSC, the Ombudsman, District Clinical Specialist Teams, integrated teams or provider networks, etc.
- **Process:** refers to all clinical activities done in providing care (preventive care, diagnosis, treatment, patient education). At a system level, processes would include practices such as clinical health treatment and preventative care. For example, in caring for a diabetes patient, process indicators will include annual HBA1C and renal function testing, eye and foot examination, and access to appropriate medication. Preventative process measures will include childhood and vulnerable population's immunisation, cervical cancer screening, HIV testing etc.
- **Outcomes:** patient recovery, functional restoration, relapses, survival, satisfaction

In the Donabedian triad depicted in the diagram above, the first two elements contain indirect measures that influence the third direct element, outcome. All elements are linked with each other, **therefore insight into just one of the three is insufficient to measure and evaluate integral quality.** However, this is not the case, for example, the South African private sector has good structure but poor process indicators have been reported.

Despite its wide application globally in health settings, one criticism of the Donabedian model is that it is too linear, i.e. it excludes environmental characteristics (cultural, political, and physical characteristics, as well as factors related to the profession itself) and patient characteristics (genetics, habits, beliefs, attitudes, and demographics).

## 2.4 Role of public and private sectors in quality

The two-pronged characterisation of the ills of the South African healthcare system as being: (1) poor quality in the public sector and, (2) high costs in the private sector, are two sides of the same quality coin. The high private costs of care are an aspect of poor quality, based on the six WHO domains above: the private health service delivery is inequitable, hinders economic access to services and is inefficient (e.g. over supply of services) on many fronts. This makes pursuit of quality health care a responsibility of both sectors, as the NHI White Paper also points out: “*Quality of healthcare must be adequately addressed in both the public and private sectors*” [11]. The preamble to the National Core Standards for Health Establishments in South Africa states that these Standards are meant for both private and public sectors. Likewise, certification and accreditation processes by the NHI Fund and the Office of Health Standards and Compliance will be applied to both sectors.

Both private sectors players including Council for Health Service Accreditation of Southern Africa (COHSASA) and Health Quality Assessment (HQA), and the public sector have quality of care tools, expertise and data that is unfortunately not standardised, comparable, or shared between the two sectors. The two sectors must collaborate and unify around quality efforts.

## 2.5 Quality of care challenges in the South African health system

The problem of poor quality in South Africa is fairly well diagnosed and almost over-debated. Unsatisfactory quality is not confined to the public health sector alone; quality challenges are also found in the private sector. Below we discuss each sector in turn.

### 8.1.3. Quality in the South African Public Health Sector

As acknowledged by the White Paper, poor quality in the public sector is a deep cutting problem. The poor quality in state clinics and hospitals is evident, and has been the focus for government interventions for years, despite little discernible improvements. Such structural challenges play a huge role in influencing the resultant poor clinical processes and patient outcomes experienced in state patients. The notable challenges are listed in the table below.

<b>Structural problems in public health care facilities</b>	
<ul style="list-style-type: none"> <li>• <i>Fragmented and inefficient service delivery</i></li> <li>• <i>High maternal and child mortality</i></li> <li>• <i>Poor infection control in healthcare facilities</i></li> <li>• <i>Malfunctioning management and support systems</i></li> <li>• <i>Lack of resources</i></li> <li>• <i>Low staff morale</i></li> <li>• <i>Over-crowded facilities</i></li> <li>• <i>Bad staff attitudes</i></li> <li>• <i>Avoidable errors</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Long waiting times</i></li> <li>• <i>Uncleanliness of facilities</i></li> <li>• <i>Under and overuse of services</i></li> <li>• <i>Poor referral system</i></li> <li>• <i>Drug stock outs</i></li> <li>• <i>Poor information and record system</i></li> <li>• <i>Variability of quality care across Public/Private sectors</i></li> <li>• <i>Variability of quality care across provinces</i></li> <li>• <i>Poor safety and security at health care institutions</i></li> </ul>

### 8.1.4. Quality in the South African Private Health Sector

The private sector is not exempt from quality failings. The high private sector costs and exploration of solutions to address efficiency have preoccupied the South African government, industry experts, and the public, to the extent that the delicate issue of quality of care in the same sector has been overshadowed.

Quality in the private health sector has for long evaded public scrutiny due to stereotypical assumptions of superior quality in the private sector. However, anecdotal

evidence, some local industry reports (including the SA Demographic and Health Review 2014/2015 and the Health Quality Assessment Industry Report 2015), as well as recent revelations from the ongoing Inquiry into the Private Health Sector have uncovered serious and shocking quality flaws in the private health system. Some examples are provided below.

- i. The frequency of adverse events in the private (and public) sectors is cause for concern. Poor infection control and some disease outbreaks reported in the private sector are examples of poor quality in the private sector. It is estimated that one in seven patients (14% of patients) using South African public and private hospitals are at risk of contracting nosocomial infections, a rate higher than the global average [12].
- ii. It is indisputable that the cost of private health care is a major concern for all South African consumers, as such costs do not allow access by a sizeable proportion of citizens. 'Access' in itself is a critical element of quality, according to the WHO definition of quality. South Africa has one of the most expensive private healthcare systems in the world, and spends more on private health insurance than any other OECD country [13]. According to the WHO, South Africa spends 41.8% of total health expenditure on private voluntary health insurance, which benefits only 17 % of the entire population [14]. The principle of **affordable quality** must be promoted. The SAMA agrees with the government on the commitment to an affordable private healthcare market in South Africa, although SAMA emphasizes that any measures or policy decisions to that effect must be sustainable and amenable to all players in the health system, including healthcare providers.
- iii. Available evidence shows that the spiralling private healthcare costs in South Africa are in no way equivalently matched to the quality of care and outcomes produced in the private sector. What tends to give private healthcare the allure of unparalleled excellence is in reality the high level of hotel services offered and unnecessary specialised care, which is enough incentive for some naïve users yet does not translate to better clinical outcomes. Evidence shows that private **outpatient** care in particular is compromised, and – especially among medical scheme members – there is less emphasis on preventive and primary healthcare services, leading to the development of disease profiles that need

a higher level care. This trend perpetuates the costly hospi-centricism that characterises the private sector.

Detailed clinical data from the HQA 2015 Industry Report reveals poor process (utilisation) indicators of quality among medical scheme patients, for the period 2010-2014. Some of the reported worrying trends are:

- A rising prevalence of chronic diseases
- Declining coverage for pneumococcal vaccine among >65year olds
- Declining indicators on coverage of chronic disease management (cardiovascular, diabetes, and other indicators)
- Stagnant (low) coverage of primary healthcare and screenings (mammograms, HIV, cancer, and glaucoma screenings)
- Rising admission rates

- iv. Poor monitoring and data reporting on quality in the private sector has impeded accountability for poor health outcomes. At issue is the lack of systematic and standardized monitoring, evaluation, and reporting of quality of care services in the private sector. The pathetic physical state and poor outcomes in government hospitals have distracted public and government's attention on quality shortfalls in the private sector.

While quality of care in the public sector is tracked and disseminated by various national tools such as the South African Demographic and Health Surveys, Public Health Facility Audits, Saving Mothers Report and Saving Children Reports, efforts to measure quality of care in private institutions have not been successful on a voluntary basis. Certain parts of the private health industry (such as medical schemes, private hospitals, and scheme administrators) may have indicator data available among their networks but this data could be incomplete, inappropriately defined or biased, and is intentionally hidden from public scrutiny. SAMA is encouraged by the ongoing Competition Commission's Health Market Inquiry, which has successfully cracked the whip on the culture of quality secrecy in the private sector. Preliminary stages of the public hearings for the Inquiry has seen major private hospitals and administrators admitting to failing to publish objective indicator data on quality of hospitals' performance that should help patients make choices, as is the norm in many developed countries [15].

## 2.6 Specific comments on potential quality interventions in the White Paper

The White Paper proposes some possible quality improving initiatives, some of which have been introduced in NHI pilot sites during the pilot phase. Our discussion of these initiatives is not meant to be exhaustive. Therefore we comment below on only the key selected initiatives:

### 8.1.5. Office of Health Standards and Compliance (OHSC)

In paragraph 215 of the White Paper, the role of the OHSC is specified, namely “to ensure compliance with norms and standards for quality by all health establishments”. The OHSC together with its Inspectorate and Ombudsperson should be a possible quality-improvement avenue. SAMA notes that the structure is already functional, with the appointment and training of several inspectors having already been accomplished, and ongoing public facility inspections since 2013. The 2014-15 nationwide facility inspection results have also been released, which highlight appalling **structural** deficiencies in primary facilities and hospitals in the public sector [16].

The SAMA commends the establishment of the OHSC as this will potentially close a long felt need: South Africa’s *Policy on Quality in Health Care* [17] recognises South Africa’s systemic problem of poor reporting on measures of quality by facilities and medical schemes, among others. The same Policy also recognises that national norms and standards are a crucial vehicle for addressing equity and ensuring that all people receive an acceptable quality of care. The OHSC is responsible for determining these norms and standards.

The SAMA is also encouraged by the publication of the Emergency Medical Services (EMS) regulations, and the White Paper’s proposed quality proposals for emergency medical services, a sensitive domain that has been particularly neglected in South Africa.

SAMA notes the envisaged progressive functions of the OHSC, but wishes to raise the following concerns:

- I. The current government fixation on re-designing the **structural** elements of the health system, while noble, should not be done to the exclusion of clinical

process and outcomes improvement and monitoring. Unfortunately the current quality movement in South Africa is about the **physical state of facilities, and not clinical outcomes such as rate of complications and survival rates.** This outcomes are directly linked with NDOH vision to ensure a long healthy life for all South African and a life expectancy of 70 years.

- II. Competition in the industry is likewise wrongly directed at volumes of patients, recent technologies, bargaining power as well as control of the patient. Competition should be shifted to competing on **outcomes** and **value** derived by the patient. While measuring outcomes is legitimately considered a challenge, it is imperative, in the spirit of value-driven, patient-centred and outcomes-based care delivery and measurement propounded by Michael Porter.

To illustrate the over-emphasis of structural elements of quality, the Health Department's recently published 2014-15 facility inspection results exclusively focused on structural issues such as availability of operational plans, availability of clean, functional toilets and tap water, patient privacy, medicine storage, refuse disposal, and patient record keeping, etc. Similarly, the Ideal Clinic Initiative, the Facility Improvement Teams, as well as the seven domains and six national core standards upon which the National Quality Standards for Health are based, have a heavy leaning towards structural performance. Unfortunately this approach, which is rewarded by OHSC's scoring and certification of qualifying institutions, and will be the basis for contracting clinics and hospitals for the NHI, **disincentives process and outcome-based performance by health facilities and health workers.**

It is important to recognise that no matter how clean, well arranged or aesthetically appealing the physical care settings may be, it is not a guarantee for achievement of life-changing clinical processes and outcomes, which have the greatest influence on value for the patient.

- III. It is stated that the OHSC, which is listed as a national public entity in terms of the Public Finance Management Act, will be accountable to the Health Minister. Also, the Department of Health will also be a provider of NHI services. This brings into question the degree of **independence** of the OHSC. SAMA raised this issue during the NHI Green Paper phase and hereby raises it again. Although the White Paper and the OHSC itself claims independence, there is

likely to be a problem of rigidity and lack of autonomy on the part of the OHSC. The preamble to the National Core Standards for Health Establishments in South Africa states that “through a national process of certification, an **external body** [emphasis ours] will formally assess each health establishment for compliance against these National Core Standards”. It is inconceivable that the OHSC is purported to be this ‘external body’. Health experts authoring the SAHR 2014-15 [18] cautiously rate OHSC’s autonomy as “considerable independence”. As in other countries, a body such as the OHSC must be autonomous, flexible and open to input and advice on quality by other bodies such as professional bodies and research institutes. The USA’s Institute of Medicine, for example, is an **independent, non-profit organization** that works outside of government and provides unbiased and authoritative advice to decision makers and the public.

#### **8.1.6. District Clinical Specialist Teams (DCSTs)**

SAMA surmises that, if properly implemented, the envisaged DCST program should contribute to better quality of care and better outcomes in more than one way. DCSTs are comprised of seven specialists: family physician, obstetrician and gynaecologist, paediatrician, anaesthetist, PHC nurse, advanced midwife and a paediatric nurse. The SAMA notes the progress already made to date, namely the appointment of 214 DCSTs by 2015 (60% of target), and the presence of the DCSTs in 45 out of 52 districts nationwide (86% coverage).

SAMA avows that it is impossible for a primary health care (PHC) system to operate effectively without a well-functioning body of specialists to whom patients can be referred. It is SAMA’s hope and belief that DCSTs will be effective as agents for clinical governance at grassroots level. In a system where task shifting is on promotion and use of midlevel workers is prevalent, DCSTs will have a critical role of supervising and overseeing quality of health services delivered. The multidisciplinary, collaborative practice approach proposed has possible quality and efficiency benefits for the patient and the entire system. Also, the district health facility will be the centre of most of the primary care services (such as child and maternal services) with specialists available at the level of primary health care. This is the level where there will be services aimed at identifying and managing diseases at an early stage hence reducing worse clinical

outcomes, and avoiding unnecessary (costly) referrals to secondary or tertiary level of care.

#### **8.1.7. Ideal Clinics Initiative**

The SAMA concurs that the current physical state of public facilities is deplorable and not conducive to the delivery of quality health services. Therefore the ongoing implementation of Operation Phakisa Ideal Clinic Realisation Programme in PHC facilities (to be implemented in public hospitals later), is a progressive step. However, as stated earlier, the emphasis on structural indices as a criterion for quality, to the exclusion of process and outcome dimensions, is evident in the Ideal Clinic initiative as defined in the White Paper. The White Paper (paragraph 177) offers justification for the high weighting placed on structural improvement and assessment of quality:

*“Outcomes will be measured and monitored through a performance management framework and will be in accordance with agreed upon performance standards. Eventually performance management will cover public health outcomes in a specified catchment population. **For this model to be successful the clinic settings and environment must comply with the Ideal Clinic model specifications**”.* [Emphasis ours].

As pointed out in the preceding sections, the Health Department’s narrow definition of ‘quality’ is limiting to the comprehensive and speedy achievement of quality in the system. Measurement of processes and outcomes that really matter to patients is unfortunately absent. The SAMA hopes that the above White Paper’s hint on future monitoring of outcomes will be realised in practice.

#### **8.1.8. Decentralisation**

Decentralisation is a strong theme in the White Paper, in the form of the envisaged decentralisation of management functions and responsibilities of central hospitals to lower levels, and the establishment of sub-national structures, specifically the District Health Management Offices (DHMOs), which in turn can delegate to individual health facilities. The White Paper (paragraph 202) conceptually acknowledges the association of decentralisation with improved quality:

*“Central hospitals will be reformed to be semi-autonomous. Full decentralisation of their management functions and responsibilities will be prioritized to ensure their effective functioning and sustainability. **This will also contribute to improved quality**”*

*of care, responsiveness to patient needs, hospital effectiveness, and affordability of health care". [Emphasis SAMA]*

Decentralisation and its health system benefits (including better quality) is experienced in countries such as America, Canada, Australia, Brazil, Indonesia and Rwanda. While cognizant of the potential downsides of decentralisation, SAMA, in line with available literature [19], recognises the following possible positive health quality impacts of decentralisation within the NHI arrangement:

- Decentralised health care is likely to be more responsive to local community needs. This aligns the 'Acceptability/patient-centeredness' dimension of the WHO definition of quality.
- Decentralised management would be more attentive to local workplace issues and would foster better staff morale, leading to enhanced efficiency and quality.
- Grassroots healthcare planning and delivery is in line with the PHC orientation of NHI
- Increased local accountability for health outcomes

A concern with regards to decentralisation revolves around the managerial competency of district level management. Decentralisation requires the delegation of authority with regards to budgetary, financial and human resource obligations. These are areas that require adequate training in order to discharge the newly acquired responsibilities appropriately.

With regards to the current legislative arrangement whereby provincial departments of health have authority over the issuing and renewing of private hospital licences, SAMA is not persuaded that transparency and objectivity exists in licencing decisions and that provincial authorities are not anti-competitively influenced by powerful private hospital groups. SAMA has also come across disquieting reports that such licences are sometimes issued without detailed quality of care assessments of such private hospitals [20].

Above examples, indicate the complexity of decentralisation.

#### **8.1.9. Social determinants of health (SDH)**

Social determinants of health (SDH) refer to the general socio-economic factors, cultural and environmental factors, living and working conditions, social and

community factors, and individual lifestyle factors that have an impact on health. Most SDH lie outside the direct influence of health and social care. As alluded to by Professor Michael Marmot [21], Universal Health Coverage and SDH are complementary: both are essential to population health. International evidence confirms a relationship between low socio-economic position and poor health status [22]. Inversely stated, there is a relationship between development and better health outcomes, according to the WHO Commission on Social Determinants of Health [23]. In South Africa, racial inequalities and the grossly uneven distribution of wealth across society are well documented, and are linked to differences in health status measures (such as under 5 mortality rate) between geographic areas, population categories, racial groups, and wealth [24].

There is increasing acknowledgement that medical and public health interventions will have limited impact without taking into account these SDH. Congruent with the National Development Plan (NDP) 2030, the White Paper's stated goal (paragraph 44) of affording needed health services to **all** "regardless of race, socio-economic status and ability to pay for services" will not be fully realized in South Africa without addressing the SDH as anticipated by the NDP, since patients will still go back to live, work and age within the same deprived circumstances that created ill-health. As expounded upon in the 'recommendations' section of this document, government needs to take measured action in this regard.

#### **8.1.10. Quality of Human Resources**

The SAMA emphasises that there must not be a compromise in quality of human resources for the sake of quantity. Human resources include both managerial personnel and coal-face personnel such as doctors and nurses. The UK's Care quality Commission rightly notes that "quality care cannot be achieved by inspection and regulation alone. The main responsibility for delivering quality care lies with care professionals, clinical staff, providers and those who arrange and fund local services" [25].

Possessing and applying relevant knowledge is one aspect of quality for health personnel. The current capacity constraints in medical school training, for example, impacts on the quality of the medical graduate. In the same vein, medical student training in South Africa has unfortunately been mainly focused on biomedical treatment, resulting in graduates who are not able to adequately address health

problems affecting the community. International experts have called for medical curricula with a strong PHC element, involving competencies in prevention, promotion, public health, social determinants on health, and understanding of inequalities in population health [26].

SAMA also respectfully notes and concurs with the noble intentions of the White Paper to raise the quality of system-level health care personnel (e.g. health managers) and service level human resources. SAMA submits that in order to increase the access to health package, health workers need to improve the quality of interaction with, and care, for the patient. There should be concerted efforts to deal with the pervasive culture of negative attitudes and unprofessional behaviour from all healthcare professionals. Not only should a culture of excellence and professional acumen be encouraged, but the Health Department should initiate motivational programs in terms of awards and recognition.

Other already operational interventions such as the establishment of the Leadership in Academy, as part of the parallel processes of NHI rollout, are welcomed as they impact on the root cause of poor service delivery and poor quality, namely poor management competency and maladministration. Also, the Foundation for Professional Development (a subsidiary of the SAMA) will offer free managerial programmes to medical students (from 2016 onwards).

Paragraph 228 of the White Paper states that:

*“A number of strategies will be implemented, including expanding the platforms for international collaboration such as with the Mandela-Castro Collaboration Program in Cuba”*

The Cuba program has been going on for years. But unfortunately it positively impacts more on **volumes** of doctors, with the quality of Cuban-trained graduates becoming a concern. Some reports suggest that the Cuban-trained doctors are not well skilled for the South African context to be able to offer responsive and high quality services.

Cuban born doctors have the additional challenge of language barrier, which affects quality of care [27].

#### **8.1.11. Adverse event prevention, reduction and reporting**

The SAMA is disappointed to note that the NHI White Paper does not mention any intended approach to recording and reporting adverse events. Yet ‘adverse events are important to healthcare organizations, not only because of their impact on patients but also because they can provide an insight into the quality of health care and an opportunity for improvement [28]. Well known international healthcare quality organisations such as the Institute of Medicine (IOM) and the WHO recognise the pre-eminence of patient safety.

In South Africa there has been no standardised national Patient Safety Incident Management System, and consequently no proper data on even the most serious adverse events [29]. Only in February 2015 were national regulations addressing adverse events published for comment, entitled: *‘Norms and Standards Regulations in Terms of Section 90 (1)(b) and (c) of the National Health Act, 2003 (act no. 61 of 2003), Applicable to Certain Categories of Health Establishments’*. These have not yet been promulgated. South Africa should implement a similar system to the American system where the IOM generates reports on adverse events, for example on vaccine safety.

#### **8.1.12. Emphasis on evidence-based medicine (EBM)**

SAMA as a professional organisation for doctors places great value and emphasis on the principles of Evidence-Based Medicine in both medical practice and policy decision making. The South African Policy on Quality in Health Care notes that “one cause of quality care problems is that the health professional has erroneous, outdated, or no information or skills” [30]. Such uninformed practices endanger the health and lives of healthcare seekers.

SAMA urges that interventions proposed in the NHI White Paper be based on sound scientific evidence. The NHI White Paper’s commitment that “South Africa will follow the best evidence on health reforms by implementing a highly effective, fair and cost-effective NHI” [31] should be honoured in practice.

## 2.7 Recommendations

In light of the sentiments expressed by the SAMA in the previous sections, the SAMA offers the following recommendations and hopes that these recommendations will be taken on board:

- a) The whole-system reforms being implemented in South Africa, complementary to the roll out of NHI, should not come at the expense of healthcare quality. The current focus on efficiency improvement should not overshadow the quality goals of the system. Especially pertaining to human resources for health initiatives contemplated (e.g. Mid-level worker (MLW) employment, personnel training initiatives), caution should be exercised that in the desperation to shore up personnel numbers, quality of care is not compromised. It is important to state that the use of MLWs should not become a substitute for the long-term plans of investing in the training of high quality doctors, nurses, and other professionals.

South Africa needs to seriously take lessons from the NHS which nearly faced total collapse due to several challenges that impact on quality of healthcare, such as long waiting lists, huge budgetary shortages, and serious doctor shortages (owing to the exodus of medical graduates and low medical school output that could not keep pace with physician attrition through aging and retirement).

- b) Currently there is lack of standardised quality metrics applied in both sectors. This must be corrected. The public and private sectors must work in harmony towards the common goal of equitable and quality healthcare. There must be a **common, comprehensive and objective framework** for measuring all dimensions of quality (effectiveness, efficiency, accessibility, acceptability, equity, and safety) in both sectors, which allows data to be openly shared and compared. Hopefully this will break the pervasive culture of quality secrecy prevalent in both sectors.

Also, government must collaborate (e.g. share expertise and datasets) with private industry agencies already involved in quality improvement and reporting initiatives, such as COHSASA and HQA. Professional bodies can also be used in determining appropriate standards and norms.

- c) The mandate of the OHSC needs to be reviewed. The present quest for structural excellence (evaluation and certification/accreditation based on physical appearance of health facilities) should not blind the OHSC and government to the task of ensuring that quality clinical processes are performed and monitored, to achieve high clinical and health outcomes for our population. While defaulting to improvements and measurement of structural elements is understandable in the South African public health sector, to create an enabling environment to quality practice, the definition of quality should be broadened, in line with the Donabedian Framework, beyond the current, evident preoccupation with buildings and mechanical improvements. The SAMA proposes an expanded mandate as this will be the most cost-effective mechanism rather than implementing a different office that will measure process and outcome indicators and most importantly there could be a comprehensive view of all dimensions of health care. Most importantly, the OHSC should have powers to implement predetermined sanctions, otherwise it will become a toothless organisation.
- d) It is noted that South Africa has some input measures and outcome mortality measures, published in reports of the Medical Research Council every five years. Outcome measures such as mortality take up to several years to manifest and are difficult to link solely to health practices since they are influenced by economic, social factors, patient, and other factors outside the care delivery system. It is therefore our submission that waiting five years to analyse mortality data may result in a missed opportunity for quality improvement. Process measures for priority health conditions and non-fatal outcomes are therefore recommended. Process measures can be measured and analysed annually as occurrences are frequent e.g. annual HBA1C testing rates and amputations in diabetic patients vs. mortality from diabetes mellitus.
- e) Solid, theoretical understanding of the complete picture of quality in all its dimensions must be instilled in all health personnel (both managerial level personnel and service-level personnel such as nurses and clinicians). Similarly, education on the quality doctrine must be extended to the public

and patients to equip them to demand what is rightfully theirs and to empower them to make wise healthcare choices for themselves.

- f) Government must use its regulatory powers to re-orient the current misplaced nature of competition in the health system, from competing on infrastructure and service volumes, to competing on outcomes. Reward and sanction mechanisms must be strictly enforced. The White Paper's hints on 'outcome' measurement (paragraph 177) should be implemented expediently, assuming that the intended definition of 'outcome' is appropriate.
  
- g) In spite of government's motivation in the White Paper about prioritising structural performance of health facilities, the SAMA is in favour of a parallel rather than serial approach, whereby structural, process and outcome performance of facilities is ensured and measured simultaneously.
  
- h) Proposed or ongoing quality initiatives in our health system on structure, which have been concentrating on the public health sector, must be extended to the private sector as well. An example is the Ideal Clinic initiative (which must be expanded beyond structural aspects). This is particularly important for proposed contracting of individual private practitioners. Likewise, national quality monitoring and reporting tools such as the Saving Mothers Report, and the Saving Children report, for example, must also collect and publish data from the private sector.
  
- i) Broader, multi-sectorial reforms targeting social determinants of health are necessary to close the current gap in health outcomes, since most of the determinants of health lie outside the sphere of the health sector. In the spirit of the NDP 2030, the government must foster inter-sectoral collaboration and accelerate equitable social development (e.g. improvement in education, living conditions, access to basic services such as sanitation, water, electricity, etc.) through developmental action in other sectors such Housing, Education, Environment, Transport, Agriculture, Public Works, among others.

- j) In a PHC-based NHI system located in a milieu of a complex disease burden where hospi-centrism and curation are the order of the day, a solid grasp of the public health approach by health workers (including doctors) is imperative. Beginning at undergraduate level or other levels of study, the healthcare personnel must be trained in social determinants of health.
- k) Decentralisation must be implemented wisely, after being satisfied that there is enough managerial capacity at district level. The previous and current governance failings in South Africa at all healthcare levels do not inspire confidence in the decentralisation of key functions.
- l) With regards to the spiralling healthcare costs and the need to derive maximum value for patients from healthcare spending, government must create the appropriate policy environment for quality. Thanks to the ongoing Market Inquiry on the Health System. Government must use its regulatory powers to influence the two components of value of healthcare as depicted below [32], by improving quality of services or by lowering costs:

$$\text{Value} = \frac{\text{Quality (perceived and technical)} \times \text{Accessibility}}{\text{Cost}}$$

*Cost*

- m) Government must practically demonstrate a willingness to engage stakeholders in the national quality effort in a collective and meaningful manner. Healthcare professionals, both in the public and private sector, need to be given a chance to participate in the design of strategies for improving and measuring quality which would work best in South Africa.
- n) Most importantly there must be enforcement of quality of care standards, and managers and independent professionals must be evaluated on these quality of measure standards.
- o) Good performance as proposed in the NHI must be incentivised through an appropriate reimbursement mechanism while poor performance should attract serious predetermined sanctions to both public and private sectors. Quality of care measures must be incorporated in the performance

agreement of provincial and district heads, facility CEOs, facility managers, individual health professionals and all categories of health workers including non-clinicians.

- p) Pilot districts should start reporting on all dimensions of quality, including mortality reports i.e. MRC mortality should be reported at district level. This process is essential in defining quality care indicators feasibility.

## **2.8 Conclusion**

SAMA congratulates the National Department of Health, the Minister and government at large for demonstrating commitment to the enhancement of health quality through proposals in the NHI White paper. The White Paper sets out a number of noteworthy ideals and commitments on quality of care in the national health system. These are rooted on the constitutional, legal and policy framework that includes the National Health Act, the Health Charter, and other South African policy documents. Unfortunately there is a wide gulf between imagined quality care and the reality experienced by South Africans. There is need for government to address quality holistically, preferably based on the Donabedian philosophy of structure, process, and outcomes. Measurement is the key to quality improvement, and should be promoted within an environment of objectivity and transparency.

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## 3. HUMAN RESOURCES FOR HEALTH

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### 3.1 Introduction

According to the World Health Organisation (WHO), the health workforce is one of the six building blocks of any health system [1]. The NHI White Paper is explicit about the unique and pivotal role of health personnel within a health system: “**The health workforce is a key pillar of the health system and the planning, development, provisioning, distribution and management of human resources will be further improved to meet the needs of the population**” [2]. The SAMA is in strong agreement with the White Paper on this aspect, since a robust human resource (HR) component is necessary for South Africa to meet its health goals. Healthcare is a very labour-intensive sector that takes 65-70% of the recurrent health expenditure in most countries [3]. According to the WHO, the ability of a country to meet its health goals depends largely on the knowledge, skills, motivation and deployment of the people responsible for organizing and delivering health services.

SAMA represents a very significant proportion of the overall medical profession in South Africa, having the following different doctor categories as its members:

- Junior doctors
- Registrars
- General practitioners
- Specialists
- Academic doctors
- Senior employed doctors

As the dominant national professional association for doctors in South Africa, with the mission of ‘*Empowering Doctors for the health of the nation*’, SAMA acts as the champion for doctors and patients, and holds the strong view that there would not be full realisation of the espoused national goal of improving the delivery of quality health care to patients, without a concerted effort by government to address current human resources challenges. The crippling effect of health worker shortages is manifesting in several ways, such as the current failure of District Clinical Specialist Teams to have enough number of the requisite team members. The SAMA and its members look

forward to working with, and advising, the government in moulding a sustainable healthcare system for all South Africans through sound human resource reform mechanisms.

This chapter articulates the SAMA's views and responses about the necessary HR approaches for building a re-engineered healthcare system envisaged in the NHI White Paper. In this chapter the SAMA adopts a four pronged view of HR based on the core HR issues, namely: **Quantity** (supply) of human resources, **Quality** of human resources, **Roles** and collaboration, and **Retention**.

### 3.2 Problem Statement

South Africa, known to be one of the most inequitable countries in the world, stands out globally for its severe **maldistribution** of human resources for health. The current staffing constraints (and consequential population health challenges) facing the nation would be less if human resources were evenly distributed, especially between public and private (but also between rural and urban).

The quality of South African trained doctors is indisputable, evidenced by their high demand in many parts of the developed world. A sizeable number of newly qualified medical doctors do not register to practice in South Africa, and a significant number of doctors is lured to other countries within five years of qualifying [4]. The main destinations for South African physicians include the United Kingdom, the USA, Canada and Australia. The high emigration potential of South African doctors (students and graduates) can only be stemmed by effective retention strategies. Any additive approaches aimed at boosting the number of doctors produced will only be useful to the extent that those professionals can be **retained** in the public sector and the country.

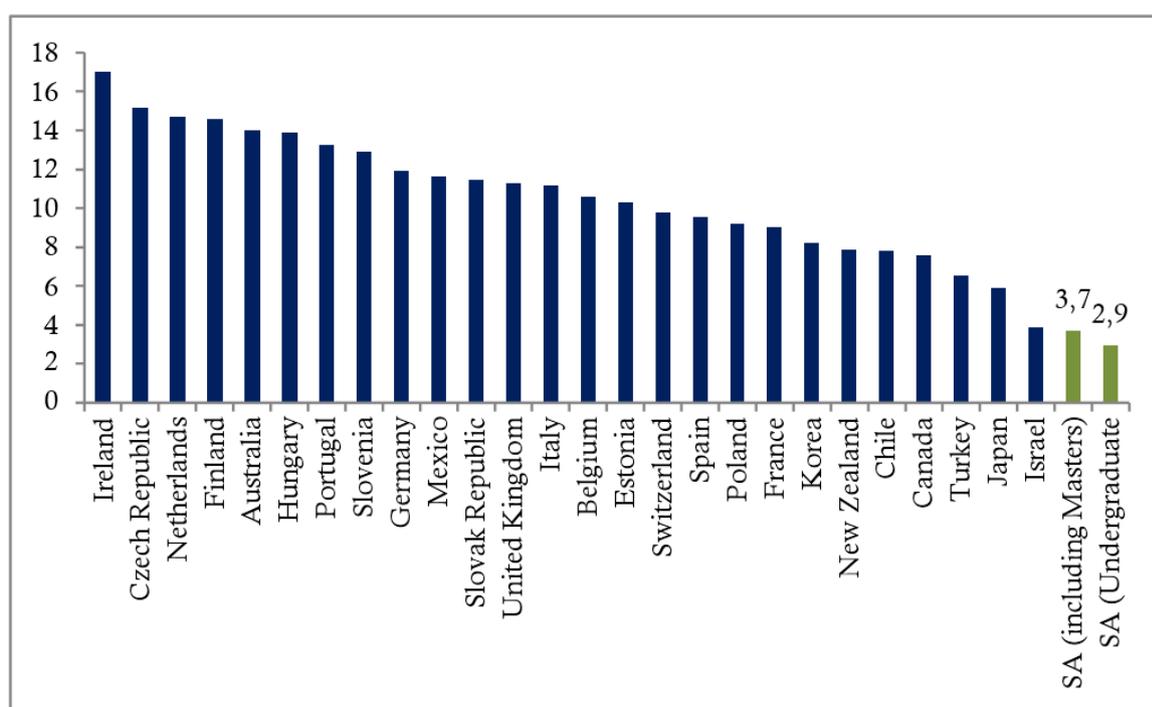
The role of the private sector in alleviating HR pressures in South Africa is a subject of huge debate. The key policy documents on human resources for South Africa, namely the 2016/17 Human Resources Strategy for South Africa and the National Development Plan 2030, both offer perspectives on potential roles of the private sector in the health sector and development in general. The White Paper also intimates a niche for the private sector. South Africa is in a different situation to other countries where the private sector has a significant share in the training of medical professionals, such as India, Brazil, Ethiopia, Tanzania, Malawi, Zambia, and Mozambique. The

South African government is adopting a conservative stance on tapping into the medical and nursing training capacity of the private sector for a number of reasons, including concerns on alignment with broad national objectives, quality of training, promotion of elitism, among other factors [4].

### 3.3 Quantitative approach to human resource improvement

The diagram below demonstrates the performance of South Africa in relation to its peers and other countries globally.

Figure 1: Medical graduates per 100,000 citizens in OECD countries and South Africa, 2012



Source: OECD, 2015; HEMIS, 2014; World Bank, 2010

The serious health staff shortages in South Africa are obvious and well documented. Currently there are only about 27 640 doctors practising in South Africa serving a population of more than 50 million people [6]; a ratio of 60 doctors per 100 000 population (or 0.6 doctors per 1000) is recorded as in 2013 [7] (compared to a global average of 152 doctors per 100 000 population for the same year), while nursing is experiencing a shortage of 44780 nurses [8]. On average 30% of accredited HPCSA registrars training posts and 75% of sub-specialist training posts are vacant, contributing to specialist shortages in the public sector [3]. More health workers are desperately needed.

According to the WHO, there is clear evidence of a direct and positive link between **numbers** of health workers and population health outcome [9]. The South African Human Resources for Health Strategy 2012/13-2016/17 also acknowledges this fact. SAMA has consistently stressed that if South Africa is to have a full complement of health workers including doctors, new and better mechanisms need to be employed in the training, recruitment and **retention** of healthcare workers, as past efforts have been largely fruitless. For example, the 2006 National Human Resources Plan for Health of the National Department of Health recommended an increase of medical graduates from 1300 to 2400 per annum, a target which has not materialised today, 10 years down the line.

The production of specialists is also happening at a snail's pace due critical factors such as lack of training capacity and high failure rate of specialists in examinations, with many passing on second and third attempts in the Colleges of Medicine of South Africa examinations. The Colleges of Medicine of South Africa confirms disturbing annual failure rates for its students studying for specialisation, especially in Colleges of: Anaesthetists, Cardiothoracic surgeons, Otorhinolaryngologists, and Paediatricians [10].

The White Paper outlines a number of strategies to boost the **numbers** of health professionals. SAMA expresses below its views on some of the strategies:

*1. Increased production of medical students (paragraph 229).*

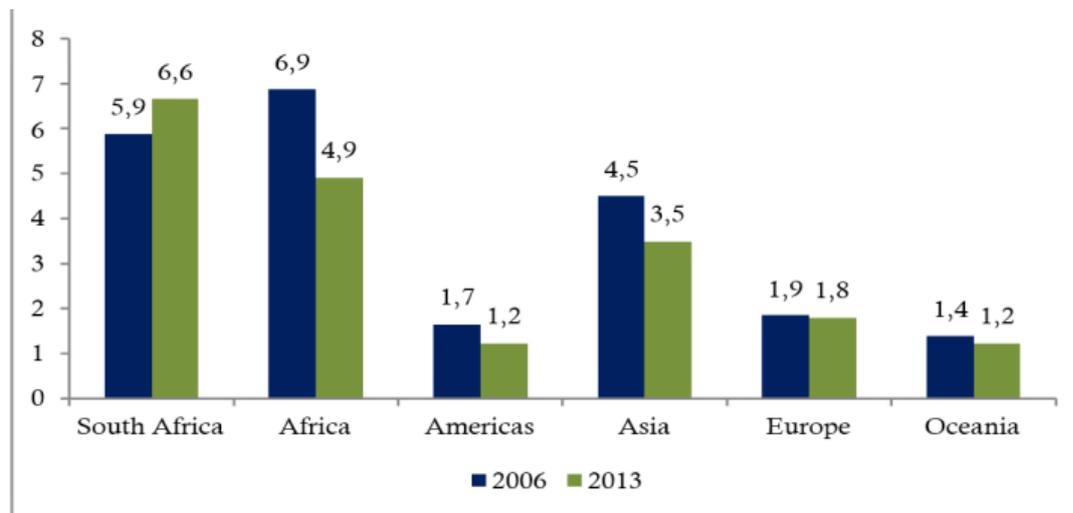
Paragraph 229 of the White Paper states that “*Medical schools will also be supported to increase their intake of students...*” The SAMA affirms that this should be one of the most promoted and foremost strategies to plug the gap. The 2016/17 HR Strategy for South Africa estimates a total shortfall of a whopping 66435 health workers in 2015, slightly over 9600 of them being medical professionals. In sharp contrast, Cuba, which is five times smaller in population size than South Africa, spends 13% less on health, yet has over 20 medical schools that produces 11 000 doctors annually. South Africa's eight medical schools have annually been producing a collective 1300 doctors for the past decade. This is clearly not enough to serve a population of 50 million people. For South Africa to keep the current General Practitioner to population ration, the country would need to double its GP output over the next 15 years [11].

25 May 2016

Nonetheless, SAMA congratulates government on the ongoing increases in medical student intakes by local medical schools parallel to the NHI program. The Health Minister's target was initially an additional 40 more students enrolled per medical university per year starting 2012. Although limited by funding availability, a number of universities have already surpassed the Minister's target (e.g. University of Pretoria which has increased enrolment by 160 students). The NDOH claims in its report entitled 'Milestones in the implementation of the National Health Insurance', that the annual intake of medical students has increased by a total of 2 931, with local universities increasing their intake by 429 since 2011, and with an increased intake of the Cuban student programme by 3 001 since 2012 [12]. The high dropout rate for medical students, as well as failing to finish MBChB in record time are worrying and must be addressed. SAMA recognises and laments the many years it will take for South Africa to close the human resource gap, given the associated limitations and the current pace of production.

SAMA also notes with appreciation that the Government has funded a new medical school in Limpopo and also plans to construct additional training hospitals. However, South Africa, which only has nine medical schools, is lagging behind other regions globally in terms of adapting its medical training capacity in response to population growth. The number of South Africans per medical school rose from 5.9 million people in 2006 to 6.6 million people in 2013; the ratios are better in other continents, namely (in 2013): 4.9 million people in Africa, 1.2 million in the Americas, 3.5 million in Asia, 1.8 million in Europe, and 1.2 million in Oceania [13]. This is shown in the diagram below:

Figure 2: Population per medical school, 2006 &amp; 2013 (millions)



The SAMA recognises the following challenges associated with the efforts to produce more health workers.

a) *Lack of training capacity at training institutions.*

Limited training capacity is a major contributor to the health worker (specifically doctors) shortages in South Africa. The Health Minister's request for medical schools to enrol more medical students came with no funding to the medical schools, which are going to need more training staff, beds, student accommodation, lecture facilities, and hospital facilities. It is clear that many medical schools do not have these extra resources at the moment and thus cannot be accredited by the HPCSA to exceed the normal annual student intake thresholds.

The number of medical student candidates far outstrips available study vacancies. For example, in one intake year, the University of Pretoria had to reject about 4000 applications and Wits University over 7000 [14] first year MBCHB applications [15].

SAMA reminds that additional intakes will also naturally demand the following:

- Hospitals will need to increase the number of internship posts and clinical professionals to supervise the interns.
- More money will need to be given to medical schools for expansion projects, including infrastructure.
- South Africa should leverage on technology to increase number of students. e.g. E-courses

- The Minister of Health has called for increased intake into medical schools. This call in itself is not a guarantee of increased intakes since enrolment targets are set by the Department of Higher Education and Training (DHET) and the training institutions themselves determine the actual size of intake they can manage.

*b) Poor absorptive capacity of the public system*

The White Paper notes that “*Post-graduate training and specialisation will be supported through, amongst other strategies, additional registrar posts*”, (paragraph 229). While this is a step in the right direction, the chronic shortage of clinical posts in the public sector is counter-productive as it has led to significant graduate unemployment as well as poor training outcomes. Not only is the challenge in specialist training but also for undergraduate training. Lack of available placements for interns has been observed. The HR Strategy 2016/17 notes a stagnant to negative growth in clinical posts from 1997-2006. According to that Strategy, despite 11700 doctors graduating between 2002 and 2010, public sector medical posts only grew by 4403 posts. Post graduate training into specialisation is currently severely stifled.

About 30% of Registrar posts were unfilled (as of 2010), while 75% of sub-specialist training posts are unfilled. The recent widely reported story about a moratorium on the filling of posts by Provincial Departments (such as North West [16]) rattled the health system and raised concern. The huge cost of training a specialist (R3.1 million for four years and R2 million for two years of sub-specialist training) limits the number of available registrar posts due to the shortage of funds [17]. Then, and now, SAMA condemns any direct or indirect ‘freezing’ of medical posts as this will undermine medical training as well as access of patients to health professionals, especially in rural areas.

An additional challenge on absorption capacity comes in the expectation on local hospitals to receive batches of Cuban-trained doctors who will come back to complete their training in South Africa from 2018 onwards.

*2. Transformational challenges*

In the post-apartheid era, South Africa made a commitment to ensure that the number of doctors in South Africa is demographically representative of this country. Available data shows little progress in transforming the number of black students entering the

medical profession. First year medical school enrolments do not reflect the dominant size of the historically disadvantaged population at national level. For example, in 2015, medical school enrolments show a small proportion of **black** students: 33.9% UCT, 12.5% Stellenbosch University, 47.2% Wits University, and 33% Free State University [18]. Also, the majority of students graduating with Master's degrees in Medical Clinical Sciences in 2013 were white [19]. In the interests of the principle of equity, university admission policies favourable to the historically marginalised and socio-economically deprived students, such as rural students, are essential. The demographic imbalances are also reflected in the teaching staff at medical schools, who are still predominantly white [20]. It is the bottleneck at intake level that has perpetuated the insignificant number of black medical professors available in this country.

a. *Foreign training and recruitment (paragraph 228).*

The White Paper recapitulates the current and historic government arrangements of recruiting doctors from Cuba, Tunisia and Iran beginning in 1996, in a bid to increase volumes of doctors especially for underserved areas of South Africa. The Cuban program saw 3,344 South African medical students training in Cuba as at 2014, according to the White Paper.

SAMA supports foreign training / recruitment only as a **temporary**, stop-gap measure. South Africa's over-reliance on foreign doctors has come under severe scrutiny, for reasons addressed later in this document. The SAMA is adamant that this arrangement still does not meet the required doctor quantities, and, in the long term, this arrangement is untenable, having implications on quality of the medical profession and being unable to sustain a strong PHC-based system as envisaged. The SAMA also believes that the training of South African doctors in Cuba at a cost of R750 000 per student [21] (R875 000 in 2015) for the six year duration is wasteful and is a missed chance to design local solutions.

3. *Task shifting*

Task shifting has become one of the volume-driven mechanisms of managing the personnel challenge in South Africa. It is known that task shifting is silently taking place in South Africa, especially in understaffed rural healthcare facilities. The White Paper is silent (or subtle?) about Clinical Associates in particular. However, it is clear for the

HR Strategy that MLWs will be used as an integral part of PHC teams such as ward teams. SAMA, while acknowledging the need to increase this category of health workers given the current staff shortages in the system, strongly cautions that the use of mid-level workers should not become a substitute for the long-term plans of investing in the production and retention of more doctors (and other health professionals). Further, as expanded in the relevant section of this document, the rollout of MLWs needs to be done in a manner that does not compromise *quality* of care.

SAMA also recognizes the role played by our nurses in the health system, being the first to welcome life and the last to see the last breath. The increased work load for the nurses through task shifting has interfered with the caring role of nurses. Whilst task-shifting to nurses is a significant response to staffing deficiencies, it must not be done to such an extent that we kill the golden goose. Where do the Nurses shift their original tasks to? Our nurses require the necessary support to be able to provide warm caring environments for patients.

*a. Distributive mechanisms for human resources*

Section 3.1.5 of the White Paper correctly diagnoses the serious challenge of misdistribution of human resources that has been gnawing at the health system for years. The misdistribution is between public and private, rural and urban, as well as between provinces or districts. South Africa's WHO-estimated doctor-to-patient ratio is eight doctors per 10 000 population. When other health professionals are considered, it emerges that South Africa's combined national average of 2.9 doctors, nurses and midwives for every 1 000 people is actually higher than the WHO-recommended threshold of 2.28 [22]. Thus the South Africa problem lies in the skewed nature of the numbers of professionals in the public and private sectors as well as rural and urban areas. This requires a robust solution, as expanded upon hereunder:

*a) Tapping into the Private Sector professional pool (item # 78 and 228b).*

Item 78 of the White Paper paints an ominous picture of public/private misdistribution of human resources in South Africa, which the White Paper acknowledges has sadly contributed to poor health outcomes. Paragraph 228(b) states that "*a range of health professionals working in the private sector **will be engaged** [emphasis SAMA] through innovative contractual arrangements to contribute to addressing the human resources*

gap". There is a sense that these private professionals are unlikely to be willing to work in rural areas. The SAMA is categorical that while tapping into the skills and capabilities of private doctors/family physicians/GPs will undoubtedly contribute to improving access to doctors in the short term, this arrangement alone will not end the chronic doctor shortages in the public sector and more needs to be done to increase the output of doctors from training institutions while strengthening retention strategies.

*b) Rural incentives*

Currently 43.6% of South Africans live in rural areas [23]. Paragraph 227 of the White Paper states that "*Incentives for attracting health professionals to work in rural and hard-to-reach areas are necessary as part of broadening access to quality services in these areas*". In addition to an overall attractive incentive scheme that will be imperative for making doctors interested in enrolling for NHI, **rural-specific incentives** are vital to attract doctors and other professionals to these under-resourced areas and improve access to health professionals. It is the SAMA's firm belief that policies based on incentivising doctors are more likely to succeed in plugging the rural personnel gap than approaches based on compulsion (such as the Certificate of Need).

In addition to financial incentives, government's focus needs to shift to **non-financial** incentives for rural professionals, as it well established that financial incentives alone will not keep health workers from migrating [24]. The Rural Allowance has not been very successful in retaining medical professionals in rural areas [25]. As hinted by paragraph 130 of the White Paper, non-financial incentives must be upheld by government. SAMA recognizes the positive effect the following non-financial incentives can bring:

- Improving schooling in the rural areas for health workers' children
- Increasing rural student intake for all health-related training
- CPD programs in rural areas (financial subsidization is necessary)
- Improving training support for young doctors going to the rural areas
- Improving the primary care and hospital facilities in the rural areas
- Improving accommodation facilities at rural health institutes
- Better opportunities for career development

- Improving civic amenities such as shopping complexes and recreational facilities

It should be pointed out that such non-financial incentives call for a multi-sectorial, integrated approach. NHI should be implemented simultaneously with a comprehensive rural development program to address key areas of development such as quality basic education, telecommunications, roads and transport, water and sanitation, and decent housing.

*b. Accreditation of providers*

NHI will be based on accreditation and certification of providers. While acknowledging the role of accreditation as a quality control measure, SAMA is concerned about the negative impact on supply of human resources that will result if, for example, the only or few health establishment(s) in rural settings fail to get accredited for NHI? This can potentially hinder access to health professionals and services by the rural population. It can be advocated that the National Department of Health (NDOH) allows for voluntary accreditation of private practitioners as part of piloting. Such a program would need to be coupled with facility improvement.

### **3.4 Quality of human resources**

The international demand for South African trained doctors is testament to the quality of doctors produced in this nation. Because of the present shortages, the current focus on boosting **quantities** of health professionals is evident in the White Paper and other policy documents of the DoH. The SAMA recognizes that such volume-based approaches would be fruitless if **retention** is not addressed. The additive philosophy should not throw qualitative issues of the human resources by the wayside. Better quality of care is premised upon high quality human capacity.

Below we discuss some issues related to quality of health human resources in relation to NHI.

*c. Production of locally responsive medical graduates*

The current **curative** philosophy infusing the health system of South Africa has its roots in decades-old training practices that persist today, whereby primary health care, prevention, promotion, public health, and social determinants training is not well emphasized in the medical curriculum. Health science institutions continue to be

primarily urban based and hence the training bias leans towards urban healthcare. Consequently medical graduates are ill equipped to deal with healthcare challenges, and particularly rural health needs, that call for the preventive, re-engineered PHC approach advocated for by the NHI White Paper. Paragraph 79 of the White Paper rightly points out that:

*“The shortage of key health professionals is being experienced at a time when there is growth in the size of the population that is dependent on public health services, increased patient visits in the public sector, increasing demands of school-going children for clinical and allied health services, the increasing burden of ill-health among the population, primarily due to the HIV, AIDS and TB epidemic and non-communicable diseases (NCDs), and unpredictable migration patterns. This has placed an extraordinary strain on public sector health services, and on the staff who work in public health facilities”.*

South Africa’s disease burden profile is unique and more severe compared to other developing countries. Especially in consideration of the huge burden of HIV/AIDS, the health worker shortage in South Africa becomes amplified [26].

SAMA recognizes the critical importance of transforming the medical curriculum to strengthen teaching of primary healthcare and public health in medical school, cognizant that public health professionals have an important role to play in the re-engineered health system. To date, only about seven public health specialists are produced annually. These numbers need to be boosted.

*d. Foreign trained doctors*

The NHI White Paper plans to increase the training of South African students in Cuba. Likewise, Cuban-born doctors continue to be recruited in South Africa to work primarily in understaffed rural areas. A two-sided quality concern has been identified by medical authorities concerning the Cuban training arrangements, and the government needs to seriously consider these concerns [27]:

- Cuban trained South African doctors who are trained in Spanish and in a different context who return home with limited clinical knowledge and skills to cope with local patterns of health problems and conditions.

- Similarly, Cuban-born doctors working in South Africa without a firm understanding of, and experience in, local diseases including tuberculosis, HIV/AIDS and complications of some lifestyle illnesses. Further, these doctors have a language barrier, which affects effective communication with patients and co-workers.

The plan to have Cuban-trained doctors come back to South Africa to do two years of training in South African institutions beginning in 2018, is an admission by the Department of Health of the deficiencies of the Cuban training program.

*e. Mid-level workers*

SAMA supports any reasonable policy mechanism that seeks to alleviate the chronic human resource shortages in South Africa, including the Clinical Associates (ClinAs) program. However, in the interest of quality of care, SAMA wishes to emphasize that the deployment of Clinical Associates needs to be well advised and regulated. The ClinAs must work under doctor supervision and must only handle clinical situations within their scope, so as to ensure that quality of care to patients is not compromised. ClinAs must be allowed to specialize through master's programmes to support rural areas especially in areas such as anaesthesia/critical care and maternal and child care.

*f. Adequate Supervision and Continuous Professional Development (CPD)*

For optimum delivery of quality care, doctors of the highest quality are needed. Doctors ought to be systemically capacitated to deliver best care, such as through conventional CPD programs. Unfortunately these CPD opportunities are concentrated in urban areas, to the disadvantage of rural-based doctors and other professionals. SAMA recognizes the need for CPD activities to be expanded to adequately cover rural health professionals so that they do not have to travel long distances to attend CPD events.

The ongoing poor supervision of junior medical staff – due to shortages of senior staff and perpetuated by RWOPS – also hampers sufficient learning and affects quality of the resultant trainee. Unfortunately South Africa is caught up in a vicious cycle whereby poorly supervised doctors will in turn have to supervise others. This perpetuates poor quality of medical personnel and needs to be addressed systematically.

*g. Working conditions and facility management competency*

Poor working conditions affect the quality delivered by the health professional. Poor working conditions, especially in the public health sector, are well documented in Chapter 2 (Quality of care and the NHI) of this document and include: shortage of equipment, long working hours, overwork and burnout, unsafe environment, and so forth. Poor working conditions are unsurprisingly one of the major push factors for doctors to seek greener pastures overseas, in the private sector or to divert to alternative professions.

One aspect of working conditions is institutional leadership incompetence. Paragraph 190 of the White Paper states that “*one of the most identifiable factors that contribute to poor quality of care in our public institutions is inappropriate, weak or poor management*”. Information at SAMA’s disposal shows that poor people management and bad manager/subordinate relationships can negatively affect health professionals’ willingness to stay [28]. Also, poor management competency leading to shortage of drugs, and poor accommodation for health staff, for example, perpetuates the frustrations that push workers away.

SAMA commends the government for the ongoing program to up-skill management in all facilities, notably the establishment of the Leadership Academy.

Whilst there are efforts to train on-the-job for admin staff, there has been little investment in training on-the-job for medical doctors. There is scope for *on-the-job* skills development training courses (e.g. ATLS, ACLS, pals, Maternal care) being standardized and availed to all health professionals at all hospitals under NHI, as part of improving the quality of healthcare services. Such training should be centrally purchased and coordinated by the National Department of Health. This is where monopsony can benefit both government and doctors as government will set prices for continuous on-the-job doctor training.

### **3.5 Role of health professionals within the NHI system**

Clear definition of roles is important to avoid inter-professional conflicts. It appears from the White Paper that the exact size of the human resource needs for the NHI is not known as the system is still evolving. However, the White Paper (paragraph 10) identifies four streams through which PHC is being re-engineered. The streams represent different roles for health professionals. The number of professionals that will

be needed will depend on the specificities and realities to be experienced under each stream. The streams are:

- i. Municipal Ward based Primary Health Care Outreach Teams (WBPHCOTs),
- ii. Integrated School Health Programme (ISHP),
- iii. District Clinical Specialist Teams (DCSTs), and
- iv. Contracting of non-specialist Health Professionals.

SAMA notes that within the NHI environment GPs can play a critical gatekeeping role and as **care coordinators or clinical leaders** of inter-professional teams (CHW, nurse, clinical associate, GP) providing primary health care (PHC). The UK National Health System provides a good model of how GPs are appropriately utilised at the coalface of healthcare. If GPs are to be put at the centre of health delivery in South Africa, this needs to be explicitly stated in any future drafts of documents and legislation on the NHI.

Although the White Paper is silent or subtle about the role of Clinical Associates, the expedient finalisation of the scope of practice for clinical associates is going to be a very important aspect of their utilisation in the system.

The failure of the GP contracting initiative to reach its target (only over 300 GPs have been contracted, and ultimately only achieved through the contracting of an external party to contract the doctors), is symptomatic of failure of government to offer attractive contract terms, leading to poor buy-in of doctors.

With regards to managerial roles of health professionals, it has been found that health institutions managed by qualified health professionals, especially doctors, perform better than those run by non-health qualified managers. To that effect, institutions in the United States of America and some in Europe offer an MBA alongside the MBChB.

### 3.6 Retention

In many countries, poor retention leading to loss of health workers is a key constraint to the achievement of sustainable development goals (SDGs) [29]. Four patterns of doctor migration in the South African health system are evident:

- i. Rural to urban
- ii. Public sector to Private sector

- iii. South Africa to overseas (greener pastures)
- iv. From medical profession to other professions [30]

South Africa is experiencing massive brain drain due to reasons documented in the chapter on Human Resources for Health in this submission. At present, the specialists are the scarcest skill and resource in healthcare in South Africa. The SAMA recognises this and insists that specific attention must be given to the retention and promotion of specialist interests. Lack of job satisfaction due to lack of resources among other issues are push factors to the private sector.

Documented specific financial and non-financial retention strategies for rural retention, but also applicable in other settings, include the following [31]:

- Appropriate remuneration
- Good working conditions
- Autonomy and respect for the professionals
- Enhanced access to medical resources and supplies.
- Increase intake of students from rural areas so that they go back there to practice [32]
- Decentralization of specialist training programme to rural areas starting with family medicine and public health, as these programs can be based on distant education and support with periodical in-service training and group tutorials, in contrast to the traditional didactic models [33].
- Rural rotation of some specialists midway through training programme. This gives registrars the opportunity to test independence, sample rural medicine, impart skills to rural doctors, and to familiarize themselves with challenges of referring rural hospitals. Besides, rural hospital managers may just up their ante as employer of choice with potential candidates in their backyard.
- Deployment of retired specialists to rural areas. This may just be a needed break from the urban rat race; however government must be willing to provide suitable accommodation as the retired doctors are less likely to purchase property in rural areas.
- Utilization of current technological developments (tele-medicine), as electronic imaging, and webcams can provide a learning media for rotations in rural hospitals.

- Differential leave incentives for studying, family responsibility and annual leave may, in the long run, improve rural retention [34]. A paid sabbatical for long serving rural doctors to allow them to pursue relevant training in urban facilities.
- Long service financial award specifically to rural doctors [35]. Knowing that one is due for a special incentive may just push people to stay longer.
- Placement of medical students in rural facilities starting with family medicine and public health. Of course this should be preceded by employment of the staff in these facilities.
- Specifically for GPs, appropriate remuneration for rural GPs through risk based capitation model, taking into consideration that the rural medicine practice domain is challenging as GPs are more likely to encounter complex patients without specialist support. Government should also lobby medical schemes to differentially reimburse rural GPs.

### 3.7 Recommendations

In light of all the points raised in this chapter, the SAMA offers the following recommendations and hopes that these will be meaningfully incorporated in ongoing NHI policy processes:

- a. South Africa has for many years endured an unsustainable human resource situation which has cost millions of lives. Serious drastic action is now needed in the short and long term.
- b. SAMA commends the government for taking the lead in reforming the health system; our Association is in support of some of the positive human resources reforms already being implemented or are being proposed in the course of NHI implementation, such as increasing medical school intake. However, the SAMA request that the supposed “lessons” [36] learned during the pilot phase be properly documented and shared (with the same keenness) among key stakeholders and the public, in the spirit of transparency, and in order to appropriately inform the next phase of implementation.
- c. SAMA recognizes the White Paper’s assertion that “PHC will be the heartbeat of NHI” [37]. In this context, the SAMA strongly recommends that NHI PHC services be **doctor-led** and that GPs be appropriately utilized at the coalface

of healthcare delivery. The UK NHS provides some valuable lessons in this regard.

- d. Certain sensitive HR-related matters inherent to NHI elements as proposed in the White Paper can potentially become automatic push factors for doctors to leave for overseas locations if not addressed carefully. A case in point is contracting and reimbursement arrangements. The slow pace of GP contracting for the NHI is symptomatic of failed negotiations. For a smoother NHI rollout process, the government should consider the merits of doctors' arguments for reasonable contracting terms.
- e. NHI goals will be achieved by working together: This entails, first and foremost, government being continuously more **consultative** with health professionals' groupings in order to properly analyse, inform and co-create a sustainable human resources platform for South Africa. SAMA is not convinced that what it proposed in its submission to the NHI Green Paper was fully considered in crafting the White Paper, judging by the poor outcome on GP contracting. The SAMA urges for more open dialogue.
- f. Multiple sectors must collaborate; certain factors affecting availability and retention of health workers can be averted if an **integrated** approach is followed in designing solutions, through collaboration between Health and other sectors such as Education, Water and Sanitation, Housing, Social services, Public Works etc. Efforts must be in alignment with the entire 10-Point Plan. To aid rural retention, rural infrastructure must be developed through cooperation of some of the above government departments. Rural development will also facilitate in retention.
- g. South Africa needs to seriously take lessons from the UK National Health Service (NHS) which nearly faced total collapse due to serious doctor shortages (owing to the exodus of medical graduates and low medical school output that could not keep pace with physician attrition through aging and retirement) [38].
- h. SAMA recommends that the resources spent on the Cuban program rather be spent to develop *appropriate* training sites in South Africa, including rural sites. Rather than training outside the country; the government should rather import qualified educators. This will be a better investment to develop health workers for the NHI. Of particular importance is the development of Rural Training

Schools of which there are several initiatives at the moment. These need to be further supported.

- i. The Cuba initiative should only be a temporary measure. At the same time, initiatives such as increasing medical graduate output and tapping into private sector personnel will only work if attraction and **retention** is strengthened. A non-financial incentive scheme, coupled with a comprehensive developmental program especially in rural areas, should be implemented to enhance retention. It is the SAMA's firm belief that policies based on incentivising are more likely to succeed in plugging the rural personnel gap than approaches based on compulsion (such as the draconian Certificate of Need).
- j. The freezing of public sector posts is not justifiable and is condemned as it affects citizens' right to health care. Government has capacity to surmount the challenges behind the urge to freeze posts (including budgetary constraints) and should utilize that capacity.
- k. In the face of a disconcerting burden of disease, and much focus on curation, medical school curricula should be adjusted to strengthen **preventive care skills** among graduates. Public health specialization should be promoted leading to more production of such specialists.
- l. Medical school intake policies should be revised to reflect the racial demographics and socio-economic dynamics of this country. Rural and deprived students should not be economically discriminated against; government should promote enrolment and subsidize rural students studying medicine.
- m. High medical school dropout, an inability to finish studies in record time, or completely failing MBChB by medical students, must be investigated and addressed.
- n. The OHSC should consider voluntary accreditation of private practitioners as part of piloting. Such a program would need to be coupled with facility improvement.
- o. Scope of practices for Clinical Associates (and other MLWs) should be finalized.
- p. There is scope for on-the-job skills development training courses (e.g. ATLS, ACLS) being standardized and availed to all health professionals at all hospitals under NHI, as part of improving the quality of healthcare services.

### 3.8 Conclusion

The reengineering of the South African health system should involve strengthening the human resource base of the health sector. The imbalance of the distribution of human resources across global regions, the twin health sectors, as well as between rural and urban is the root of the human resources crisis in South Africa as it leads to migration. The abandonment of the public sector by health workers in favour of local (private sector) and international greener pastures highlights the critical need of government to focus on revamping the public sector. The focus should be on attracting and **retaining** health professionals through several proven means including the use of non-financial incentives.

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## 4. NHI PILOTING AND PRIMARY HEALTH CARE RE-ENGINEERING

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### 4.1 Background information

There are three successive documents appraising NHI pilot sites, available on the DoH website. The reports cover both the NHI pilots as well as non-pilot, wider NHI-related activities. The reports give some findings on what has been implemented as outlined below. The documents are entitled:

- i. *Status of NHI pilot districts. 12 month progress report. Prepared for the NDoH.30 May 2013.*
- ii. *Status of NHI pilot districts. 12 month progress report. An independent review prepared for the DG of the NDoH.18 August 2014.*
- iii. *Status of NHI pilot districts. 12 month progress report. Prepared for the NDoH, dated 25 May 2015.*

Some of the key findings are highlighted below:

1. Primary facilities scored more poorly than hospitals in terms of infrastructural improvements.
2. District clinical specialist teams have been established in all pilot sites although some teams are not fully constituted. This is a symptom of shortages of specialists. The DoH has published a Handbook for DCSTs. DCSTs are not only being implemented in pilot sites.
3. The HPV school program was very successful, with more than 95% of the targeted girls reached during two outreach activities in 2014.
4. The Central Chronic Medicines Dispensing and Distribution Program (CCMDD) is being rolled out in 10 districts, with encouraging results.
5. GOVERNANCE-RELATED: a lot of pilot districts, Tshwane excluded, already have in place full time NHI project managers and NHI district task force teams.
6. DISTRICT HEALTH MANAGEMENT TEAMS: In the majority of districts, there is poor scoring on a number of established and functioning clinic committees. Encouragingly, many districts have NHI conditional grant business plans, district health plans, and conduct quarterly review meetings.

7. HUMAN RESOURCES STAFFING LEVELS: WISN training was implemented in the majority of districts and piloting in selected NHI facilities was implemented and completed in the majority of pilot districts. It is not clear if the outcome of WISN was implemented and if it was evaluated.
8. GP CONTRACTING: Only about 300 GPs have been contracted. An independent service provider was engaged to recruit and place GPs, in the form of a group of organisations led by FPD, but including WHRI, Aurum, Broadreach, and Right to Care. No contracting out of GPs was tested
9. WARD BASED PHC OUTREACH TEAMS: all but three districts do not have teams in place. The selected PHC outreach team essential for prioritized conditions. More monitoring and evaluation required to assess the impact. To date, no baseline health indicators are publicly available from pilot sites. The SAMA recommends that health outcomes be monitored for pilot sites. MRC data is currently at provincial level, but this data needs to be available at districts as they monitor long-term outcomes. After all the baseline non-negotiable is improved health outcomes, how will we know if we don't measure it?
10. QUALITY IMPROVEMENT: The majority of pilot sites have facility inspection teams and a quality assurance coordinator, quality assurance team, and quality improvement plan in place.
11. Concern has been raised about grant expenditure on 'equipment', whereby it is found that only 55% of expenditure is classified as medical equipment, with computer-related equipment being the largest component of non-medical equipment.
12. A suggestion from lessons from the contracting exercise is that contracted doctors (since they are not employed by the State) should be covered for indemnity by the State.

## 4.2 Problem statement

### 4.2.1 Utilization of GPs in delivering sound and solid primary healthcare

An excerpt from the 1997 White Paper for the Transformation of the Health System in South Africa states that:

*"We intend to decentralise management of health services, with emphasis on the district health system, increase access to services by making primary health care*

*available to all our citizens, ensure the availability of safe, good quality essential drugs in health facilities, and rationalise health financing through budget reprioritisation”*

For all most 20 years, South Africa has been recognising Primary Health Care (PHC) as the cornerstone of healthcare. Although major strides were made in improving access to PHC, not all South Africans have access to primary healthcare and accessing a doctor is still a challenge for both medical aid beneficiaries and government-dependent populations. Access to general practitioners and primary healthcare for many medical aid beneficiaries is funded out-of-pocket as primary and preventative care are not prescribed minimum benefits. These patients are often turned away from the clinics as they have medical aids.

There is a paucity of information in the White Paper on GP involvement as well as lack of clarity on unifying private and public. Whilst there is mention of private practice in NHI, it is not apparent how GPs will be involved. Private GPs are not part of the district health services despite their ability to contribute to the district health service package of care. Currently the only model that is used is contracting in GPs. Is the involvement of GP NHI White Paper lip service or a true wish? We specifically note that contracting out of GPs has not been piloted.

Because in South Africa we have always assumed the PHC will be nurse-driven, we have not fully explored GP-driven service and its potential impact on health outcomes. Besides the shortage of doctors, utilisation of doctors in primary healthcare is inefficient. Medical doctors have always been visitors in primary healthcare through locum or as an outreach from hospital. It is only recently that some clinics will include a full time doctor position in the staffing establishment.

Regarding the Central Chronic Medication Dispensing and Distributions (CCMDD), the contracting of corporate pharmacies for distribution, although increasing the economies of scale, will affect the rural areas as the pharmacies do not have a rural footprint. The NDoH should be careful that such arrangements do not disadvantage rural populations. In high risk populations (i.e. non-adherence, sick, poly pharmacy, elderly, children) GP practices must be used as drop-off points. Rural GP practices may reduce costs of medication by acting as drop-off points for medicines.

The HPCSA's Ethical rule 8A (which states that '*A practitioner shall not share his or her rooms with a person or entity not registered in terms of the Act*') prohibit multidisciplinary practice with professions not registered under HPCSA. Unless this rule is changed, multidisciplinary private practices will not be possible.

#### **4.2.2 Reimbursement and competition**

With respect to reimbursement and competition, the SAMA notes the following:

- Currently the Competition Commissioner ruling considers price negotiations between practices as anti-competitive. Monopsony can result in market failures unless healthcare professionals are unionised (public sector) or are able to negotiate for prices.
- Delayed reimbursement artificially inflates the costs of healthcare.
- Section 335 of the NHI White Paper proposes that the NHI Fund, in consultation with the Minister, will determine its own pricing and reimbursement mechanisms. This process is unfair, unconstitutional, and dictatorial; a lack of consultation will place the NDoH at risk of legal challenge.

#### **4.3 A case for contracting out GP services**

- Existing infrastructure belonging to GPs can be utilized to fill the shortage gap for healthcare facilities in the country. According to the WHO, SA has a shortage of facilities and facilities are overcrowded, with each facility serving on average 13000 heads instead of 10000.
- Re-organisation of private primary healthcare and employment of nurses in primary health services will ensure that those who need the doctor access his/her services without delay. This will reduce the upstream costs of complicated diseases.
- Unification of the health system should not seek to eradicate the private sector. Government should utilize this platform for the benefit of all South Africans. It is a wish of every South African to have access to a doctor, timeously without unreasonable waiting periods.
- Implementation of NHI should not seek to reduce access to doctor based primary healthcare by the affluent who will bear the tax burden, and should be treated fairly by not reducing their access to GPs.

- In the ethos of distributive justice, the burdens and benefits must be equitably distributed amongst the citizens. NHI should not only benefit those who have no access to healthcare but also those who will carry the burdens of contribution.
- The most sick need a GP. South Africa has a number of GPs that, when contracted, can appropriately ensure access to care that will not differ according to patient's socio-economic status.
- The private sector has contributed to job creation and economic development.
- Because of a lack of red tape, the private sector is responsive to change i.e. it is more likely to implement NDoH priorities than the public sector.
- The private sector can compete on outcomes, not costs, as is the case currently. This will assist the Ministry achieve its 2030 National Development Plan goals.

#### 4.4 Recommendations

##### 4.4.1 Recommendation for inclusion of General Practitioners

- a) Existing GP practices to be incorporated to form part of district health services
- b) Piloting must include contracting **out** of services to GPs.
- c) Role of a GP can include the following:
  - i. GP-based nurse practitioners or nurses will see the majority of the cases.
  - ii. GPs will see complex patients referred by the nurses from government clinics as well as those arising from within their practice and occasionally from community health workers (we noted that competent community workers can identify very sick patients who need doctor intervention).
  - iii. GPs will have oversight of good clinical governance i.e. patients are accessing health services and treatment they are entitled to, protocols and guidelines are followed, and coordination of services is done to ensure improvement of health outcomes.
  - iv. GPs will be part of a ward and contribute towards ward-based primary health care activities including health forums.
  - v. Provision of, and participation in, onsite/ward-based training of junior doctors, nurses and community workers through integrated health teams' continuous education and training.

#### **4.4.2 Recommendation for reimbursement**

- a) The SAMA recommends transparent price determination, where all stakeholders are involved. The SAMA intends to develop practice costs studies. The NDoH will be involved in the development of costing methodology to reduce health professions bias.
- b) Determination of reimbursement fees must be scientific (that is cost-input must be determined using verifiable and good quality data e.g. practice costs studies).
- c) Capitation fees must be reimbursed one month in advance; this reduces financial uncertainty associated with the failure of government to pay on time.
- d) SAMA supports the submission of performance indicators to measure accountability given the capitation model.
- e) SAMA recommends annual revision of capitation fees and methodology. The methodology should be revised annually until we are sure that all assumptions hold, then the period of methodological review can be increased to three years.

#### **4.5 Conclusion**

Access to primary healthcare, and accessing a doctor, is still a challenge for both medical aid beneficiaries and government-dependent populations. There are several roles for the GP which government must consider. Contracting out of GPs must be piloted and price determination for reimbursement must be transparent and fair.

## 5. NHI FINANCING

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This section analyses projections for NHI, identifies potential problems and possible solutions for financial resources for NHI, and proposes mechanisms for better efficiency.

### 5.1. Expenditure Projections and Cost Estimates of NHI

The NHI White Paper cites a research brief by the World Health Organisation (WHO, 2015)<sup>1</sup> which identifies a number of areas that are of concern when using current costs as a basis for projections:

*“First, we don’t know where we are on the cost function. Cost is a function that describes the relationships between inputs and outputs. Any unit cost that we observe in a cost accounting study is just one point on a curve – but we do not observe that curve.”*

This is substantially true for South Africa. Despite numerous studies, primarily in the private sector, the government does not have (or has not published) any research that indicates the comprehensive cost of providing a service, e.g. caesarean section, tonsillectomy, or any other service.

For the record, cost is a factor of the product that is sold or the service that is provided. The package needs to be defined first before embarking on a costing exercise. For instance, the current expenditure is based on a fee for service environment, with little or no bundled payments. The discussion on cost can only take place once we have made a determination on what will be capitated, where are we going to be contracting on global fees, and as to what remuneration models will be in use.

What would be most workable is to paint and model various scenarios and then have them costed. Projections should then be based on the preferred model. Following the determination of the package of service, the costing for the package of service must be completed. Only after the costing of the package of service is completed, can any determination be made as to the source of funding, as this is dependant on the scope of funding required.

The aforementioned WHO research brief further states:

*“Second, we don’t want to lock today’s inefficiencies into future estimates. The observed costs –or more accurately, expenditures –also embody inefficiencies that exist in the health system.”*

In terms of the Auditor General’s reports of the Provincial Departments of Health, the following must be noted:

2013/2014					
R'm	Qualified	Unauthorised	Irregular	Fruitless and wasteful	Total
EC	Yes		149.30	51.40	200.70
FS	Yes	32.80	1,102.90	12.50	1,148.20
GP	Yes		233.90	161.60	395.50
KZN	Yes	322.80	1,219.70	0.70	1,543.20
LP	Yes		870.00	33.80	903.80
MP	Yes	18.30	818.40	0.33	837.03
NC	Yes	26.50	1,003.10	20.20	1,049.80
NW	No	59.40	725.10	8.80	793.30
WC	No		88.00		88.00
National			0.19	0.04	0.23
<b>Total</b>		<b>459.80</b>	<b>6,210.59</b>	<b>289.37</b>	<b>6,959.76</b>
<i>Source: AG PFMA Reports 2013/14</i>					
<b>Budget</b>					
Provincial Departments of Health					130,690.00
National Department of Health					2,243.00
<b>Total</b>					<b>132,933.00</b>
<b>Unauthorised, Irregular and Fruitless and Wasteful as % of Budget</b>					<b>5.24%</b>
2014/2015					
R'm	Qualified	Unauthorised	Irregular	Fruitless and wasteful	Total
EC	Yes	90.4	451.8	74.4	616.60
FS	Yes	Not yet released			-
GP	Yes		124.4	159.8	284.20
KZN	Yes	Not yet released			-
LP	No		544.9	43.4	588.30
MP	Yes	10.6	1918.9	3.6	1,933.10
NC	Yes	91.6	622.5	6.3	720.40
NW	Yes	262.6	763.8	20.4	1,046.80
WC	No		49		49.00
National			398.3	0.19	398.49
<b>Total</b>		<b>455.20</b>	<b>4,873.60</b>	<b>307.90</b>	<b>5,636.70</b>
<i>Source: AG PFMA Reports 2014/15</i>					
<b>Budget</b>					
Provincial Departments of Health					140,889.00
National Department of Health					3,955.00
<b>Total</b>					<b>144,844.00</b>
<b>Unauthorised, Irregular and Fruitless and Wasteful as % of Budget</b>					<b>3.89%</b>
(Excl FS and KZN)					

We draw attention to the fact that, at the time of producing this report, the Auditor General reports for the PFMA 2014/2015 for the Free State and KwaZulu Natal provinces, have not yet been made available publicly.

The continued existence of qualified audit reports in the majority of provinces as well as continued expenditure that does not meet the requirements of the Public Finance Management Act, do not bode well for the health system. The unauthorised, irregular and fruitless expenditure in 2014/15 was about 4% of the entire national health budget (excluding the figures that are not available for the Free State and KwaZulu Natal). It is projected in the NHI report that the funding shortfall could be between R27 billion and R108 billion - therefore a complete managerial overhaul in the provincial management could help fund part of the NHI shortfall. As an example, the Western Cape's unauthorised, irregular and wasteful expenditure is 0.2% of its 2014/2015 budget – indicating that it is an attainable target for other provinces.

The WHO brief goes on to say:

*“Thirdly, changing the health system’s cost structure by re-configuring service delivery is a legitimate objective of many health reforms. Therefore, costing studies can be very useful – but only if they reveal information on the underlying cost structure of service delivery and enable the modeling of different scenarios using various assumptions about prices, the impact of incentives, changes in service delivery configuration, and levels of service use, e.g. primary care driven system.”*

The SAMA agrees with this statement, with focus on the requirement that costing studies must be performed at a procedural level. Only then can different scenarios be used for planning purposes.

It is indisputable that the cost of private health care is a major concern for all South African consumers. Annual increases in medical aid funding consistently exceed published CPI figures, and is evident in published figures of medical aid scheme membership (as per the CMS annual report 2014/2015). The membership of open schemes has been flat since 2005 (2005: 4.91million, 2014, :4.90million), with the only growth coming from restricted schemes. This is as a result of the increase in the number of government employees, who have then subsequently become members of GEMS.

It is a known fact that South Africa has a dearth of doctors, and with only approximately 1200 doctors qualifying each year, it is unlikely to eliminate the need in decades to come. To this end, the government has engaged with Cuba to train doctors. In a

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written reply to a parliamentary question in 2015, Gauteng Health MEC Qedani Mahlangu indicated the following:

2012 – 105 students at R25.6m (R243,809/student)

2013 – 115 students at R33m (R286,956/student)

2014 – 138 students at R37.2m (R269,565/student)

Training expenditure is indicated for 2015 as being roughly R875,000/student per annum. As a comparative example, the cost of undergraduate enrolment for a medical doctor (non-resident) at the University of Botswana is BWP77,250 (roughly R110,000). The training in Cuba is for six years, and in 2019 students that finalised their studies will need to complete an additional two years of study in South Africa. The recent substantial devaluation of the Rand/US Dollar exchange rate will further exacerbate the unaffordable nature of doctor training. Increasing the number and/or size of medical schools and/or looking towards other countries for more cost effective training solutions will increase the number of doctors without increasing the training budget. Michael Porter's Five Forces model attempts to analyse the competitive forces within an industry and business strategy development. In terms of the private healthcare market, the forces are discussed briefly below:

i. Threat of new entrants:

Capital requirements are significant (cost of technology of doctors' practices, cost of hospital infrastructure). Once this barrier to entry can be overcome, players will enter into the market space (and have done so, evident through the number of private providers and hospitals)

ii. Threat of substitute products or services

In this area, the market is primarily segmented into two – private health and public health. Consumers who are able to pay for private services (often at the cost of other important discretionary spending such as life insurance, short term insurance and education) do not view the public health system as a viable alternative to private health care. In the White Paper (paragraph 63) the structural problems in the public sector are identified. Until, and unless, these are addressed, the typical private health consumer will not view the public sector as a viable alternative for purchasing health services.

iii. Bargaining power of customers

As a result of point 2 above, customers do not have significant bargaining power due to a lack of threat of purchasing from the State. The Health Market Inquiry is in the process of understanding the dynamics that are driving the cost of private health care – one of the outcomes is likely to be that the government is not offering a viable alternative, thereby allowing private healthcare providers a free reign.

iv. Bargaining power of suppliers

Inside the private health segment, suppliers (herewith seen as medical professionals) have limited bargaining power with funders (medical aid schemes). This is due to the fragmentation and the lack of collective bargaining that e.g. doctors have with medical aid schemes. The strong unified power of hospital groups, however, are much better positioned to negotiate for the funds available in the funding industry. This is evident through the increases of payments to hospital groups annually, viz-à-viz the payments to medical professionals. The Competition Commission's consent order that was entered into by the SAMA and BHF has taken away the medical practitioner's right to negotiate and bargain with medical schemes and it is recommended that this order be rescinded in order for medical practitioners to be placed in the same position as other suppliers of services to medical aid schemes.

v. Intensity of competitive rivalry

- a. The intensity of competitive rivalry in the private healthcare industry is substantial, primarily due to the lack of membership increases of medical aid schemes.
- b. That being said, there is limited competitive rivalry within the health industry as a whole (encompassing both the public and the private health sectors). This is owing to the fact that consumers of private health services do not view the public sector as an alternative.
- c. The private healthcare industry remains strong, cost are increasing although population covered remains constant. This reduces access to health services in turn.

## 5.2. Raising revenue to finance NHI

As outlined in the White Paper, there are a number of possible sources of funding for NHI. We now deal with them individually, and in no particular order:

- a. **Personal Income Tax** – A marginal increase in personal income tax will go a long way towards helping to finance NHI. Given the pressures on the already burdened taxpayer, it is unlikely that this motion will be embraced by taxpayers. NHI will comprise a mandatory core package and medical aids will be expected to provide supplementary and later on complementary services. At the initial phase, cost of supplementary medical aid cover with tax maybe unaffordable to the citizens. The extend to which NHI provides quality services, will dertermine the future role of medical schemes, and overall financial buredrn on the citizens. The cost of complementary services will cost less than the present medical aid premium, in that the core package benefits will be catered for via NHI. Part of the premuium will therefore go towards the tax surcharge and the balance will fund the complementary benefits.
- b. **Corporate Income Tax** – The same principle as above will apply. The only corporates that will feel the pinch are those that are on a total cost to company. Those that still subsidise their employees will utilise the subsidy towards the tax surcharge.
- c. **Payroll taxes** – The success notched through the collection method used for UIF, COID and Skills development levies makes payroll tax a very attractive option. It is also a very reliable way of collecting revenue and will decrease the cost of administration associated with the collection of premiums. The only short fall is that is it will be difficult to implement with the informal sector and the self employed.
- d. **Value Added Tax** – The good thing about VAT is that everyone will pay for it and it is an indirect way of collecting revenue. It is, however, difficult to predict and the revenue collection for NHI cannot rely solely on it.
- e. **Carbon Taxes** – These are taxes we should not forego, in that they have a direct impact on the healthcare budget, owing to their impact on the quadruple burden of disease, including vehicle accident-related injuries and disabilities.

- f. **Sin Taxes** – Sugar, alcohol and cigarettes also have a bearing on the quadruple burden of disease and increasing excise taxes on them will hopefully reduce their consumption and dampen their effects on health.

The funding requirements in the White Paper presents three scenarios in terms of economic growth forecasts – 2%, 3.5% and 5% per annum up to 2025. However, the economic forecasts from various sources indicate that the growth assumptions used in the White Paper are overly ambitious. The table below indicates the GDP growth in real terms forecast:

Source	2016	2017	2018	2019	2020
Nat Treasury	0.9%	1.7%	2.4%		
Bloomberg	0.9%	1.6%			
IMF	0.7%	1.8%			
Merrill Lynch	0.4%				
OECD	2.2%				
Investec	1.0%	1.5%	1.6%	2.1%	3.1%
World Bank	1.4%	1.6%	1.6%		
The Economist	0.7%	1.4%			

It is important to note that the National Treasury has a growth rate forecast that is below that of the lowest growth assumption of GDP growth in the White Paper.

Historical actual GDP growth figures (in real terms) are indicated below (Source: World Bank).

2011	2012	2013	2014	2015
3.2%	2.2%	2.2%	1.5%	1.3%

The forecast and historical figures for growth in GDP growth indicates that the revenue assumptions made in the White Paper are out of synch with recent local and international developments, thus further emphasising the requirement to properly cost the implementation of the NHI prior to determining the source of funding.

### 5.3. Options for expanding public funding of health services

#### 5.3.1. Value Added Tax

Apart from the sections noted above with regards to the current funding of the health system to be sufficient (should inefficiencies in procurement and supply chain management be addressed), it is noted from paragraph 292 that a relief for zero-rated goods in the Value Added Tax Act will be felt mostly by middle and high income earners. No evidence is provided to support this statement. The following 19 basic food items are zero-rated for VAT purposes: *brown bread, maize meal, dried mealies, dried beans, lentils, tinned pilchards/sardines, milk powder, dairy powder blend, rice, vegetables, fruit, vegetable oil, milk, cultured milk, brown wheaten meal, edible legumes and pulses of leuminous plants.*

Apart from these basic food items, illuminating paraffin is also excluded from VAT. The list above has clearly been designed specifically to improve access to essential food for lower low socio-economic classes. An increase in the VAT rate, as well as adding more items (e.g. unprocessed chicken, whole or in pieces) to zero-rated goods, will alleviate the burden on the poor whilst adding to the tax revenue. Furthermore, although VAT is a regressive system, it adds fairness to the utilisation of the health system. The poorest of the poor, through purchasing of primarily zero-rated goods, will benefit from access to a funded health system and food security, whilst all other classes of citizens (irrespective of whether they are exempt from income tax) will contribute proportionately to their spending patterns.

#### 5.3.2. Other sources of revenue

It must be said, that apart from the R270 per month (for the main beneficiary and 1<sup>st</sup> dependent) and R190 per month for other dependents, no other tax credit exists. Therefore, any further expenses that are paid to providers for medical services (including but not limited to doctors) are done with discretionary, post-tax funds. However, when receipted by medical professionals, the revenue less expenses, are then taxed by the Receiver of Revenue. The government therefore earns 28% of profit before tax (in the event of legal entities) on all activities provided in the health sector – funds which then flow into the government coffers. As an example, the three large hospital groups (Life Health Care, Medclinic and Netcare) contributed R2.026bn in

terms of tax in 2015 – tax that was the result of operations generated through after-tax discretionary spending by customers.

The medical aid subsidies should be removed in order to subsidise NHI. NHI will be for everyone. The core package will be carved out and will vest in NHI. Only complementary benefits will be provided by medical schemes. The same will apply to the tax credits and the tax deductibility of medical expenses for the over 65's. There will be no co-payments at the point of service in the NHI environment. The government currently subsidises public sector schemes (POLMED, GEMS, PARMED etc), to the tune of R20billion per year. This should go towards NHI, once fully implemented. The removal of the subsidy should be carefully considered and should be a timing issue. This should ideally be done in the final phase of NHI implementation, to avoid disrupting transitional arrangements that are working well.

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\*xisting medical aid reserves pooled could be run as a private equity fund, with public healthcare infrastructure as the investment mandate. The private sector should then access these funds and upgrade facilities via PPP arrangements. This will help the fund grow through risk free investments in public sector projects, with the Department of Public Works as a client and thereby ensuring that the fund's funds are used on a creditworthy client. The fund will, in time, experience the same level of growth and returns that the PIC currently enjoys. The legality of this needs to be confirmed and considered in medical scheme amendments.

#### 5.4. Changing landscape of inter-governmental arrangements

It should be highlighted that according to paragraph 312 of the White Paper, NHI will provide for **essential** personal services. The word essential brings an element of rationing. **Such rationing must be fair and transparent**

SAMA welcomes the provider/purchaser split. However, NHI fund benefits must not be based on the ability of provinces/individuals to provide services, but on needs of the population. This will allow the private sector to compete with government, increasing efficiency. For example, if NHI benefits include hip replacements and provincial hospitals cannot offer the service timeously, patients should have a choice to attend private sector facilities.

## 5.5. Pooling of revenue

Paragraph 83 of the White Paper, states:

*“Within the public sector there are multiple funding pools across the three spheres of government. The fragmentation is exacerbated by several funding streams namely equitable share allocations, conditional grants and locally generated revenues. These do not allow for effective planning, and contribute towards uncertainty in the availability of funding of services.”*

The National Department of Health needs to address this issue as a matter of urgency. Pooling all funds that are made available through National Treasury and managed centrally, will have an immediate and significant impact on unauthorised, irregular, and fruitless and wasteful expenditure – negating the need to find additional resources.

The governance of the NHI fund includes the creation of an entity to govern this – thereby adding costs to the health system. No mention is made of the anticipated cost of managing the NHI or the re-deployment or retrenchment of employees who are currently in provincial departments of health as a result of this intervention.

Generally, administration costs for nationally administered insurances are below 5%. Therefore, estimates of NHI requirement should include these costs.

## 5.6. Summary and Recommendations

National Health Insurance aims to address universal health coverage. To be able to fulfil this vital need for the South African population, it will require an additional investment into the national health budget vote.

However, determining the quantum of the amount required remains a substantial uncertainty and is not addressed adequately in the White Paper. Economic growth assumptions (which ultimately provides a potential increase of funds available to be channeled to the health system) is overestimated, given the view of several respected international institutions, including the South African government.

Before the source of funding can be addressed, it is required to cost the services that will be provided. Prior to determining the cost of services to be provided, it is required to determine the package of services that will be rendered at the different types of health facilities (as well as by whom these services will be delivered). Increased

access will have an impact on personnel numbers required – knowing full well that current shortages exist in the public sector, it will need to be determined what the quantum is of medical practitioners who will be required, and what a reasonable, fair market rate that will be required to secure uninterrupted services.

It is therefore premature to present the figures in relating to increased requirements for the health budget to render services through the NHI when neither the services nor the particular costs of those services have been determined.

In order to attain estimates with a higher reliability factor, the following is proposed:

1. Increase the number of NHI pilot sites to 20 (approximately 40% of the number of districts in South Africa).
2. Infrastructure investment into these sites must be focused and fast, ensuring compliance to the standards and guidelines set by the OHSC.
3. Ensure that the selection of the NHI sites results in clustering, i.e. that NHI sites are adjacent to each other. This should be done in order to include referral facilities up to and including tertiary facilities.
4. The complete suite of the proposed NHI interventions must be delivered in these districts - e.g. centralised procurement for these services, the contracting of medical practitioners (inclusive of specialists as well as private health facilities), well-managed referral pathways (both upward and downward) and delegation of authority to district and facility level.
5. Substantial investment is to be made into monitoring and costing the utilisation and services rendered in these districts, down to the smallest detail.
6. The newly established pilot districts must be operational for a period of at least 5 years to ensure that trends in costs and utilisation can be measured.
7. Following the 5 year pilot period, the extrapolation of data received from the pilot sites will inform the funding requirements for the NHI on a national basis.

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## **References**

WHO, 2015. Costing Health Care Reforms to move towards Universal Health Coverage (UHC): Considerations for National Health Insurance in South Africa, World Health Organisation.

## 6. UNIVERSAL HEALTH COVERAGE FOR MENTAL HEALTH

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### 6.1. Introduction

The World Health Organization (WHO) defines health as *“a state of complete physical, mental and social well-being and not merely the absence of a disease”* [1]. When symptoms of mental illnesses present themselves, they are associated with significant distress and impairment in human functioning, including learning abilities, work or family relationships, and ability to earn a living. Mental health is an essential element of health, and is crucial to the overall well-being of individuals and society.

Because of its low mortality rate, mental health is often placed low on the priority list. Evolution of mental healthcare in South Africa has been very slow despite post-1994 health transformation. In spite of the implementation of the National Department of Health Mental Health Policy Framework and Strategic Plan 2013- 2020, it is unclear whether the 2014/15 targets were reached. Whilst the government has good intentions of deinstitutionalising mental health, much of the public is not ready to accept the mentally ill in the community due to stigma. Mental health patients are generally discriminated against, not only by the health system, but by society at large and by government departments.

SAMA, in recognising that mental health is high burden, and probably a key contributor to loss of productivity, singled out this disease to emphasise and lobby for prioritisation in universal coverage. In doing so, the SAMA will be representing the voice of its members and advocating for mental health patients who by nature of illness and stigmata, have restrictions in exercising their rights.

SAMA supports and commends the National Department of Health on the development of the Mental Health Policy Framework and Strategic Plan 2013- 2020. This policy development is a step in the right direction to improve access to mental health, on condition that the policy is implemented correctly.

We also believe that in order to integrate mental health into primary healthcare (as proposed by the Mental Health Policy Framework), sufficient funds must be allocated for additional nurses, community psychiatrists, occupational therapists, counsellors, and psychologists, among others. We also believe that the district specialist teams or district health package must include psychiatrists. In order to establish community based mental health services, funds must be ring-fenced for appointment/procurement of community based mental health multidisciplinary teams/services. Integration of mental health services in PHC will improve the prevention of mental health illness, self-care, early detection, treatment and rehabilitation, as well as reduce associated hospital based costs.[2]

We believe such allocation in accordance with the Mental Health Policy Framework and Strategic Plan will be cost-effective in the long run as mental health populations are likely to be economically active (and contribute to the NHI Fund) and raise children who will be less dependent on the government. There will also be some positive impact on communicable and non-communicable diseases (NCDs) including injuries, as mental illness is a risk factor and disease modifier (comorbidity can worsen outcomes) for these conditions.

SAMA notes with appreciation the inclusion of mental health in the following NHI White Paper:[3]

**Paragraph 96:** Mentions the South African quadruple burden of disease, namely: communicable diseases such as HIV and AIDS and TB, maternal and child mortality, NCDs such as hypertension and cardiovascular diseases, diabetes, cancer, mental illnesses, chronic lung diseases such as asthma, as well as Injury and Trauma. The combined impact of these epidemics has had an effect on the doubling of death rate between 1997 and 2006 in South Africa.

**Paragraph 131:** Lists the comprehensive package of health service deliveries that will be covered, namely:

- i. Preventive, community outreach and promotion services
- ii. Health counselling and testing services
- iii. *Mental health services including substance abuse*

iv. Prescription medicines

**Paragraph 169:** Addresses barriers to learning with the help of the Integrated School Health Programme (ISHP), to improve the physical, **mental** and general well-being of children also including a focus on screening for health-related barriers to learning such as vision, hearing, cognitive and related developmental impairment.

**Paragraph 199:** Mentions Specialised Psychiatric Services that may be provided in general hospitals (usually acute psychiatric wards only) but are mostly provided at specialised facilities designed for care of mentally ill patients. These services may be Regional, T1, T2 or T3 depending on complexity of care, multi-disciplinary nature and/or the supporting infrastructure and services required.

**Paragraph 341:** Mentions that there will be a process of identifying key gaps in the Essential Drugs List (EDL) and other guidelines e.g. mental health services and long-term care.

Our submission provides a case for prioritisation of mental illness, and advocates for fair treatment of these patients. Using evidence, we highlight current problems and propose evidence-based solutions for successful integration of mental illness. We will also highlight the gaps within NHI that could potentially create barriers for access to mental health.

## 6.2. Problem Statement

### 6.2.1. Burden of mental illness

The National Mental Health Policy Framework and Strategic Plan 2013-2020 provide the following statistics: [2]

Globally, mental and neurological disorders account for 13 percent of burden of disease. There is no evidence that there are any differences between racial groups or cultural groups in the prevalence of mental disorders. However, there are important gender differences: women are at increased risk of developing depression and anxiety disorders, whereas men are at increased risk of developing substance use disorders, which further increases their risk of violence and chronic diseases of lifestyles such as cancers. Between 11% and 63% of HIV-positive people in low- and middle-income countries have depression and are prone to anxiety, stress and panic disorder. Whilst their mental health illness is mainly due to HIV, the co-occurrence of stress further

depress their immunity and have adverse impact on adherence to antiretroviral treatment. [4]

South Africa is ranked third in its overall burden of disease. [2] It is estimated that annual prevalence of mental disorder is between 16.5% and 17% (1 in 7 people) in adults and children respectively. The increase in mental health disorders and distress has been associated with being an AIDS/HIV orphan. Thirty percent of adults will at least experience a common mental disorder in their lifetime. The most common type of mental illness disorder include anxiety disorder (8.1%), followed by substance misuse (5.8%) and mood disorder (4.9%). Although accounting for most admissions, schizophrenia and bipolar occur in 1% of the population. [2]

The most prevalent type of child and mental health disorders in children include general anxiety disorder, depression and dysthymia, oppositional defiant, conduct and attention deficit disorder. See table 2 below.

These statistics are probably an underestimation as many people would not voluntarily disclose mental health symptoms due to associated stigma. [5]

*Table 1: 12-month prevalence of adult mental disorders in South Africa*

Disorder	%
<b>Any anxiety, mood, impulse or substance use disorder</b>	16.5
<b>Anxiety</b>	8.1
<b>Substance Use</b>	5.8
<b>Mood</b>	4.9
<b>Impulse</b>	1.8
<b>Schizophrenia</b>	1.0
<b>Bipolar</b>	1.0

*Table 2: 12-month prevalence of child and adolescent mental disorders in the Western Cape*

Disorder	%
<b>Any child and adolescent disorder</b>	17
<b>Generalised Anxiety</b>	11
<b>Depression &amp; Dysthymia</b>	8
<b>Posttraumatic stress</b>	8
<b>Oppositional Defiant</b>	6
<b>Attention Deficit Hyperactivity Disorder</b>	5.0
<b>Enuresis</b>	5

<b>Social Phobia</b>	5
<b>Conduct Disorder</b>	4.0
<b>Separation Anxiety</b>	4.0
<b>Agoraphobia</b>	3
<b>Simple Phobia</b>	3
<b>Bipolar</b>	1
<b>Schizophrenia</b>	0.5
<b>Obsessive Compulsive</b>	0.5

### **6.2.2. A highly strung society: Association of mental health and other diseases**

Mental disorders are a risk factor for, and can worsen, other communicable and non-communicable diseases, maternal and child health illnesses and injuries. Mental health has been shown to increase work related injuries, and those who suffer from mental illness are often unfairly discriminated against. Whilst mental health patients are at risk of causing personal and interpersonal injuries, the clients are at risk of dying from societal and police assaults[6].

Prolonged exposure to stress, associated hostility, and anger have been shown to suppress the immune system as well as increase the risk of cardiovascular disease. Some of the major stressors that citizens of the country are currently exposed to include financial concerns, job stressors and lack of job opportunities. Hostility has been shown to be a better predictor of heart disease and better predictor of heart diseases in older men than smoking, drinking, high caloric intake, and cholesterol levels. [7]

The South African Stress and Health (SASH) Study 9 (2009) [8] was the first large-scale population-based study of common mental disorders in South Africa. The study, which involved over 4000 adults, found that South Africans have a lifetime prevalence of 33.3%, and anxiety disorder was the most prevalent condition. Twenty six percent of disorders listed in the DSM-IV were considered severe in South Africa.

The conditions within which the majority of South African live (poverty, family discord, work place stressors, injuries etc.), expose them to a high risk of acute stress disorder (ASD). With fragmented healthcare, health professions often miss the underlying stress when patients present with physical symptoms. Sometimes the patients even get labelled as suffering from psychosomatic illness and are not provided necessary mental healthcare.[9, 10]. ASD can turn into chronic stress if endured on an ongoing

basis and can have a detrimental effect on both the body and the mind of the individuals suffering with it. The people who experience this type of stress come to see this as a way of life and as the expected norm and thus will not always seek help. Chronic stress can lead to burnout<sup>1</sup>, and other symptoms can include suicidal tendencies, a violent nature, heart disease and diabetes. [11]

Exposure to a traumatic event (e.g. war, physical assault, sexual violence and or abuse, natural disasters, or a severe car accident) can lead to PTSD. High levels of anxiety could be partly due to PTSD as South Africans have high exposure to traumatic events. [12]

### **6.2.3. Learning disabilities, conduct disorder and mood disorder**

Learning disability refers to children or adolescents who struggle with one or more areas of learning. The determination of learning disabilities intelligence is divided broadly into three different areas: verbal intelligence, non-verbal intelligence, and scholastic disorders [13, 14]. Causes of learning disability include environmental exposure to toxins (e.g. lead), genetics, as well as exposure to drugs and alcohol.

Problems associated with learning abilities include conduct disorder, oppositional defiant disorder, or major depressive disorder. South Africa has a significant portion of children who are unable to learn, not because of underlying biological factors but because their environment is not conducive for learning or they have a comorbidity such as physical or mental illness.

Some of the causes that can be attributed to disruptive, impulse-control, and conduct disorders also include physical and sexual abuse, parental neglect and rejection, harsh discipline, lack of supervision, early institutional living, frequent change in care givers, among other factors. [10, 15]. The risk factors in South Africa are largely due to the recent HIV epidemic. HIV orphans of the early 2000 have now become parents. These new parents did not receive sufficient parenting themselves and probably have had some form of mental illness or behavioural disorder. Children with mental illness generally are unable to learn. In our country, it means at least 1 in 7 children will not be able to learn due to mental health illness.

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<sup>1</sup> Burnout is a type of psychological stress. Occupational burnout or job burnout is characterized by exhaustion, lack of enthusiasm and motivation, feelings of ineffectiveness, and also may have the dimension of frustration or cynicism, and as a result reduced efficacy within the workplace

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Early childhood programmes have been linked with improved outcomes in children. Early childhood programmes are multi-sectorial, involving departments of Health, Social services, and Education, and should include early identification of problems that impede learning and decrease chances of higher educational attainment, whilst reducing health risks such as delinquencies, alcohol and drug use and risky sexual behaviour and substance misuse.

These programmes play a big role in the prevention, onset, and worsening of mental health conditions into adulthood, leading to increased productivity and economic development. benefits of early childhood programmes have been documented for up to 27 years in high-income countries and for up to 17 years in low- and middle-income countries, and have been shown to improve subsequent school enrolment rates, age of school entry, school retention, academic performance, children's social skills, self-confidence, relationships with adults, and motivation. These programmes have also proven to reduce problems such as mental and physical health conditions, substance abuse, incarceration, and unemployment experienced in adulthood. [5]

The South African mental health policy framework correctly states that in resource-constrained and high risk contexts, mental health promotion and prevention initiatives which target key developmental stages can assist in breaking the cycle of poverty and mental ill-health through improving resilience in the context of widespread risk. These interventions are particularly important during childhood and adolescence given that most mental disorders have their origin in childhood and adolescence. There is an increasing body of evidence on the efficacy of mental health promotion and prevention interventions that target these key developmental stages.

SAMA commends the Department of Health and the Department of Education for implementation of the **Integrated School Health Programme in quintile 1 and 2 schools**, which are the neediest schools and experience the worst risk factors. The ISHP should have been implemented with the Department of Social Development as this Department plays a crucial role in poverty reduction and early childhood learning. Early interventions provided by Social development are likely to have positive impacts *at minimal costs*

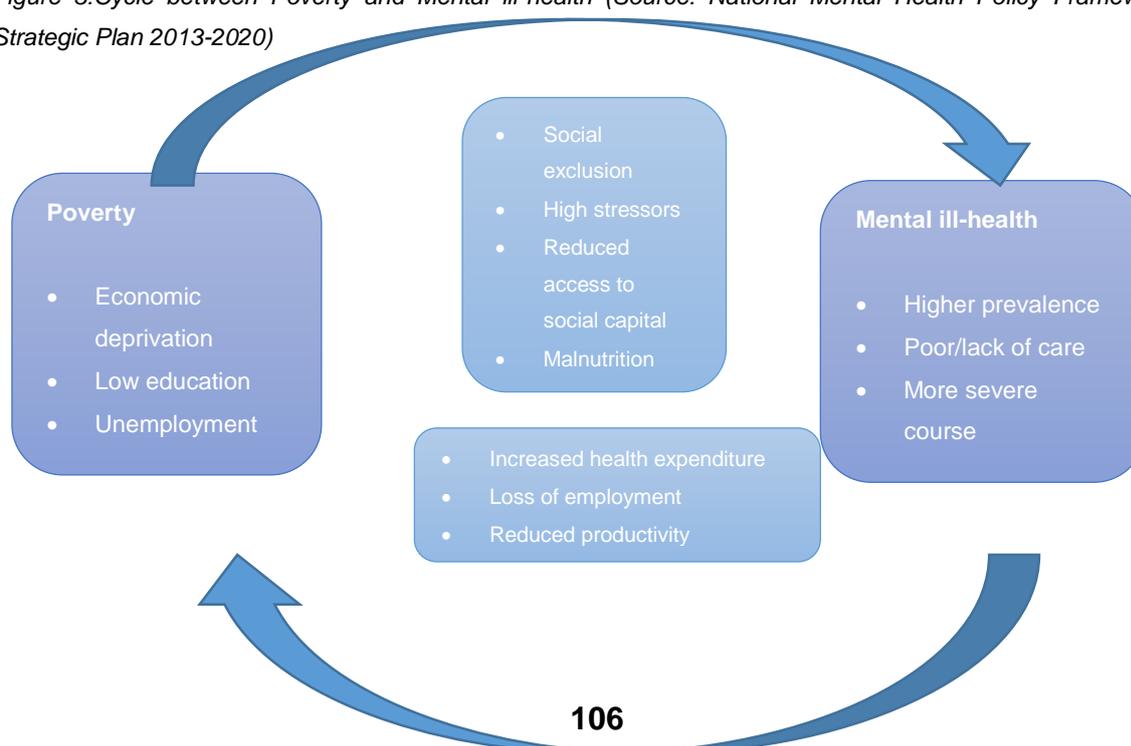
SAMA recommends that due to increased risk factors for mental health such as eroded family structures, exposures to poverty and illicit substances, ISHP should include multidisciplinary teams of health professions including nurses, counsellors, occupational therapists, etc., and should also include pro-active screening and early intervention programmes.

While according to the School Health Policy referral networks are available, services that can be offered within the school such as counselling and occupational must be provided to reduce absenteeism. This will assist with onsite provision of services as opposed to screening and referral.

#### 6.2.4. Mental health and Social Determinants of Health

People living in poverty are at increased risk of developing mental disorders through stress, increased obstetric risks, lack of social support, and increased exposure to violence and physical health. The opposite is also applicable for those who live with mental illness, as they have an increased risk of falling into poverty, due to increased health expenditure, loss of income, reduced productivity, loss of employment and social exclusion due to stigma. This population is therefore at high risk of financial catastrophe and is a vulnerable population.

Figure 3: Cycle between Poverty and Mental ill-health (Source: National Mental Health Policy Framework & Strategic Plan 2013-2020)



Stressful conditions place people at a higher risk of developing mental health conditions. Poverty and mental health conditions interact in the following ways: [1, 5, 16]

- Lack financial resources to maintain basic living standards.
- Fewer educational and employment opportunities.
- Exposed to adverse living environments such as slum areas or dwellings without sanitation or water.
- Less ability to access good-quality health care, therefore increased disability and early death.
- People with mental health conditions sometimes are unable to work because of their symptoms.
  - Due to discrimination, some are denied work opportunities or lose employment.
  - Many have no means to pay for needed treatment
  - Money is spent on costly mental healthcare.

#### **6.2.5. Economic impact of mental illness**

Long-term mental health difficulties are, according to a WHO report, one of the three leading causes of disability, along with cardiovascular and musculoskeletal disease. The International Labour Organisation (ILO)'s mandate on disability issues is laid down in the ILO Convention concerning Vocational Rehabilitation and Employment of Disabled Persons No. 159 (1983), which establishes the principle of equal treatment and employment for workers with disabilities. The United Nations estimates that 25% of the entire population is adversely affected in one way or another as a result of disabilities.

Mental health problems have serious economic and social costs. These include direct costs related to the provision of healthcare, and indirect costs, such as reduced productivity at home and work, loss of income and loss of employment. These costs have a direct effect on the mental healthcare user and their families' financial situation

Mental health problems do not just affect the individual. They impact the entire community. The United Nations estimates that 25% of the entire population is adversely affected in one way or another as a result of disabilities. [17]

The indirect cost of mental disorders outweighs direct treatment costs by two to six times in developed countries and may be even higher in developing countries. In the first nationally representative survey of mental disorders in South Africa, lost earnings among adults with severe mental illness during the previous 12 months amounted to R28.8 billion, which outweighs the spending on mental healthcare for adults (approximately R472 million). [2]

Therefore to reduce the risk of mental health in the country, the government should also reduce the disparities in social determinants of health whilst addressing those affected through structured universal health coverage.

#### **6.2.6. Mental Health Stigma and discrimination**

Many people with mental illness experience shame, ostracism, and marginalisation due to their diagnosis. Organizations such as the World Health Organization [18-20], the World Psychiatric Association (WPA) [21] and the World Association for Social Psychiatry [22] to name a few, have all recognized stigma as a major public health challenge.

Stigma is a barrier to access to mental health services, including self-care and informal community based mental health services. The effects of stigma have been described as having worse consequences than the mental illness itself, and might also be stronger in minority ethnic communities, due to complex cultural and community factors. Mental health problems act as a barrier to access social security services such as housing and grants, which can cause mental health to deteriorate. In the USA, ethnic minority groups were associated with high risk of mental illness. [23]

Ninety three percent (93%) of participants experienced discrimination (in finding or keeping a job, in housing or education, and in forming relationships or having a family), and 49% allege discrimination from mental health staff, including racial discrimination. Two examples of stigma in both men and woman. The high rate of suicide among men, can be attributed to so called “Boy Code” existing of a certain set of expectations

about how boys and men should think, feel and act (“be tough”, “don’t cry”, “go it alone” and “don’t show any emotion except for anger”). This is also particularly true in South Africa where there are expectations for men of all racial groups and cultures to “man it up”.

#### **6.2.7. Interventions to reduce stigma to mental health**

Stigma reducing intervention takes place population and individual level [24, 25]. Population interventions include education focusing on the entire population not just at risk population. Such interventions were associated with attitude change. At individual level, anti-stigma interventions had a potential to reduce stigma whilst specific group target e.g. schools and universities were associated with improved attitudes and knowledge.

The Time to Change Programme is an anti-stigma program in England that aims to minimize the effects of mental health stigma. The program has individual, target group and population wide interventions, using media, focus groups, community events and activities [26]. At one year post-implementation, discrimination experienced by affected clients reduced by 38%. Discrimination against employment had also reduced although discrimination from mental health professionals did not reduce. [27]

The World Psychiatry Association (WPA) was initiated in 1996 specifically to fight stigma in patients suffering from schizophrenia. The Open-the-Doors program is an international consortium of members, all of whom endorse three core principles. The programme is running in about 19 countries. The programme is unique in that that program goals and objectives are to be developed from the priorities and needs of people who live with schizophrenia, garnered from quantitative and qualitative needs assessments and realized through their active participation in all aspects of program development, implementation, and evaluation. The programme also encourages broad participation from community members, making a concerted effort to move beyond the mental health sector. The planning groups include those who live with schizophrenia and target. There is no evidence of anti-stigma interventions against people suffering from mental illness in South Africa. There are also no specific HIV anti-stigma interventions despite strong evidence that stigma exists in the country. [28]

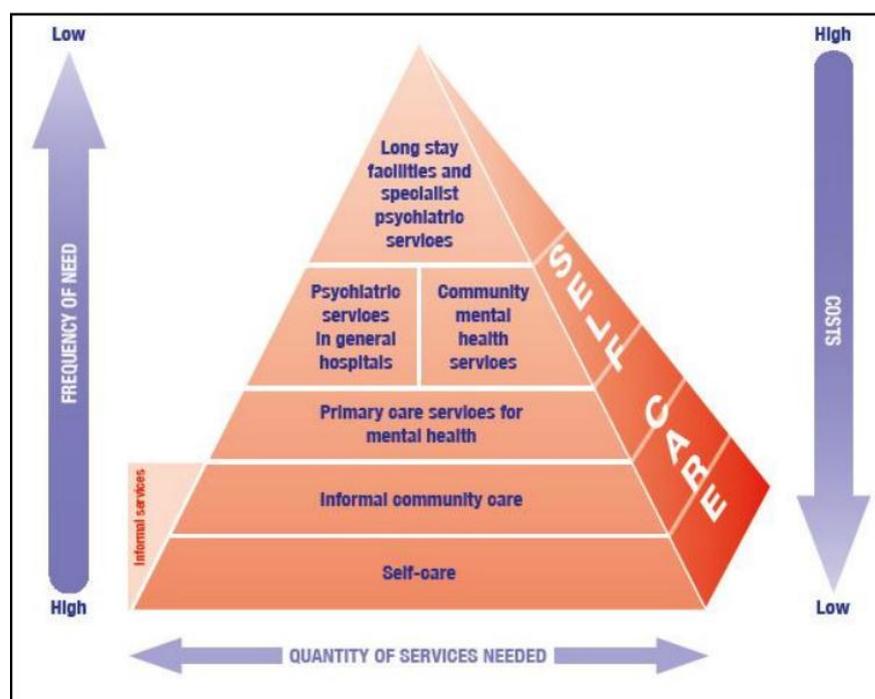
Stigma is a barrier to self-care and informal community care. Delayed diagnosis results in patients being diagnosed late and increases sufferings and unintended consequences of mental health.

Therefore the SAMA proposes that as part of universal access to mental health services, the NDoH engages in effective antidiscrimination strategies. We also recommend that the NDoH advocates for access to social security in mental health patients and engage in labour to promote anti-discrimination against mental health patients in the workplace to access services both in private and public. Although this was an objective of the Mental Health Policy Framework, there is no evidence that this was achieved.

### 6.2.8. Access to mental health services and resources

The World Health Organisation (WHO) provides the following pyramid of care, as the ideal structure for mental healthcare in any given country: [16]

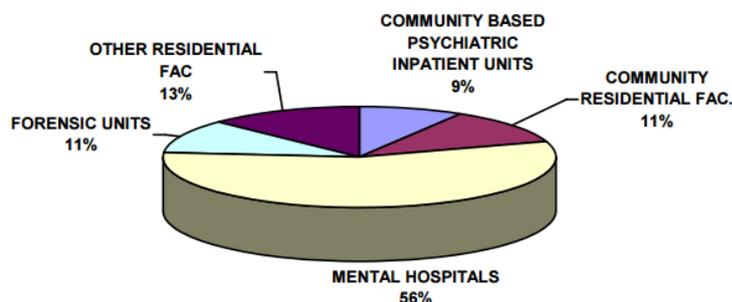
Figure 4: WHO Pyramid of care The WHO AIMS report on South African mental health facilities, reports the following figures on beds available for mental health patients in mental health- and other residential facilities (Figure 5)[29].



As can be seen from both figure 4 and 5, South African mental health services are predominantly hospital based with only 20% of the beds being in the community. Whilst there are informal community care through churches, non-governmental

organisation, and traditional healers, these resources are fragmented, uncoordinated and do not link to formal mental health services.

Figure 5: Beds in Mental Health Facilities and Other Residential Facilities



Mental health assessment and treatment protocols for key mental health conditions in primary health care clinics were inadequate. When available, majority were for non-physicians. There is an urgent need for multidisciplinary care protocols and guidelines.

### 6.2.9. Access to medicine

With regard to the availability of psychotropic medicines, three provinces reported that 81-100% of physician-based primary health care (PHC) clinics have at least one psychotropic medicine of each therapeutic category (anti-psychotic, antidepressant, mood stabilizer, anxiolytic, and antiepileptic). One province reported that 51-80% of these clinics have such medicines. In non-physician-based clinics, four provinces reported 81-100% availability, three provinces reported 51-80%, one province reported 21-50%, and one province 0%. [29] Coverage for antidepressants, antipsychotics was 15% and 20% respectively. The authors set a coverage target of 25% and 80% respectively.[30]

Medical Scheme Act Regulations only cover two mental health conditions with chronic medication, namely bipolar mood disorder and schizophrenia. The list of medications prescribed for this conditions is outdated.

**Paragraph 341:** Mentions that there will be a process of identifying key gaps in the EDL and other guidelines (e.g. mental health services and long-term care).

Compared to the 2008 PHC EDL, the 2014 EDL had more psychotropic medication. This is encouraging however we would like to caution that availability on the EDL does not translate to availability at the shelf, due to poor stock management.

Access to mental health care is not only an issue in the public sector. In the private sector, the prescribed minimum benefits (PMBs) are limited and encourage fragmented, hospital-centrism and uncoordinated care. The Medical Schemes Act 131 of 1998 Regulations on chronic disease list only covers two chronic mental conditions, namely bipolar disorder, and schizophrenia. Treatment is limited to three weeks in-hospital admission or 15 psychotherapy sessions, with a provided formulary. The provided formulary is outdated and many patients face co-payment for newer drugs with a better side-effects profile. Public sector quaternary EDL provides better access to medicines than PMB provisions. [31]

Table 3 below outlines the diagnosis and treatment pair entitlements in accordance with Medical Schemes Act. The package itself promotes hospital-centrism and expensive care. Whilst anxiety and depression are very common in South Africa, PMBs do not cater for any medical treatment. Lack of ambulatory care results in worsening of conditions with delayed diagnosis and treatment. Beneficiaries of medical schemes often face catastrophic expenditure as their benefits get exhausted well before year end. Very sick patients particularly for bipolar mood disorder and schizophrenia end up being referred to the public sector and this displaces the indigent patients and perpetuates shortage of beds in public sector.

At best these services are non-existent as very sick patients require a longer period to stabilise and the majority of minor cases can be managed out-of-hospital. Whilst depression is covered with hospitalisation, medication is not included as a prescribed minimum benefit. Anti-depressants are very costly and most of these patients find themselves having to fund for medication out of pocket. [31]

As can be seen in table 4, the majority of mental health patients do not have access to sufficient consultation for mental illness, rehabilitation or medication. The package itself incentivises hospitalisation, which is neither cost-effective nor in accordance with community based mental health services.

Cost of medicine in private sector is extremely expensive. Affordable medicines may make it possible for those who need to pay out of pocket in the interim.

Table 3: Medical Schemes Act 131 of 1998 Regulations on Mental Illness

MENTAL ILLNESS		
Code:	Diagnosis:	Treatment:
182T	Abuse or dependence on psychoactive substance, including alcohol	Hospital-based management up to 3 weeks/year
184T	Brief reactive psychosis	Hospital-based management up to 3 weeks/year
901T	Acute stress disorder accompanied by recent significant trauma, including physical or sexual abuse	Hospital admission for psychotherapy/counselling up to 3 days, or up to 12 outpatient psychotherapy/counselling contacts
902T	Major affective disorders, including unipolar and bipolar depression	Hospital-based management up to 3 weeks/year (including inpatient electroconvulsive therapy and inpatient psychotherapy) or outpatient psychotherapy of up to 15 contacts
903T	Attempted suicide, irrespective of cause	Hospital-based management up to 3 days or up to 6 outpatients contacts
907T	Schizophrenic and paranoid delusional disorders	Hospital-based medical management up to 3 weeks/year
908T	Anorexia nervosa and bulimia nervosa	Hospital-based management up to 3 weeks/year or minimum of 15 outpatient contacts per year
909T	Treatable dementia	Administration for initial diagnosis; management of acute psychotic symptoms – up to 1 week
910T	Alcohol withdrawal delirium; alcohol intoxication delirium	Hospital-based management up to 3 days leading to rehabilitation
910T	Delirium: amphetamine, cocaine, or other psychoactive substance	Hospital-based management up to 3 days
910T	Acute delusional mood, anxiety, personality, perception disorder and organic mental disorder caused by drugs	Hospital-based management up to 3 days

### 6.2.10. Barriers to accessing and diagnosing mental health services

The Programme for Improving Mental healthcarE (PRIME) South Africa, has conducted several researches with regards to mental illness. A pilot study revealed the following challenges in accessing quality mental health care [32]:

- Lack of referrals by primary healthcare nurses to counsellors for depression
- Underdiagnoses of alcohol use disorders
- Poor follow-up of counselling
- A high default rate of patients receiving follow-up medications for mental illness at the primary healthcare clinics
- Poor uptake of the psychosocial rehabilitation intervention by caregivers of patients with schizophrenia

Reasons given for these included:

- *On the part of patients/caregivers:* poor mental health literacy was a barrier to help-seeking for depression; defensiveness in divulging alcohol consumption was a barrier for identification of alcohol use disorders.
- *On the part of nurses:* barriers to identification and/or referral rates of depression and alcohol use disorders was a result of low self-confidence in ability to diagnose common mental disorders, unattended personal issues, focusing on underlying social problems, and referral to social workers without attending to the presenting mental disorders, and lack of confidence in lay counsellor abilities.
- *On the part of counsellors:* in addition to unattended personal issues, marginalised status and unclear roles, low confidence, and poor suitability of some counsellors emerged as being reasons for poor follow-up of patients referred to them for counselling.
- *Structural and organisational challenges* that impeded identification and/or referral of depression or alcohol use disorders by nurses included high patient loads and space constraints that limited consultation.
- *Space constraints* also emerged as limiting confidentiality of counselling.
- *With regard to the psychosocial rehabilitation group intervention,* a high default rate and poor tracing of individuals who defaulted limited the number of patients who could be referred to the groups by the primary healthcare nurses.

### **6.3. Financing of Mental health services**

Although there has been considerable mental health policy developments, financing has been inadequate and prioritisation of other diseases translates into mental health being side-lined. Although financing decisions were made as early as 2003, much has not been realised due to competing interests.

Successful implementation of mental health services involves putting together a range of human resource (multidisciplinary teams) and physical resources (counselling rooms).

On average South Africa needs at least a mental team of 4.7 mental health professionals/100000 population. In order to achieve successful PHC based mental health the following estimates are made:

*Table 4: Human Resource needs at target coverage levels of intervention package delivery in five non-specialised healthcare settings*

	<b>Kenneth Kaunda district</b>
<b>Human resource category</b>	<b>(South Africa)</b>
Psychiatrist	0.2
Other physician/doctor	0.6
Nurse	1.7
Psychologist	0.3
Other psychosocial worker	0.8
Other providers/workers	1.1
<b>Total</b>	<b>4.7</b>
<b>a. includes community health workers</b>	

Only 0.2 psychiatrist/100 000 population were estimated. At least an additional 1.7 nurses per 100 000 population are needed. The medication coverage for depression needs to be increased from 15% to 25%, and psychosis from 20% to 80%. In order to do that, the cost per capita allocation for mental health was 2 USD per capita per year. The financial requirements are quite high and maybe unaffordable. In order to realise the goals the health professional targets can be reached with wise use of midlevel workers.

Support for individuals with severe mental illness (SMI) is particularly challenging in resource-poor sub-Saharan African nations, including in South Africa, due to a lack of availability and/or access to community-based mental health services. Preventing

psychiatric re-hospitalization requires an approach to addressing unmet needs that go beyond temporary management of psychotic symptoms at tertiary mental health institutions. In addressing unmet needs of individuals with SMI, the PRIME cost studies suggest that strategies to improve the provision of support will require close attention to especially vulnerable groups. [30]

#### **6.4. Recommendations**

In light of the facts highlighted above, SAMA makes the following recommendations:

a) Early Childhood interventions:

- i. The Integrated School Health Programme must incorporate mental health workers such as professional counsellors, psychologists and social workers, as the prevalence of mental health risk factors is high in our population. School-based mental health programmes are able to assist children once they are enrolled and help children stay engaged in the education system. Mental health workers are able to identify and support children with mental health problems and can provide ongoing services to those students with severe forms of mental conditions. These programmes also enable schools to reach a broader population with minimal stigma. Some of the programme activities include anti-bullying, stress management and life skills development programs. [5]
- ii. Integrated School Health programmes must start at pre-school. Early interventions have been shown to be more effective.
- iii. Integration of mental health services in maternal care clinical guidelines, as interventions in pregnancy have been shown to have considerable impact in low resource settings and this will be in accordance with South African Mental Health Policy Framework.

b) Mental health at District level:

Integration of comprehensive mental health into PHC requires additional capacity at Primary health care. Simply shifting patients to PHC and community without additional resources will result in dismal failure of the mental health policy framework.

c) Human resource recommendations

- i. Specialist mental health professionals must be available to support primary care. The integration of mental health services into primary care must be accompanied by complementary services, particularly secondary care components to which primary care workers can turn for referrals, support, and supervision. Ideally one of each team per district hospital should serve the needs of the generalists at the hospital, the CHCs and PHCs, residential homes and day care facilities and to provide inter-sectoral engagement with education/SAPS/correctional services/ social development etc. The teams are also required to provide specialist assessment and treatment at community level and to ensure continuity of care with hospitals – as per the Policy.
  - ii. Medical doctors with a Diploma in Psychiatry can provide community based services with minimal psychiatrist support. Revision of remuneration will create incentives for postgraduate diploma training. As the Colleges of Medicine Diploma is distance learning, this could provide a non-financial retention strategy for rural doctors. See more information on Human Resources Chapter (rural retention section) of this document.
  - iii. Mental health coordinators should be employed to coordinate informal and formal mental health services including the traditional practitioners as they play a huge role in especially the psychosocial model and communal care by family.
  - iv. Midlevel workers have a huge role to play in community based mental health services, and staffing plans must include them.
    - Availing resources of the HPCSA - registered professional counsellors will ensure rural areas have access to psychology services.
    - Clinical Associates can be valuable in history taking and assessing mental status examinations and follow-up of patients. Career pathing with in-depth knowledge of mental health may provide an opportunity to expand their roles.
  - v. On-the-job training: Existing healthcare professionals will require on-the-job training to improve quality of mental health services.
- d) Improving access to medicines:

- i. Maximise provisions of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement and improving regulatory capacity, see more details in the proposed legislative framework.
  - ii. Strengthening of local pharmaceutical sector.
  - iii. Harmonisation of medicine pricing regulation. Exemption of the State from SEP regulations disincentives the government from aggressively regulating medicine prices and further exacerbates inequities between private and public sector. It is a common argument that prices in private sector for medicines are high as they subsidise low costs in government.
  - iv. Access to medications is very poor. The government must review the patent laws and implement strategies to reduce the cost of medicines to improve accessibility. See more on the Chapter on Legal perspective on NHI.
- e) Monitoring and evaluation and quality improvement:
- i. Development of a national mental health information system, integrated with the district health management information system or any other databases, based on a set of nationally agreed indicators and a minimum data set.
  - ii. Development of quality assessment indicators and improvement strategies for mental health.
- f) Providing financial resources to improve quality of care:
- Building capacity for and implementation of integrated mental health services should be made an element of the NHI district pilot conditional grant. Pilots must be explicit about monitoring and evaluating integration of mental health services.

## 6.5. Conclusion

Mental health is a subject which has been downplayed within the health sector, despite the fact that it affects a greater population than expected. With difficult times facing South Africa, the population is experiencing higher volumes of stress, leading to co-morbidity with diseases such as heart disease, diabetes and HIV and AIDS, which are all killers within the country. Reaching our children early with preventative and educational programmes, as well as affordable medications, will enable us to reduce greater difficulties and be able to produce a more productive and healthy population. Integration of mental healthcare services in PHC will assist in case detection and facilitate early access to treatment. Population based awareness and anti-stigma

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campaigns will reduce stigma faced by mental health patients and may lead to increased community participation in informal mental health services.

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## 7. MONOPSONY AND LABOUR MARKETS

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The White Paper alludes to a monopsonist NHI environment characterised by one large buyer (NHI Fund) that controls a large proportion of the market and strategically uses this to drive down prices. This section analyses monopsony and the impact it will have on the welfare of doctors and on quality of care. Whilst monopsony poses a risk in welfare of SAMA members, the SAMA realises that success in universal coverage in most countries is backed by monopsony. The SAMA provides recommendations that will allow monopsony without compromising the welfare of doctors and quality of care.

### 7.1 Impact of Monopsony

Monopsony is generally defined in literature to mean a labour market with one buyer and many sellers. In the context of National Health Insurance in South Africa, government will become the biggest buyer of health services through the National Health Insurance Fund. There are several impacts that such an evolution in the healthcare system will have on the labour market insofar as the welfare of doctors and other service providers under the scheme are concerned.

London and Baird describe the three determinants of salaries in a monopsony as follows:[1]

- The **ability** of government to pay: *the National Development Plan acknowledges that economic growth is fundamental for the implementation of the NHI. Poor economic growth may erode government's ability to pay doctors, however, the converse also holds true that should South Africa manage to turn its economy around, government will be able to pay doctors.*
- The **willingness** to pay: *this will require unity within the medical profession to speak with one voice. Unionisation of doctors will ensure successful bargaining and counteract possible low wages offered by a monopsonous employer.*
- The elasticity of supply of employees: *under the NHI as envisaged, the current plans and programmes to increase the number of medical doctors trained in, and out of the country, will result in a higher number of doctors entering the system.*

*NHI, similar to OSD, may influence the migration of doctors from public to private, or vice versa, and migration in or out of the country.*

Accepting that NHI will create a monopsony in healthcare, there is a need to examine such an impact in other countries and systems. Pauly [2] found that under monopsony the welfare of consumers may be increased but the overall economic welfare will be reduced.

In analysing the impact of monopsony in health insurance monopsony, Herndon[3] states that the textbook model of monopsony that is typically employed in analysing health insurance monopsony power does not adequately describe the supply decision of physicians confronting a dominant health insurer. He further states that rather than restricting purchases in order to extract a lower price for provider's service, monopsonistic insurers are able to obtain discounts from providers without experiencing a decrease in quantity when physicians are forced to operate along their "all-or-none" supply curve.

The reality is that under the NHI, doctors both in the private and public sectors will be significantly affected in terms of reimbursement. This calls for unconditional unity between medical doctors of all walks of life and affiliations. Anything short of strong unity within the medical profession will lead to fragmentation, competition and antagonism at a huge financial loss to the doctors.

Bates and Santerre [4] found that the empirical results provide evidence that greater health insurer buyer concentration is not associated with monopsony power. Instead, some evidence is found to suggest that higher health insurer concentration translates into increased monopsony-busting power. That is, metropolitan hospitals offer increased services when the buyer-side of the hospitals services market is more highly concentrated. Pauly[5] found that empirical evidence suggests that some versions of physician and hospital reimbursement have increased the level of medical spending relative to the level that would be experienced under prospective payment.

Health reforms lead to diverse political, philosophical and financial views and impacts. Immegut [6] found that medical associations in Switzerland, France and Sweden had opposed national health insurance on the grounds that doctors preferred to work as private practitioners and not as government employees. He further found that

“socialized medicine”, it was thought, would undermine professional autonomy. Switzerland rejected the NHI, France accepted it, and Sweden enacted NHI and converted its health system to a de facto national health service.

NHI provides both opportunities and threats (if not properly planned, properly implemented and efficiently managed). The greatest opportunities can be found in the improvement of access to healthcare services for all, regardless of socio-economic status. This is in line with the World Health Organization Declaration of the Alma-Ata in 1978; the declaration reaffirms the WHO definition of health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. The declaration highlighted that the inequality between the developed and the developing countries and termed it politically, socially and economically unacceptable. It is therefore politically, socially and economically acceptable for government to seek a healthcare system that is equitable and accessible to all its citizens.

## **7.2 Benefits and harms of monopsony**

Monopsony gives government buying and bargaining power and has the potential to control prices of healthcare. Monopsony improves value for money, and when funds are utilised efficiently (utilising economies of scale), it allows for increases in population and scope coverage. The monopsonist can also act as a useful counter weight to a monopoly/oligopoly e.g. private hospitals.

The bureaucratic nature of the monopsonistic enterprise means that the monopsonist is very good at bargaining over price (measurable) and very bad at bargaining over quality (harder to measure and verify, and enforce).

If prices are set so low, the hospitals and professionals may compete on “better” bad quality, i.e. the quality of care will not increase to the standards that benefit the population although there will be significant variations between healthcare professionals and hospitals.

When prices are very low, the market may consolidate, leading to oligopolies. Since implementation of NHI and the Central Chronic Medicines Dispensing and Distribution (CCMD) programme, it is evident that the pharmacy space is consolidating and in a

few years' time oligopolies consisting mainly of cooperate pharmacies will exist in the country.

### 7.3 Recommendations

SAMA supports monopsony in terms of the government being a single purchaser; however, in order to protect and promote the welfare of doctors as well as to ensure that monopsony does not result in market failure, the medical profession and the South African Medical Association recommends the following actions:

- a. Review of competition laws to allow healthcare professionals to negotiate tariffs
- b. Establishment of the **Pricing Commission** for transparent determination of prices.
- c. The NDoH to consider the SAMA coding manual as a basis for coding. All over the world, medical association play a role in coding matters. Unlike SA, the processes in other countries are and inclusive of all stakeholders. As the SAMA manual is developed by doctors for themselves without the involvement of stakeholders, bias towards doctors may exist. Therefore SAMA proposes that the NDoH establishes a stakeholder panel to review the SAMA coding manual with an intention to address its shortcomings and for possible use as basis for coding. Already the manual is used by medical scheme industry and to our knowledge there isn't existing coding manual.
- d. Conduct empirical cost studies to determine fair tariffs. SAMA has started this process and would invite NDoH to comment on the methodology.
- e. Improve the working conditions of doctors.
- f. Set salary levels for doctors working under the NHI at competitive levels to reduce brain drain to the private sector, to non-health professions, and to first world countries.

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## 8. MORAL HAZARD

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### 8.2. Introduction

Moral hazard was raised as a concern and a risk for NHI sustainability by the SAMA members. Moral hazard is defined as “circumstance that increases the probability of occurrence of loss, or a larger than normal loss, because of a change in an insurance policy applicant’s behaviour after the issuance of policy. It may be due to the presence of incentives that induce the patient/health professionals to act in ways that incur costs to the funder”. [1]

SAMA members identified user moral hazard as a threat to sustainability.

In addressing moral hazard, the SAMA conducted a literature review to unpack the concept of moral hazard, assess if proposals in the White Paper are sufficient to curb moral hazard, and to propose further recommendations. .

### 8.3. Proposals within the white paper to deal with moral hazard

#### 8.3.1. User moral hazard

**Paragraph 128.** ‘Patients who need to be treated by specialists or in hospitals will have to be referred by PHC providers to certified and accredited public and private hospitals and specialists. This means, except in emergencies, patients cannot go straight to a specialist or a hospital without being seen at the PHC level, be it at a clinic or by a general practitioner. The accredited specialists and hospitals will deliver the appropriate package of services in accordance with clinical protocols and referral guidelines.’

**Paragraph 137.** ‘Moral hazard may occur when beneficiaries of NHI get involved in undue risky behaviour and/or incur unnecessary expenditure because they are protected against the associated health risks. Some beneficiaries may also expose themselves to risky behaviour such as smoking, taking excessive alcohol or eating poor diets with the knowledge that they are covered by NHI’.

**Paragraph 138.** ‘In order to effectively manage moral hazard, a strict referral system supported by effective gate-keeping will be implemented and supported by health promotion and disease prevention programmes. Measures will be put into place to

prevent moral hazard of abusing portability of services and to ensure that resources are available to meet the health needs of patients’.

### **8.3.2. Health professions, laboratories and hospital moral hazard**

**Paragraph 133.** ‘Detailed treatment guidelines, which are based on available evidence about the most cost-effective interventions, will be used to guide the delivery of the comprehensive health entitlements. The treatment guidelines will be based on available evidence regarding the most cost-effective interventions. Additional guidelines will be developed for interventions where such guidelines do not exist. All treatment guidelines will be routinely reviewed to take into account the assessment and appropriateness of new technologies. Efforts will be put into place to ensure that the general public is provided with the relevant information to support access and ensure empowerment regarding these guidelines.

**Paragraph 134.** ‘Changes to the comprehensive service benefits including diagnostic tests covered by under NHI will be informed by changes in the burden of disease, the demographic profile of the population and the evidence on cost-effectiveness and efficacy of health treatments, interventions and/or technology development locally and internationally. Health technology assessment will be used in priority setting and therapies that have little impact on positive health outcomes will not be paid for under NHI whilst the most cost-effective evidence-based strategies will be deployed. Changes and adjustments to the service benefits over time will be accompanied by a budget impact analysis’.

**Paragraph 135.** ‘An inventory of pharmaceutical, medical supplies and devices will be linked to the Essential Drug List (EDL) and will be updated on a regular basis by the NHI Benefits Advisory Committee.

**Paragraph 136.** ‘Though the NHI service entitlements will be comprehensive, effort will be directed at ensuring that the covered evidence-based services are medically necessary and have a positive impact on population health outcomes’.

## 8.4. Possible moral hazard within NHI

### 8.4.1. Patient/User Moral hazard

Moral hazard in patients exists when there are incentives to use/overuse healthcare or engage in risky behaviours because health care costs are borne by the third party. Users/patients moral hazard can exist in the following ways in the universal coverage:

- a) As identified in the White Paper, when consumers engage in risky behaviours because they do not bear the costs of healthcare. Examples are: smoking, alcohol, unsafe sex etc.
- b) When patients make demands on the health system e.g. caesarean section vs. normal vaginal delivery, specialist vs. general practitioner or nurse, in-hospital vs. out of hospital care because they do not pay for healthcare or feel they are justified to make such demands as per their monetary contribution.
- c) When consumers neglect cost-effective self-care and preventative measures in lieu of costly health professional services because they directly don't bear the costs. E.g. instead of purchasing paracetamol over the counter users visit clinic to obtain the same for free.

Insurers originally viewed moral hazard unfavourably because it often meant that they paid out more in benefits than expected when setting premiums, hence the negative term. The fear of moral hazard lies behind co-payments, deductibles and a general 'lack of enthusiasm by health economists for the expansion of health insurance coverage'. [2]

#### 8.4.1.1. *Studies looking at moral hazard*

During the late 1970s, the Rand Corporation did an extensive study on moral hazard. Families were randomly assigned to health plans with a co-payment level of 0%, 25%, 50% and 90%. As expected, the higher the co-payment, the lesser the healthcare utilisation. Unfortunately, not only did they cut down on superficial care, but on primary care as well. When it comes to healthcare, the focus on moral hazard suggests that we do certain procedures only because we have insurance i.e. getting a mammogram, our moles checked, our teeth cleaned. These routine checks could nevertheless prevent unnecessary health costs or even death. [3, 4].

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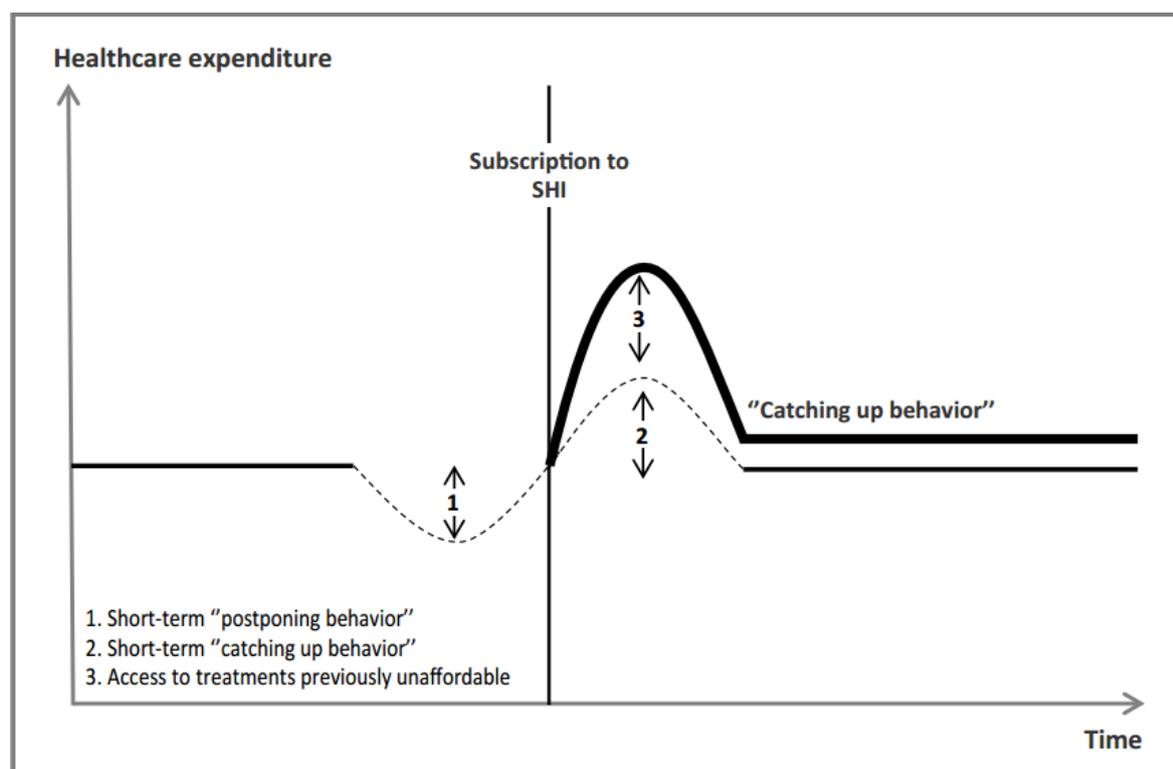
During the early nineteen-eighties, Ghana introduced user fees for healthcare resulting in a sharp and significant reduction in the utilization of healthcare and prevented access for the poor. In 2003, in an effort to offer health insurance, the government of Ghana introduced the national health insurance scheme (NHIS) to promote access to healthcare. In an analytical cross-sectional study done at the Winneba Municipal Hospital (WHM) in Ghana between January and March 2010, involving 170 insured and 175 uninsured out-patients, findings suggested consumer and provider moral hazard may be two critical factors affecting the sustainability of NHIS.[5] With the removal of user fees as a barrier to healthcare, changes in health seeking behaviours changed. The NHIS is experienced galloping cost doubled within a 6 year period since implementation. The increased visit by insured consumers posed challenges to the ability of Municipal NHIS to cope with the financial implications of the multiple visits, and the capacity to care optimally for the increase of patients. **The study illustrates consumer moral hazard exerting an enormous strain on the health system.**[5]

A Taiwanese study showed that demand in healthcare is associated with high income, risky lifestyles (tobacco and alcohol consumption) and unhealthy lifestyle. In South Africa, health expenditure and utilization amongst the richest 20% is already high. In China, 10 year data confirmed that participating in a publicly subsidized insurance was associated with increased (although quantitatively small) smoking, alcohol drinking, unhealthy diets and obesity [6]. Implementation of universal coverage has shown that did not lead to moral hazard in uptake of preventative activities; it however increased utilization [7]. Older age, higher education and high socio-economic status were predictors of high utilisation. Whilst utilisation in elderly can be explained by aging, the same cannot be said of higher education and high SES. This is particularly important for South Africa, once NHI is implemented similar patterns of utilisation may be observed, this will not address existing inequities. Therefore NHI implementation must be coupled with education and interventions that promote access in the low SES. In Mexico, using the Seguro Popular data, there was increased moral hazard, particularly reduced demand for self-protection.[8]

### 8.4.1.2. Theory of pent-up demand

Franc et al [9] analysed the existence and persistence of moral hazard over time to test the assumption of pent-up demand<sup>2</sup>. He demonstrated that initially there could be an increased uptake of services among the uninsured population however this will even out over time as health needs are met. Universal insurance does have a significant influence on the number of times a patient uses out-patient care. This effect is strong and significant only during the first three semesters of enrolment; however this effect decreases over time and is non-significant after the fourth semester of enrolment. Franc's observation is particularly important for NHI budgeting, as utilization will increase within the first few months of implementation as populations who did not have access start having access.

Figure 3: illustration of the pent-up theory



In summary, data suggests that utilization of health services increased with having a health insurance/financing, being elderly, higher socio-economic status and education level. Utilisation by the elderly and by people who previously did not have access to

<sup>2</sup> Pent up demand is used to describe the general public's strong return to consumerism following a period of decreased spending.

healthcare services could lead to better societal welfare. Therefore such moral hazard should be embraced.

Unhealthy lifestyle and risky behaviours as outlined in the White paper should not be taken lightly. Whilst the country has made considerable strides in reducing tobacco and salt consumption, unhealthy diets and alcohol remain top risk factors for non-communicable disease and injury. As South Africa cannot afford individualized prevention strategies, the SAMA urges the Government to continue implementing population based strategies and supports the implementation of proposed sugar tax a means to curb the Diabetes and obesity epidemics. This prevention strategies will ensure that NHI is financially sustainable.

The real risk for moral hazard and perpetual inequities within NHI is increased utilization by the affluent and well educated, which may lead to displacement of the indigent due to the scarcity of resources. The societal neglect of self-care may reduce in the event of NHI.

The above examples demonstrate that moral hazard and inappropriate utilisation of services is complex. Co-payment can act as barriers to access to healthcare. However, lack of control of access to healthcare can result in serious cost-escalation and possible future unaffordability.

Although the White Paper suggests bypass fees for patients jumping primarily level care going straight to higher levels of care, the value at which bypass fees is set must consider possible inequities. If the fees are set very high, only the affluent will be able to afford it, creating barriers to access for the less affluent. If set too low, such fees will not serve as a deterrent.

#### **8.4.1.3. Solutions for dealing with patient moral hazard**

##### **a. Co-payment**

There are various arguments that controlling moral hazard through co-payments have led to underutilization of essential healthcare services, resulting in increased morbidity as well as more preventable hospitalizations, and deaths among the low and middle income classes than their more affluent counterparts. Large portion of moral hazard health spending actually represents a welfare gain, not a loss, to society. [2]

Deductibles can inflate the costs of healthcare. In South Africa, split billing and co-payments has increased patient out-of pocket expenditure for members and remain barriers to health care access in medical scheme beneficiaries.

***Based on the above argument the SAMA is in agreement with the NHI White Paper on free access at point of care.*** Co-payment may result in underutilization of healthcare, perpetuate inequities and inflate health care costs.

**b. Administrative Gatekeeping**

Physicians are often viewed as the "gatekeepers" between the best treatment for their patients and the cost of that treatment. Paragraph 128 of the White Paper outlines the gatekeeping process:

**Paragraph 128.** 'Patients who need to be treated by specialists or in hospitals will have to be referred by PHC providers to certified and accredited public and private hospitals and specialists. This means, except in emergencies, patients cannot go straight to a specialist or a hospital without being seen at the PHC level be it at a clinic or a general practitioner. The accredited specialists and hospitals will deliver the appropriate package of services in accordance with clinical protocols and referral guidelines'.

***The SAMA supports administrative gatekeeping, however, bypass fees for specialist care must be based on income levels so as to not perpetuate inequities. The case-based reimbursements of specialists may also encourage the keeping of bypassing patients in specialist care.***

Medical doctors can help ensure that patients access good quality treatment in accordance with the well-developed and evidence-based clinical guidelines, protocols and formularies. Due to the compassion element that normally characterises medical practice, bedside rationing may not always be feasible, a fact that has not been embraced by medical schemes and should be accepted by the NHI Fund.

**8.4.2. Doctor and hospital induced demand**

The relationship between provider and patient in the healthcare market is often characterized as a principal-agent relationship. The principal (the patient) appoints an agent (a health professional) to advise the principal in making decisions about

treatment or to make decisions on the principal's behalf. The health professional is expected to be a perfect agent, combining professional knowledge with the patient's preferences to determine a choice that the patient would make based on that information. *The principal-agent problem arises as the doctor chooses instead to maximize his or her own interests, which in many cases do not align with the patient's interests.*

**SAMA is in agreement that implementation of treatment guidelines and protocols will reduce doctor induced moral hazard, however such development of protocols and guidelines must be patient-centric, evidence-based and transparent.**

Often government is very slow in developing and reviewing guidelines (e.g. outdated chronic disease list algorithms). Resources must be allocated for frequent review of protocols, this should be coupled with transparency and accountability.

As fee for service is often associated with hospital/doctor induced demand, capitation may minimise the demand.

***i. 'Defensive medicine'***

Defensive medicine is when a provider chooses to practice to reduce litigation instead of providing appropriate care in appropriate amounts. This tends to result in over servicing and increased costs. This calls for the urgent attention of the litigation system in the country.

***ii. Support Service provider (hospitals/lab/radiology)-induce demand***

Service providers have both financial and liability incentives to accept and treat patients sent by a recommending physician even if they consider the services excessive.

Hospitals, testing labs, radiology facilities, and other healthcare service providers rely on the recommendation of the general practitioner or specialist to maintain a steady revenue stream. It is essential to their long-term viability that they continually invest in the latest technologies, both to remain competitive and to limit legal liability. As per the CMS 2015 annual report, the hospitals, laboratories and radiologists account for a huge portion of health expenditure.

This moral hazard can be deterred by well-developed protocols and guidelines

#### **8.4.3. Pharmaceutical induced demand**

Pharmaceutical companies continuously research and develop new products. Marketing focuses on new products and targeted physicians innocently prescribe the new technology despite the lack knowledge of cost-effectiveness and impacts on budgets. The pharmaceuticals not only target the physicians but also the politicians for inclusion of new technologies in the national formularies. Pharmaceuticals also disinvest in older working medicines to maximize revenue. In South Africa we have observed an exodus where old working medicines were de-registered by the Medicines Control Council. This is despite evidence that older, cheaper technologies lead to the same outcomes. South Africa had to resort to section 21 of the Medicine and Related Substances Act in order to access effective deregistered medicines.

#### **8.5. Recommendations and conclusion**

- a. User moral hazard is a risk for NHI implementation. The SAMA is in agreement with free access at point of care for essential health services, with bypass fees imposed for patients bypassing the primary healthcare system. In order for bypass fees to be appropriate, they must be based on income and set at high enough levels to minimize abuse.
- b. To reduce the health professions related moral hazard, the SAMA supports the development of treatment protocols, essential lists (medicines, surgery, devices, etc.) and guidelines. The development of practice guidelines must be:
  - Transparent, including decision making criteria
  - In accordance with evidence-based medicine principles, cost-effectiveness and affordability, explicitly stating criteria for cost-effectiveness and affordability to reduce subjective biases. Whenever possible, user perspective vs. funder perspective should be utilized especially for conditions with indirect health costs, e.g. mental health
  - Conflict of interest must be managed
  - Composition of guideline development group must be inclusive of relevant health professionals, patient representative groups including

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non-clinician representatives such as health economists, epidemiologist, and public health practitioners. Multi-stakeholder involvement with equal powers reduces the risk of bias.

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January 2016].

## 9. CORRUPTION

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### 9.1. Introduction

The SAMA membership identified corruption as a risk for successful and sustainable NHI implementation. Corruption is defined as the abuse of public resources or public power for personal gain. Grand corruption is the abuse of high-level power that benefits the few at the expense of the many, and causes serious and widespread harm to individuals and society. It often goes unpunished. In South Africa corruption cuts across all government and the private sector. Grand corruption is particularly prevalent amongst political figures. Corruption is a hazard for taxpayers and it is not very moral. Corruption is the result of personal decisions, most often motivated by greed.

In a survey involving 582 health consumers, post NHI green paper consultation, corruption was flagged as a serious concern and barrier to achieving health outcomes.[1]

Corruption Watch is a voluntary advocacy group against corruption. In 2015, three percent (3%) of all the incidents of corruption reported to Corruption Watch were in the health sector. Abuse of power made up the bulk of corruption reports at 38%, followed by bribery at 20%, and procurement corruption at 14%. South Africa was ranked at 61 out of 170 countries with a corruption score of 44 (100 being perfect and 0 being completely corrupt). [2] South Africa is ranked among those countries perceived to have a serious corruption problem, with the ranking perilously close to those countries suffering from endemic corruption.[3]

Corruption is a matter of increasing concern for the international development agenda and was recognized as one of the biggest impediments to the world's efforts to reach the Millennium Development Goals (now Sustainable Development Goals).

The risk of neglecting basic governance principles in healthcare delivery is that well-intentioned spending may have no impact. Priorities cannot be met if institutions do not function and scarce resources are wasted. Bribes, corrupt officials and misprocurement undermine healthcare delivery in much the same way they do for police services, courts and customs whose functions become compromised by the culture of poor governance and corruption. [4]

SAMA members' concerns on corruption are valid and verifiable. SAMA expects the NDoH to consider corruption seriously and implement proposed measures to reduce corruption. We expect corruption to be eliminated from the country's leadership right up to the lowest level employee.

## 9.2. Types of corruption in health sector

Typically corruption in healthcare can take place in the following way:

1. Kickbacks to politicians to award tenders
2. Cronyism
3. Kickbacks to regulators-perverse relationships between regulated entities and regulators
4. Theft of medicine and other medical supplies/property
5. Medical scheme fraud: "ghost patients"
6. Foreign bribery by suppliers is possible. Whilst European countries were considered clean by the corruption index, the European firms were found to be corrupt in other countries. This possibility could arise when dealing with multinationals for procurement of medicines and medical supplies.
7. Theft of time through absenteeism

## 9.3. Effects of corruption

### 9.3.1. Public corruption is not all about missing money. It is about people's lives too.

Corruption inflicts damage on society. Corruption literally violates human rights, as people are denied the care that their governments are obligated to provide. Corruption increases child and infant mortality rates, likelihood of skilled birth attendance, and low birth weight and immunization. This association was still significant after control of income, education level and public health spending.[1] South African infant and mortality data remains high, despite public health spending and progress made in educational attainment and reduction in poverty through social security measures. Although the high mortality rates were attributable to quality of care in public sector, HIV pandemic, the possibility of this indicators explained by corruption remains.

### **9.3.2. Corruption can drive up the price and lower the level of government output and services**

Whilst the country has sound procurement policies, processes are manipulated by government officials and politicians for personal gain. The prices paid for tenders are often inflated. The huge corruption likely to be experienced in the implementation of NHI is probably in the procurement of pharmaceuticals, medical expenses and appointments for key positions. The question is what is a loaf of bread or toilet paper providers through tenders? We suspect probably higher than the rates in grocery stores. The irony is in a monopsony we expect government to negotiate prices, in a corrupt system monopsonous government will negotiate high prices..

### **9.3.3. Corruption can stifle economic development**

Corruption reduces funding for health, depreciates national currency, and slows down long-term domestic and foreign investments. Small businesses within the country often find it impossible to overcome the "start-up costs" required because of corruption.

Recent direct impacts on the depreciation of the Rand (as a result of political instability) resulted in consideration to increase single exit prices of medicines for the second time this year. Doctors and patients will struggle to provide, and access, necessary healthcare this year.

Corruption also reduces investment in human capital through **reduced employment opportunities and low levels of education**. Human development is a social determinant of health. Without improvement in human development indicators South Africa will not realise its intended goals. Key to NHI success is increase in employment rate. This will be a quicker and easier way to increase the fund size.

## **9.4. Absenteeism and productivity in the public sector**

Absenteeism from the workplace is a form of corruption by health workers. Although not documented, its impact on quality of care can be huge. This can reasonably be extrapolated to the South African context, even though we could not find published data on absenteeism in South Africa. Whilst RWOPS provide opportunity to increase welfare of doctors, this has been abused by some doctors.

A World Bank study of health worker absenteeism in six countries: Bangladesh, Ecuador, India, Indonesia, Peru, and Uganda, showed that well-equipped health facilities with better infrastructure had absentee rates roughly half those of facilities with poor infrastructure. The study identified the physical state of health facilities and availability of medical supplies as two important factors that affect attendance. [7]

Absenteeism is encouraged by weak management and performance management, lack of supervision, and an exceedingly low probability of being disciplined. While disciplinary action for health worker absences is often included in official regulations, in practice it is extremely rare. Lack of resources in the public sector has been cited as a reason for dual practice. [4]. Workloads, poor pay, burnout and lack of career progression were also associated with low morale and absenteeism.[8]

Reimbursement mechanisms and salary structures, including irregular non-payment of salary, has also been linked to absenteeism. A review of the limited literature on the effect of salary earnings on physician clinical behaviour across the OECD concluded that physicians whose earnings are based on salary rather than fee-for-service, bonus payments or capitation showed lower productivity, lower levels of care and higher wound rates for surgery.

## **9.5. Recommendations**

### **9.5.1. Recommendations to deal with official corruption:**

- a) Integrate, or mainstream transparency and accountability initiatives, into the health sector. This strategy is likely to work well in health because people care deeply about their health. Studies have shown that citizens in many countries are aware of corruption in the health sector and see it as a problem.
- a. Because medicines account for a huge proportion of health expenditure, the minister should make recommendations on the transparent pricing of all medicines sold in the country i.e. both public and private sector in accordance with section 22G (2) (a) of the Medicines and Related Substance Act 101 of 1965.
- b. Prosecuting corruption as required by law will restore faith among people who no longer believe in the institutions that are supposed to protect them.
- c. Transparent prices for medical supplies and other health related services.

- d. Regularly monitoring prices of common medical goods and holding purchasing managers accountable if prices substantially differ from those of other hospitals or benchmark prices.
- e. Improvement in governance and accountability, including unbiased measurement of performance indicators.

#### **9.5.2. Recommendation to deal with absenteeism**

- a. Revision and appropriate management of the RWOPS
- b. Improved working conditions for doctors, with humane working hours to reduce burnout.
- c. Employment of appropriately qualified facility, district and provincial managers
- d. Appropriate remuneration of health professionals and clear career progression.
- e. Provision of medical supplies, equipment and drugs to increase job satisfaction.
- f. Commissioning of study(s) to identify factors associated with absenteeism among healthcare professionals in South Africa.
- g. Where appropriate and deserved, Performance based bonuses must also be awarded to health professionals employed in facilities, and not only be reserved for national and provincial department of health administrative staff. Each and every facility must have a performance bonus budget.
- h. Managers should account for absenteeism and manage it appropriately, including implementation of disciplinary processes.

#### **9.6. Conclusion**

Corruption is a serious concern in our country and a barrier to achieving a long healthy life for all South Africans. Whilst it is known that health resources are scarce, increasing financing on a leaking, inefficient, corrupt system with poor management and governance is wasteful and an abuse of people's hard-earned money. Whereas many citizens will view the NHI as means to access universal coverage, for those who have defrauded the system, this may be a malicious opportunity to enrich themselves.

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## 10. LEGAL PERSPECTIVE ON THE NHI WHITE PAPER

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### 10.1. Introduction

SAMA is cognisant of the fact that the White Paper precedes legislation in respect of National Health Insurance (NHI), with specific reference to the draft NHI Bill referred to in the White Paper; the latter first to be published for public comment by the Minister of Health, before the Bill will be tabled before Parliament for the usual processes of parliamentary public hearings and debate. Once the latter processes have been completed, and following enactment, regulations to address specific aspects of the NHI framework will be promulgated. Not being able to comment on explicit aspects to be contained in the NHI Bill, which is not yet available for this purpose, we therefore limit our response in respect of our legislative and regulatory review of the White Paper to specific predominant concepts rather than a detailed legal analysis.

### 10.2. The Rule of Law, Governmental Authority, and Constitutional Democracy

In the words of the Honourable Mogoeng Mogoeng, Chief Justice of South Africa<sup>3</sup>: “In my view, it essentially boils down to the role of the judiciary in promoting peace, good governance and sustainable economic development. And at the heart of it is the observance of the Rule of Law, which the Constitutional Court of South Africa explained in these terms: ‘The exercise of public power must ... comply with the constitution, which is the supreme law, and the doctrine of legality, which is part of that law. The doctrine of legality, which is an incident of the Rule of Law, is one of the constitutional controls through which the exercise of public power is regulated by the constitution. It entails that both the Legislature and the Executive ‘are constrained by the principle that they may exercise no power and perform no function beyond that conferred on them by the law’. In this sense the Constitution entrenches the principle of legality and provides the foundation for the control of public power.”

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<sup>3</sup> Transcript of an address to a meeting of the Trustees of the Africa Justice Foundation – “The Rule of Law in South Africa: Measuring Judicial Performance and Meeting Standards”, 25 June 2013, Chatman House. Available at: <https://www.chathamhouse.org/sites/files/chathamhouse/public/Meetings/Meeting%20Transcripts/250613Mogoeng.pdf>

The Rule of Law and constitutional democracy are related and mutually reinforcing principles. The Rule of Law is a fundamental concept in an advancing democracy, and is defined as a system in which the following four universal principles are upheld:

- The government and its officials and agents as well as individuals and private entities are accountable under the law;
- Second, the laws are clear, publicised, stable, and just; are applied evenly, and protect fundamental rights;
- Third, the process through which the laws are enacted, administered, and enforced is accessible, fair, and efficient,
- And, fourth, justice is delivered timeously by competent, ethical, and independent representatives and neutrals who are of sufficient number, have adequate resources, and reflect the make-up of the communities that they serve.<sup>4</sup>

The most important application of the Rule of Law is the principle that governmental authority is legitimately exercised only in accordance with written and publicly disclosed laws.<sup>5</sup>

SAMA submits that strict adherence to the principles entrenched in the Rule of Law, and reinforced by the South African Constitution, will be essential for the success of the NHI. It is imperative that any introduction of the concepts set out in the NHI by the government is done only within the scope of its authority, so derived from the necessary duly promulgated legislation.

We further acknowledge that Parliament, when considering NHI legislation, must not only take into account the Ministry of Health's proposals on the NHI, including possible necessary legislative changes foreseen, but also the National Treasury's abilities to fulfil the financial implications to the State created by the proposed NHI.

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<sup>4</sup> Musuva, Catherine, Rapporteur: Centre for Conflict Resolution – “Constitutional Democracy and the Rule of Law in South Africa”, November 2015. Available at:

[http://www.ccr.org.za/images/pdfs/CCRPB26\\_constitutional\\_democracy\\_16nov2015.pdf](http://www.ccr.org.za/images/pdfs/CCRPB26_constitutional_democracy_16nov2015.pdf)

<sup>5</sup> <http://www.lexisnexis.co.za/ruleoflaw/rule-of-law.aspx>

### 10.3. The South African Constitution and the State's duties in respect of health care

SAMA is in agreement that the Constitution places a duty on the State to progressively ensure the provision of affordable health care services to all its citizens. However, noting that in terms of the White Paper every South African will be required to join the NHI and pay for it, SAMA is also aware of the argument that in terms of Section 18 of the Constitution<sup>6</sup>, guaranteeing every person the “right to freedom of association”, this aspect of the envisaged NHI may still be constitutionally challenged. SAMA acknowledges that the right to freedom of association may be limited to the extent reasonable and justifiable in terms of Section 36, to counterbalance the right to health care services set out in Section 27 of the Constitution, but cautions that a careful process should be followed in this delicate balancing act, as more fully set out below.

Section 27 of the Constitution also addresses access to social security (funding of healthcare), of which the NHI can be seen as an example, covering patients against the risk of ill health and the costs thereof. It is foreseeable that the right to funding of healthcare will also be limited (for example by restrictions in respect of the providers and facilities whose services may be used) and that each such limitation will also first have to be considered in terms of Section 36.

### 10.4. Legal precedents – Constitutional Court guidance

The Constitutional Court has provided direction on a variety of legal principles to be followed in respect of NHI-related legal matters, of which SAMA considers the following noteworthy:

#### **State obligation to provide healthcare services – limitations imposed by budget constraints**

There have been decisions handed down pertaining to the right to access to healthcare services enshrined in the Constitution's Bill of Rights, weighed up against the State's obligation to progressively effect these services. The most well-known of

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<sup>6</sup> Act 101 of 1996

these is **Soobramoney v Minister of Health, KwaZulu-Natal**<sup>7</sup>. In this matter the Constitutional Court decided that, as a result of its limited resources, the State was not obliged to enter the appellant into the State's renal dialysis program, notwithstanding the appellant's dire need for renal dialysis treatment. The argument was that the State could not afford to provide all South Africans suffering from chronic renal failure with dialysis treatment in terms of its available health budget. The Court was satisfied that the State had a reasonable dialysis program in place given its budget limitations.

It follows that, should medical aid schemes only be available for "top up cover" regarding health services **not** covered by the NHI, as suggested in the White Paper, and should some of these services be restricted due to budget constraints, those who currently have access to these services (more specifically with reference to Prescribed Minimum Benefits) through medical scheme contributions are at risk of not having access to these services through the NHI, which will adversely affect them and deny them their basic rights to healthcare and freedom of association, albeit paid for by their own contributions. It is SAMA's submission that these possibilities should be carefully reconsidered when limiting the scope of top-up services to be provided by medical aids.

Similarly, in **Minister of Health and Others v Treatment Action Campaign and Others**<sup>8</sup>, where the provision of Nevirapine to expectant mothers was considered, the Court held that "the socio-economic rights of the Constitution should not be construed as entitling everyone to demand that the minimum core be provided to them" and that "... all that can be expected from the State, is that it acts reasonably to provide access to the socio-economic rights identified in sections 26 and 27 on a progressive basis." These decisions are a stark reminder of the socio-economic realities of South Africa - a noble vision of the provision of healthcare to all may not be achievable with the funds available to achieve this purpose. SAMA cautions against unrealistic expectations in this regard. The White paper even acknowledges, in section 125 thereof, that "NHI will not cover everything for everyone".

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<sup>7</sup> 1997 (12) BCLR 1696 (CC)

<sup>8</sup> 2002 (10) BCLR 1033 (CC)

Whilst acknowledging that the NHI is focused on primary healthcare, it would remain imperative to ensure continued facilitation and improvement of post-primary quality healthcare necessities, such as renal dialysis treatment services, hopefully to a lesser exclusion of worthy recipients.

In **Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others**<sup>9</sup> the Constitutional Court amongst others found a number of individual regulations promulgated unlawful in respect of the powers they purported to allot to the Director-General and Minister of Health, which were not permitted by the Medicines and Related Substances Act<sup>10</sup> (the Medicines Act). As discussed under the Rule of Law above, this decision supports the principle that both primary and secondary legislation must be drafted cautiously and carefully, and will be subject to full constitutional scrutiny.

In general, and in respect of any administrative actions executed by an organ of state, the reasonableness of such action will be considered in terms of the Promotion of Administrative Justice Act<sup>11</sup> (PAJA), along the guidelines – the reasonableness review – explained in detail by the Constitutional Court in **Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs**<sup>12</sup>. The latter was quoted with approval in the **New Clicks** case where it was held that if a dispensing fee is not “appropriate” (as required by section 22G(2)(b) of the Medicines Act), it would be “inconsistent with section 6(2)(a) of PAJA”.

SAMA submits that the regulatory framework envisaged by the NHI must take cognisance of the **New Clicks** and **Bato Star** constitutional court decisions and the authority quoted therein, these decisions enunciate the importance of a balance of power between the Minister and Department of Health on the one hand and external expertise on the other, to ensure responsible decision-making that can be successfully defended against legal challenges. An appropriate balance must be struck between the interest of the public in being able to have access to affordable healthcare and the

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<sup>9</sup> 2006 (2) SA 311 (CC)

<sup>10</sup> Act 101 of 1965, as amended

<sup>11</sup> Act 3 of 2000

<sup>12</sup> 2004 (4) SA 490 (CC)

interests of suppliers, hospitals and healthcare professionals and their viable livelihood.

The **New Clicks** judgment also indicates that while co-operation of all interested parties is essential for a regulation drafting process, the onus lies on the State to justify limitations placed on fees charged – which onus will also apply to the NHI fee development – based on transparency and the “foundational value of the rule of law”. It would therefore be prudent for the Minister of Health and the various committees assigned to the NHI development to ensure that they take these principles into account when drafting legislation and subsequent regulations, and when considering the purpose of such legislation

#### 10.5. Legislative framework relating to health matters

There is a plethora of statutes, and regulations promulgated in terms thereof, currently administered by the Department of Health. To effectively facilitate the NHI implementation, all of these will have to be cautiously considered and reviewed. To name but a few, the National Health Act<sup>13</sup>, the National Health Amendment Act<sup>14</sup> (and the Office of Health Standards Compliance established in terms thereof), the Medical Schemes Act<sup>15</sup>, the Council for Medical Schemes Levy Act<sup>16</sup>, the Medicines and Related Substances Act<sup>17</sup>, the Medicines and Related Substances Amendment Act<sup>18</sup> (in terms whereof the South African Health Products Regulatory Authority was created), the Health Professions Act<sup>19</sup> (and the Health Professions Council (HPCSA) created in terms thereof, currently functioning inadequately), the Allied Health Professions Act<sup>20</sup>, the Nursing Act<sup>21</sup>, the Pharmacy Act<sup>22</sup>, the Mental Health Care Act<sup>23</sup>, the Choice on Termination of Pregnancy Act<sup>24</sup>, the Sterilisation Act<sup>25</sup>, the Human

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<sup>13</sup> Act 61 of 2003

<sup>14</sup> Act 12 of 2013

<sup>15</sup> Act 131 of 1998

<sup>16</sup> Act 58 of 2000

<sup>17</sup> Act 101 of 1965

<sup>18</sup> Act 59 of 2002, as amended

<sup>19</sup> Act 56 of 1974

<sup>20</sup> Act 63 of 1982

<sup>21</sup> Act 33 of 2005

<sup>22</sup> Act 53 of 1974

<sup>23</sup> Act 17 of 2002

<sup>24</sup> Act 92 of 1996

<sup>25</sup> Act 44 of 1998

Tissue Act<sup>26</sup>, the Tobacco Products Control Amendment Act<sup>27</sup>, the Foodstuffs, Cosmetics and Disinfectants Act<sup>28</sup>, regulations promulgated in terms of all of these acts, policies, rules and professional guidelines prescribed by various statutory councils such as the Health Professions Council and the Boards that their authority is delegated to, as well as provincial health legislation and municipal bylaws.

Extending beyond the direct realm of health-specific legislation, other reviewable legislation that will impact in one way or another on NHI will include those focusing on finance, such as the Income Tax Act and Public Finance Management Act (to provide for a system on a specific new kind of tax collection and administration), and short and long-term insurance laws (in relation to anticipated changes in the Medical Schemes Act and medical scheme environment) to some extent incorporated in the Financial Services Laws General Amendment Act<sup>29</sup>. Others Acts include intellectual property laws (for example medicines and medical devices, the availability and pricing thereof), the Children's Act,<sup>30</sup> the Consumer Protection Act,<sup>31</sup> (medicines and medical devices are among others covered under the definition of "any particular goods or services marketed in the ordinary course of the supplier's business"), the Patents Act,<sup>32</sup> (protection of medical innovations and the ownership thereof), the Intellectual Property Laws Amendment Act,<sup>33</sup> the Traditional Health Practitioners Act<sup>34</sup> and the regulations published in terms thereof in November 2015 (although, notably, there is no mention of traditional health practitioners in the NHI White Paper), the National Environmental Management: Biodiversity Act,<sup>35</sup> the Road Accident Fund Act,<sup>36</sup> the Compensation for Occupational Injuries and Diseases Act,<sup>37</sup> the State Liability Act,<sup>38</sup> the Competition Act,<sup>39</sup> the State Information Technology Act,<sup>40</sup> the Intergovernmental Fiscal Relations

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<sup>26</sup> Act 65 of 1003

<sup>27</sup> Act 12 of 1999

<sup>28</sup> Act 54 of 1972

<sup>29</sup> Act 45 of 2013

<sup>30</sup> Act 38 of 2005

<sup>31</sup> Act 68 of 2008

<sup>32</sup> Act 57 of 1978

<sup>33</sup> Act 28 of 2013

<sup>34</sup> Act 22 of 2007

<sup>35</sup> Act 10 of 2004

<sup>36</sup> Act 56 of 1996, as amended

<sup>37</sup> Act 130 of 1993

<sup>38</sup> Act 20 of 1957

<sup>39</sup> Act 89 of 1998

<sup>40</sup> Act 88 of 1998

Act,<sup>41</sup> the Public Service Commission Act,<sup>42</sup> the Protection of Personal Information Act,<sup>43</sup> although not yet fully signed into law by the President, and a flurry of secondary legislation promulgated in terms of these acts. The National Department of Health and NHI system will be expected to comply with all the aforementioned legislation.

It is the SAMA's submission that the numerous acts mentioned above cannot be successfully addressed to complement the NHI through mere repealing or amendment by the envisaged National Health Act. **It will be necessary to prudently investigate each of these acts individually in conjunction with the National Health Bill, once published for comment, to ascertain the veracity of changes necessitated by the National Health Bill applicable to each individual piece of legislation.**

## 10.6 Foreseeable changes to current legislation

Due regard being had to the wide-ranging impact of the National Health Bill that cannot be sufficiently addressed through comments on the NHI White Paper without the proper reference framework of the Bill being available, the SAMA wants to highlight only some intricacies foreseen in changes to current legislation and creatures of statute:

### 10.6.1 Quality control of health services

#### **The Office of Health Standards Compliance (OHSC) – the National Health Amendment Act**

In terms of the National Health Amendment Act, parliamentary oversight of the OHSC has been to some extent ensured by providing the Minister of Health the authority to table a copy of the annual report, financial statements and audit reports of the OHSC (within a specified time of receiving such documents from the CEO) at parliament. These documents will be made public once so tabled, but it would seem that the Minister has to date neglected or omitted to fulfil his duties in respect of this body, as explained below.

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<sup>41</sup> Act 97 of 1997

<sup>42</sup> Act 46 of 1997

<sup>43</sup> Act 4 of 2013

It is concerning to note that although the OHSC was established three years ago, the final regulations to be promulgated by the Minister of Health, detailing the norms and standards hospitals and clinics must be measured against, have yet to be published. Without these norms and standards being promulgated, the OHSC cannot enforce them against those health establishments not abiding by the regulations and cannot prosecute those establishments for non-compliance, nor can the OHSC inspect current self-regulating private healthcare facilities.

A draft set of Norms and Standards Regulations was published for comment in February 2015, with the aim to apply these to all public sector hospitals, clinics and community health centres, as well as all private sector acute hospitals and primary health clinics. This draft has been criticised for being vague and poorly drafted, and for potentially duplicating or conflicting with provincial legislation.<sup>44</sup> While a final version is still being awaited, the OHSC is left without the ability to enforce compliance and impose sanctions as consequences of non-compliance, will have no credibility and remains ineffectual. SAMA is concerned about this state of affairs in the wake of NHI implementation – the credibility of the OHSC as an instrument to effect improvement in the quality of healthcare will, after all, be judged against its ability to enforce compliance.

The SAMA appreciates the efforts already made by the Department of Health in this regard, as set out in its annual report for the period 2013-2014, mentioning extensive efforts of their OHCS cluster to disseminate National Core Standards, through training of CEOs, support of district-level staff, onsite feedback, re-inspections and the requirement for establishments to conduct self-assessments in gap-analysis format in an effort to develop improvement plans to address the gaps identified (pursuant to which a significant number of facilities developed annual quality improvement plans).

There is unfortunately little statistical evidence available on the implementation and success levels of these developed plans. It is the SAMA's contention that the momentum so created should not be lost but rather enhanced by capacitating the OHCS to continue with these efforts in respect of implementing quality assurance successfully, through the promulgation of the Norms and Standards Regulations as a matter of urgency.

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<sup>44</sup> South African Health Review 2014/2015, Health Systems Trust, first chapter

In a presentation briefing to the Portfolio Committee on Health on its inspection results regarding public health facilities in South Africa,<sup>45</sup> the OHSC provided photo evidence of a number of health establishments assessed during the 2014/2015 financial year where acute intervention was needed on an urgent basis in respect of, *inter alia*, a lack of policy and operational plans, procedures relating to the management of medicine not being followed, good pharmacy practice not being followed, patients not treated with respect and their privacy being compromised, the non-availability of safe drinking water for patients, medicines not dispensed in accordance with the Pharmacy Act, infection prevention and control practices not adhered to, waste not properly managed and patients' safety compromised, to name but a few.

It is in light hereof clearly essential that the OHSC must urgently be provided with the necessary "teeth" to enforce quality assurance compliance at all health establishments, as set out above.

#### **10.6.2 Health Standards Ombudsman**

The National Health Amendment Act also makes provision for an Ombud, expected to act independently but again to be appointed by the Minister. The Ombud's actions must be independent, impartial and "without fear, favour, bias or prejudice" (section 81b). The Ombud is authorised to investigate complaints from the public relating to health norms and standards and even to launch investigations on his or her own initiative.

SAMA again notes with appreciation the Department of Health's efforts (as set out in its annual report for 2013-2014) to improve management of patient complaints in preparation for the establishment of the Ombud on a new in-house complaints management database, to review the national complaints protocol, and to enhance its capacity through the complaints protocol and the revised Patient Satisfaction Survey protocol, facilitating a heightened awareness of users' experience of health services.

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<sup>45</sup> Briefing paper 22 March 2016

Both the OHSC and the Ombud are expected to be critical components in the proposed system of accreditation for the purposes of National Health Insurance, and in this regard SAMA supports the principle that, in both instances, total independence from undue influence by the State is essential.

### **10.6.3 The Medical Schemes Act and medical schemes**

Insofar as foreseeable legislative changes are concerned, the one Act that is regularly mentioned in the White Paper as earmarked for change (during the second phase of NHI development), is the Medical Schemes Act, including the medical schemes regulated in terms thereof. It is unequivocally stated that with the implementation of NHI, the role of medical schemes in the health system must change (paragraph 400). Medical schemes are to play a supplementary role during the transitional phase of NHI and only a complementary one once NHI is fully implemented (paragraph 399). It is made clear that this complementary role will only extend to services that are not included within NHI service benefits (paragraph 401). A complete overhaul of the prescribed minimum benefits system is foreseen (paragraph 401), the funds currently allocated to medical schemes to which State employees belong will be reallocated towards NHI funding (paragraph 400), and the number of medical schemes would decrease from 83 to a “much smaller number” on full implementation of NHI (paragraph 402).

The White Paper therefore has a markedly more limited view on the role of medical schemes than the previous view depicted in the Green Paper, which also made provision for contributions by everyone to the NHI, but without limiting their choice of medical scheme benefits in addition to their compulsory contributions.

It can be argued that medical scheme membership will naturally decrease when quality health services are available through NHI and when compulsory contributions to NHI will make it less affordable to belong to a medical scheme in addition thereto. However, to drastically limit the benefits that medical schemes may provide outside the realm of the NHI before empirical evidence exists that those services provided by NHI are indeed functionally provided and of adequate quality, will be ill-advised, especially in relation to a lack of public trust in the current public healthcare system. If an efficient and effective public health system existed, there would after all not have been a need to belong to medical schemes or buy private health insurance products.

Those employed by the State would also be resistant to the loss of their medical aid subsidies (as suggested in the White Paper) without proof of the effective functioning of NHI.

The White Paper is disconcertingly vague on the specifics in relation to NHI versus the future of medical insurance and medical schemes. In this regard SAMA refers to the so-called “demarcation regulations” drafted in terms of the Medical Schemes Act, clearly delineating the boundaries between medical schemes and health insurance products, which would seem to find application in the NHI context but has yet to be published in final format. With these regulations in place, clear separation between health insurance products (underwritten by commercial insurers) and medical schemes (based on solidarity principles) would be possible. Although the scope of the Medical Schemes Act does not extend to a regulation of the Short and Long-term Insurance Acts, these policies fall within the definition of the business of a medical scheme, as amended by the Financial Services Laws General Amendment Act,<sup>46</sup> and SAMA supports both the stricter control of these policies as envisaged in the draft regulations, and a possible amendment of the financial services laws to fully accommodate these changes if necessary as an interim measure, to enhance regulatory control.

In regard to the latter, Treasury mentioned the following: “[T]he revised second draft regulations will acknowledge that while health insurance products have a role in the marketplace, these products must operate within a framework whereby they complement medical schemes and support the social solidarity principle embodied in medical schemes.”

In a 2014 study conducted under the auspices of the WHO<sup>47</sup> it was noted that, insofar as private health insurance was concerned, government regulation of private health insurance varies considerably across the OECD. Generally, private health insurance regulation was based on the prominence of private health insurance in the health system and covered provisions on access to private health insurance coverage,

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<sup>46</sup> Act 45 of 2013

<sup>47</sup> Kumar, A. *et al.* (2014), “Pricing and competition in Specialist Medical Services: An Overview for South Africa”, *OECD Health Working Papers*, No. 70, OECD Publishing. <http://dx.doi.org/10.1787/5jz2lpxcrhd5-en>

premiums and the content of insurance contracts. Many governments also intervene to provide some form of risk equalisation to support the financial viability of covering high risk persons or subsidies towards the cost of premiums, as suggested in the White Paper. It came to light that countries with a similar role for private health insurance such as that in South Africa do not prescribe prices in the private sector, but they also tend to have much larger public healthcare systems. None of the eight countries where private health insurance plays a similar role to that in South Africa (Australia, Finland, Ireland, Italy, New Zealand, Portugal, Spain and the United Kingdom) directly intervened to regulate prices of medical services settled between private health insurers and private hospitals. Recognising the role of private health insurance as a voluntary product for those with the capacity and willingness to pay for additional services, the scope of regulation is focused on assuring the financial position of private health insurers (prudential regulation) and reducing scope for some consumers to face discrimination in accessing insurance products.<sup>48</sup>

As apparent from the first two weeks of the Health Market Inquiry, the SAMA agrees that the private healthcare industry is indeed “very big business”. “While patients actually consume healthcare services, medical schemes drive many buying decisions and have enormous influence over healthcare practitioners.” Although there “appears to be strong support for price regulation in the private healthcare market, interfering in this way with markets can have unintended consequences.”<sup>49</sup>

However, compelling factors that necessitate regulatory change include the fact that medical aid contributions had increased at a pace 50% higher than the inflation rate between 2005 and 2014 and are still continuing this trend, the fact that the hospital industry is dominated by a three-way oligopoly: Life, Mediclinic and Netcare, worth a combined approximately R200-billion on the JSE, claiming more than a third of relevant medical aid expenditure every year, and the fact that the funding industry is also concentrated in an oligopoly with Discovery, Metropolitan and Medscheme as administrators, controlling three quarters of the market.<sup>50</sup> None of the economies of

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<sup>48</sup> Ibid

<sup>49</sup> <http://www.medicalbrief.co.za/archives/we-assess-infrastructure-not-quality-of-care-hospital-licensors>, 9 March 2016

<sup>50</sup> Ibid

scale that should benefit these oligopolies seem able to decrease or at least contain prices.

However, it is SAMA's submission that the White Paper's suggestion that the only cover to be provided by medical schemes will be complementary and not a duplication is too drastic and should be reconsidered, and that a utilisation of the existing regulatory system and enhanced regulatory controls mentioned above, once promulgated, will provide a better basis for a gradual metamorphosis into the White Paper's envisaged goals. Gap cover and hospital cash plan insurance products should still have a role to play in the market as foreseen by Treasury, provided that these products are scrutinized diligently for openness, transparency and efficacy. Although not at all discussed in sufficient depth in the White Paper to allow for satisfactory comment, it is nevertheless the SAMA's submission that medical schemes and insurance products for a variety of health services should still find regulated application under NHI up until such time as a proper public sector health service system can carry the weight of adequate health services without the need for these additional insurance products.

#### **10.6.4 Prescribed minimum benefits**

The White paper proposes that the Medical Schemes Act be amended so that schemes will no longer provide the prescribed minimum benefits, removing schemes as primary providers of healthcare funding. The paper suggests that, as a result, the number of schemes will decrease significantly from the current 83.<sup>51</sup> In November 2015 the Supreme Court of Appeal ruled that Genesis medical scheme must pay for Prescribed Minimum Benefits (PMBs) in full, regardless of what its own rules say.<sup>52</sup> Whether the highly contentious Regulation 8 will be further contested in the Constitutional Court on appeal to this decision remains to be seen, but it has to be pointed out that current PMBs include 270 medical conditions, 26 chronic conditions and life-threatening emergency care. Currently PMBs (including HIV, TB and diabetes) protect medical scheme beneficiaries against running out of funds in respect of these

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<sup>51</sup> Du Preez, Laura: NHI proposals relegate medical schemes to the sidelines, 19 December 2015. Available at: <http://www.iol.co.za/business/personal-finance/nhi-proposals-relegate-medical-schemes-to-the-sidelines-1962035>

<sup>52</sup> *The Council for Medical Schemes v Genesis Medical Scheme* (2015/14) [2015] ZASCA 161 (16 November 2015)

serious health events and prevent the overburdening of the public health sector.<sup>53</sup> The Minister of Health's intention to change Regulation 8 alongside NHI implementation is noted, but the SAMA has to caution that any capping of the current "payment in full" obligation of medical schemes without effective alternatives firmly in place will be detrimental to patients who cannot afford co-payments and who will have only the current public sector facilities (with, for example frequent stock-outs of life-saving antiretroviral) to rely on. Any foreseen regulatory changes in this regard will have to be approached with the utmost caution.

### **10.6.5 Access to medicines, availability, price regulation and procurement**

#### ***10.6.5.1 The affordability of medicines as an essential part of the right to access to healthcare***

The SAMA supports the right afforded to government to regulate the price of medicines, provided that such regulation is effected within practical and reasonable parameters and in an open and transparent manner, due regard being had to economic viability.

The White Paper (paragraph 39) mentions the positive regulatory changes implemented since 1994 in the improved affordability of and accessibility to medicines, including a national drug policy, an Essential Drug List (EDL), improved public sector procurement systems, the introduction of a transparent pricing system and a single exit price mechanism (SEP) in the private sector. It also lists pharmaceuticals and medical equipment among the main cost drivers in the public health sector (paragraph 64). The White Paper considers the key components in implementing a successful NHI procurement process to include "transparency, cost containment, technical capacity, implementation of operational principles, purchasing for safety, adhering to appropriately selected health products list, timely and accurate information, ensuring quality products, and proper budgeting and financing" (section 385). Having listed a number of envisaged price determination strategies, it further states that "Government will put into place the necessary regulatory and policy interventions to determine tariffs for health services (including provider tariffs, and prices for pharmaceuticals and

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<sup>53</sup> <http://www.bdlive.co.za/business/healthcare/2015/11/18/minimum-benefits-must-be-paid-in-full>

related products). The law will equally apply to public and private providers including suppliers of medicines” (paragraph 392(iii)).

It is noted that the White Paper’s suggested interventions amongst others include a national formulary of medicines and health products, comprising a selection of medicines based on burden of disease, efficacy, safety, quality, appropriateness and cost-effectiveness (paragraph 388), and, with reference to “many other countries”, possible “stronger and more direct control of pharmaceutical prices through improving regulatory capacity around determining and capping drug prices accompanied by mandatory generic substitution ... and health technology assessment being increasingly used as a mechanism to promote efficiency in the health system” (paragraph 392).

Without sufficient detail provided in the White Paper on what exactly these “necessary regulatory and policy interventions” will entail, the SAMA can only comment and caution in respect on the existing regulatory framework and probable changes to bring such framework in line with NHI goals, including draft policies and regulations published for public comment but not yet promulgated.

It is important to note the Constitutional Court’s judgment in **Minister of Health v Treatment Action Campaign (No 2)**<sup>54</sup> 2002 (5) SA 721 (CC), in terms whereof access to healthcare services unequivocally includes access to medicines. In light hereof, the government has the constitutional responsibility to progressively facilitate access to essential medicines. “This does not mean that government must just act as a provider of goods and services. It must also put in place a legal framework so that individuals are able to realise their rights through their own action. This duty refers directly to the government’s role as a regulator, rather than as a provider. Thus even if the government provides certain essential medicines free of charge in the public health sector, it is still under a constitutional duty to take steps towards reducing the prices of these drugs in the private sector.”<sup>55</sup>

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<sup>54</sup> 2002 (5) SA 721 (CC)

<sup>55</sup> Section 27: Health & Democracy. Chapter 14 – Access to essential medicines. Available at: <http://www.section27.org.za/wp-content/uploads/2010/04/Chapter14.pdf>

**10.6.5.2 The Medicines and Related Substances Amendment Act, 2015 and SAHPRA**

It is a well-known fact that the Medicines Control Council (MCC) currently operates under a back-logged timeline of three to four years to approve medicine applications, which is unacceptable by international standards, and deprives the public of quick access to cost-effective generic medicine alternatives. The increased generic volume in turn exacerbates the backlog referred to above.<sup>56</sup>

For this reason the SAMA is in support of the South African Health Products Regulatory Authority (SAHPRA) created by the Medicines and Related Substances Amendment Act, which body will supersede the MCC and be tasked with an extensive mandate of regulatory responsibilities regarding pharmaceuticals, biologics, medical devices, in-vitro diagnostics, complementary medicines, and food and cosmetics. It is further encouraging to note the Department of Health's undertaking that SAHPRA will be established with effect from 1 April 2017. The independence of SAHPRA to function under the auspices of a CEO and Board, as a public entity with the power to retain the fees it generates from applications to register medicines is welcomed.

Noting that SAHPRA will function independently from the Department of Health, and is meant to have adequate human resources to support its objectives (including new pharmacy graduates trained in regulatory affairs to assist in eliminating backlogs), SAMA is hopeful that SAHPRA will manage to accelerate the medicine registration process to such an extent that quality-approved generics can rapidly enter the health system, while maintaining quality standards, since the use of generics to limit expenses can provide low-cost effective public healthcare in line with NHI objectives and simultaneously incentivise local generic manufacturing.

However, the increased functionality envisaged for SAHPRA, to be functioning in a similar vein to the American FDA, will only be realised if sufficient and well-trained manpower is made available to address the extent in scope as promised; if not, the SAMA needs to caution that the expanded scope of SAHPRA may lead to an exacerbation of the current state of affairs.

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<sup>56</sup> Paul Ruff, MD - Head of the Medical Oncology Division with the University of Witwatersrand Faculty of Health Sciences: <http://am.asco.org/regulation-and-funding-medicines-south-africa> 31 May 2015

Insofar as SAHPRA's envisaged income is concerned, the SAMA notes the following with reference to the financial statements of 2013-2014 contained in the Annual Report of the Department of Health for the same period:

"The revenue grew from R33, 8 million in 2012/13 to R71, 6 million in 2013/14, at an average of 111, 66%. The main source of revenue is from fees from registration of medicines which yielded a significant increase of 78, 73% in 2013/14. The tariffs charged by the Department in this regard are in terms of the provisions of the Medicines and Related Substances Act of 1965 as published in the Government Gazette on 7 November 2012. The majority of revenue collected by the NDoH is derived from applications for registration of medicines, which falls under the Medicines Control Council (MCC)." (Emphasis added.) T SAMA is hopeful that the NHI Fund will be able to recoup the loss of approximately R70 million to be reallocated to SAHPRA in future through NHI contributions, and that this has been taking into account in NHI budget planning.

The exceptionally high rate in which registration fees increased indicates that there has been an equal increase in the number of medicines registered. Whether this line of income is necessarily in line with the public health provision goals of the NHI is questionable. One would anticipate a decrease in the number of new medicines registered in favour of successful procurement and availability of essential medicines at low cost to fulfil public needs.

It is SAMA's submission that SAHPRA, taking cognisance of the patent law issues discussed below, should pursue avenues to allow joint recognition of products available in other countries to allow these products to get fast tracked during registration processes, which could include international regulatory cooperation through agreements with selected foreign regulatory authorities.<sup>57</sup>

It is interesting to note that SAHPRA will also become a facilitator for the Pan-African 'Model Law for Pharmaceuticals', a regulatory regime framework initialized by the

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<sup>57</sup> "New body to take over from MCC in 2017", 26 January 2016. Available at <http://www.medicalbrief.co.za/archives/new-body-to-take-over-from-mcc-in-2017/>

African Medicines Regulatory Harmonization (AMRH) Program, implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA), being supported and funded by the UN, NEPAD, African Union Commission, Pan African Parliament, World Health Organization, World Bank, Bill & Melinda Gates Foundation, and the US Government.<sup>58</sup> The SAMA trusts that SAHPRA will continue with the current MCC membership of the International Consortium of Medicines Regulatory Authorities (ICMRA) – a USA FDA based consortium, where regulators explore market options for the increased availability of medicines.<sup>59</sup>

All these initiatives are fully supported by SAMA, which believes that an international harmonization of medicine laws is essential for the continued provision and availability of essential and other medicines to South Africans.

It is generally accepted that the current two-tiered pricing system for medicines in the country – one for the public sector and one for the private sector – is unsustainable and will have to be efficiently addressed for successful NHI implementation. Whether or not the current proposed answer to this issue provided in the White Paper, i.e. to have a single strategic purchaser in the form of the State (the NHI Fund will be an active purchasing organisation – paragraph 327), purchasing services for the entire population and paying for all health care costs on behalf of the population, is a viable solution, however, is questionable. The White Paper proclaims that “the NHI Fund will be able to reap the efficiency benefits of monopsony purchasing power and economies of scale, and ensure that incentive structures for healthcare providers are integrated and coherent”.

SAMA’s position in this regard is more fully addressed in Chapter 7 of this submission.

The British NHS system, in passing, follows an approach of controlling prescription drug prices, while rewarding basic research for breakthrough drugs. The British have a national board that negotiates with the industry. Nationally negotiated price schedules have worked well for years and saved billions. The British approach goes further, by rewarding breakthrough research and discouraging “me too” research or patent manipulation. It regulates profits, not prices, by having companies submit financial records and by determining set proportions for expenditures (e.g., a limit of

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<sup>58</sup> Ibid

<sup>59</sup> Ibid

7% of sales for spending on marketing) on in-patent branded drugs. If prices result in higher profits than allowed, the excess profits are paid back. The British approach both ensures and limits profits. Meanwhile, providers are given drug budgets within which they have to live.<sup>60</sup> South Africa can learn from this system.

### ***10.6.5.3 The Medicines and Related Substances Control Act – Single Exit Price***

The single exit price applicable to the private sector has its origins in sections 22G (2) and 22G (3) (a) of the Medicines and Related Substances Control Act. The WHO Guideline on Country Pharmaceutical Pricing Policies<sup>61</sup>, compiled to provide advice to countries on managing pharmaceutical prices by (i) consolidating evidence from countries at all income levels, (ii) building on the reviews done as part of the WHO/HAI project, and (iii) reflecting experiences from a range of countries, including a detailed South African study, warns against the following unintended consequences of mark-up regulation such as South Africa's single exit price regime):

- Regulation of mark-ups can have unintended negative consequences on availability and access through distortion of prices,
- There is a potential for lack of transparency in the development of mark-up structures,
- Regulation of mark-ups without adequate enforcement appears ineffective,
- Mark-up regulation can be relatively inflexible and may not be sufficiently sensitive to market changes.

Single exit price regulations in the private sector have succeeded to reduce medicine price inflation, due to the fact that the single exit price obliges all manufacturers and importers to sell their products at an identical price to all private sector buyers, regardless of volumes of orders, and prohibits them from offering any discounts.

The National Department of Health is allowed to negotiate national tender prices with pharmaceutical companies for medicines to be used at State hospitals in the public

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<sup>60</sup> Light, Donald: Universal Health Care: Lessons from the British experience. Am J Public Health. 2003 January; 93(1): 25–30. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447686/>

<sup>61</sup> World Health Organization 2015, available at [www.who.int](http://www.who.int)

sector. These tender prices are comprehensively less than the single exit price, negotiated based on large volumes of patients and the pharmaceutical company's corporate social responsibilities.<sup>62</sup> However, these prices usually pertain only to essential medicines and recommendations by the National Essential Medicines List Committee. This tender process is supposed to promote competition between different pharmaceutical companies, further reducing prices, and is subjected to the provisions of the Public Finance Management Act<sup>63</sup> and National Treasury Regulations.

However, even where government is obliged to make use of tender processes complying with the five principles for procuring goods or services set out in the Constitution (procurement procedures must be fair, equitable, transparent, competitive and cost-effective) intellectual property rights (such as patents on original medicines for which there is no equivalent) an organ of state may have no option but to contract with the right-holder in question, i.e. make use of single-source procurement, failure of which may prevent the State from having access to the latest advances in medicine.<sup>64</sup> Unfortunately, single source procurement also lends itself to abuse by nature, with no competition and transparent price mechanism.

#### **10.6.5.4 The South African Patent Act<sup>65</sup>, TRIPS and DOHA**

In South Africa patents are not examined – the Companies and Intellectual Property Commission (CIPC), being the custodian of all patents and patent applications, does not investigate the inventive merits or substance of a patent but only verifies the documentation filed. Registered patents are protected (i.e. granted exclusive rights) for 20 years. It is argued that patented medicines provide an incentive to pharmaceutical companies to develop new drugs, since such development is expensive, whereas it is relatively easy to copy existing drugs quickly.

The Declaration on the Agreement of the World Trade Organisation (WTO) on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health (the DOHA Declaration),<sup>66</sup> although providing some answers in respect of the interpretation of the

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<sup>62</sup> Ibid

<sup>63</sup> Act No 1 of 1999

<sup>64</sup> Bolton, P. "Grounds for dispensing with public tender procedures in Government Contracting" PELJ 2006 9 (2)

<sup>65</sup> 57 of 1978

<sup>66</sup> Adopted at the 2001 ministerial conference of the WTO

flexibilities available in TRIPS, does not address the basic rationale still justifying product patents in the health sector but instead fortifies these patent rights.

SAMA supports the view of the Lancet Youth Commission on Essential Medicines Policies (YCEMP)<sup>67</sup> namely that simply creating new mechanisms to promote the use of TRIPS flexibilities, or the enforcement of the Doha Declaration, will be insufficient to secure the system changes that are needed to make access to medicines genuinely equitable worldwide. Instead, a new system should be developed to replace the present TRIPS/pharmaceutical patents system that recognises the public importance of medicines, and better balances the rights of patients and consumers with those of innovators, having regard to the important role of continued research.

SAMA further agrees with the YCEMP that the notion that pharmaceutical patent protections are inevitable, and inseparable from trade law, undermine access to medicines and block discussions around the implementation of a replacement system that could work more effectively for all stakeholders.

TRIPS is now (incorrectly) seen as an entrenched institution from which pharmaceuticals cannot be removed, and stringent intellectual property protections for pharmaceuticals are also perceived as inarguable. This is simply untrue. TRIPS and its attendant requirements for reform of individual countries' patent protections for pharmaceuticals, does not adequately balance the needs and rights of innovators and patients, and there is no sufficiently compelling historical or public policy reason why this system in its current form needs to remain in place.<sup>68</sup> The use of compulsory licenses, although promoted by both the WTO and WHO, has also been very limited. The present system will have to re-evaluated and changed.

The TRIPS agreement has resulted in intellectual property also becoming essential in trade agreements – not just those negotiated through the WTO – with the result that changes to national IP regimes are made not for health improvement, but to effectively pay for trade concessions, with the immediate effect of preventing access to medicines.<sup>69</sup> The inherent imbalance in TRIPS away from public health, and towards

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<sup>67</sup> Jarvis, Jordan: The Lancet Youth Commission on Essential Medicines Policies, 29 February 2016. Available at: <http://www.unsgaccessmeds.org/inbox/2016/2/29/0c8710dtsq8u5k6crcl4ttc8d2sw7q>

<sup>68</sup> Ibid

<sup>69</sup> Ibid

increased patent protection for pharmaceuticals, has raised the price of medicines in developing countries, putting the benefits of research out of reach for many. According to certain commentators, TRIPS “virtually assures” that diseases affecting the poor will be neglected.<sup>70</sup>

In light hereof, SAMA supports a formal process involving all stakeholders, including the pharmaceutical industry, to remove pharmaceutical patent protection from TRIPS.

The SAMA is in agreement that the dichotomy in price structures currently regulated to facilitate variances between private sector and State prices must be addressed by the necessary legislation changes to facilitate efficient implementation of NHI. It is, however, SAMA’s contention that State intervention to reduce medicine expenses require a multi-tiered approach. No single intervention will suffice. Available measures for intervention have been summarized as follows:<sup>71</sup>

- Producer price control measures – these include direct price controls, reference pricing systems, the practice of equity pricing, as well as generic-friendly policies.
- Distribution chain cost controls – these include controls over mark-ups, fixed professional fees, limits or removal of value-added tax.
- Bulk purchase measures – these include the use of tender and negotiation strategies, as well as regional initiatives.
- International trade agreement relief measures – these include compulsory licensing and parallel importing.
- Demand side measures – these include measures to ensure rational medicine use, as well as such tactics as co-payments that may limit demand by patients.

#### ***10.6.5.5 External reference pricing***

The government’s proposed use of external reference pricing (ERP) benchmarking (comparator countries to include Australia, Canada, New Zealand and Spain as per the applicable Regulations) for the purpose of negotiating the price of a product is

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<sup>70</sup> Ibid

<sup>71</sup> Gray AL. Medicine Pricing Interventions – the South African experience. Southern Med Review (2009) 2; 2:15-19

supported by SAMA insofar as it is considered a relatively easy method for price determination on both on-patent and off-patent medicines.

However, the WHO warns<sup>72</sup> that certain technical issues need to be considered in the application of external reference pricing, such as ensuring appropriate comparisons of formulations and adjustment for currency exchange rates. The WHO also states that although claims have been made that this type of price referencing has been effective in terms of reducing the prices of medicines, it found no supporting evidence from monitoring reports or rigorous analytical studies that this is indeed the case. “The underlying assumption justifying the use of ERP is that prices in reference countries are somehow right, appropriate, or fair and thus by definition the ERP derived local price structure will also be appropriate. This assertion is clearly very difficult to assess without objective criteria.”<sup>73</sup>

The WHO Guideline on Country Pharmaceutical Pricing Policies concludes that use of external reference pricing can be helpful in respect of price negotiation, setting and verification, but that the biggest risk in its use is the incorrect choice of reference countries, i.e. countries with substantially different market places or structures. It warns that one of the challenges with external reference pricing is to understand the nature of published medicine prices. Depending on the legislative framework or administrative arrangements in countries, published prices may not represent true prices paid. True prices may be concealed for purposes such as rebates or risk-sharing arrangements.

It recommends as follows: Although countries should consider using external reference pricing as a method for negotiating or benchmarking the price of medicine, it should do so as part of an overall strategy, in combination with other methods, for setting the price of medicine. In developing an external reference pricing system countries should define transparent methods and systems to be used (i.e. in their regulatory framework) and should select comparator countries to use for external reference pricing based on economic status, pharmaceutical pricing systems in place, published actual versus negotiated or concealed prices, exact comparator prices supplied, and a similar burden of disease.

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<sup>72</sup> Ibid

<sup>73</sup> Ibid

It is SAMA's contention that, for the Department of Health to effectively implement external reference pricing as part of medicine price regulation in South Africa, it would have to require data of true negotiated prices rather than shadow prices, and that its legislation framework for the use of external reference pricing will have to be sound, including criteria of choice for reference countries.

#### **10.6.5.6 Generic medicines**

The promotion of generic medicines is supported, on the assumption that the use of generic medicines will result in lower prices and thus increase access, and provided that quality assurance in respect of the preferred generics can be given. In this regard the WHI Guidelines mentioned above recommend as follows:

- Countries should enable the early market entry of generics through legislative and administrative measures that encourage early submission of regulatory applications, and allow for prompt and effective review.
- Countries should use multiple strategies to achieve low priced generics, depending on the system and market. These strategies may include: within-country reference pricing, tendering, and/or lower co-payments.
- In order to maximise uptake of generics, countries should implement (and enforce as appropriate) a mix of policies and strategies, including:
  - Legislation to allow generic substitution by dispensers,
  - Legislative structure and incentives for prescribers to prescribe by international non-propriety name,
  - Dispensing fees that encourage use of low price generics,
  - Regressive margins and incentives for dispensers; and,
  - Consumer and professional education regarding quality and price of generics.

South Africa already has a number of these measures in place, such as legislation to allow generic substitution and regulated dispensing fees.

*The regulatory approach to complementary medicines* has been clarified by amendments to the General Regulations to the Medicines Act, defining

complementary medicines in relation to three elements, all of which must be met. This much-needed clarity, coupled with the Medicines Control Council's guidelines on the assessment of complementary medicines in relation to quality, safety and efficacy, can, in SAMA's opinion, be successfully incorporated in the NHI system, allowing for cost-effective alternatives, especially in primary healthcare. In this regard the NHI Bill must take account of Government Gazette Notice 870 of 15 November 2013, pronouncing on the legislative control of complementary or alternative medicines. It is also noted that the Medicines Control Council (and/or its successor SAHPRA) undertook to have all remaining pharmacological classifications in regard to complimentary medicines completed by December 2019. SAMA supports efficient and effective regulatory control of the very large complementary medicine industry to be incorporated in or cross-referred to in the eventual NHI Act, based on a risk-based approach under the auspices of SAHPRA.

#### ***10.6.5.7 Essential medicines list***

The SAMA is in full support of the White Paper's essential medicines list recommendations (more details available in Chapter 8), but cautions that transparency in relation to how and by whom the national essential medicines are determined will be essential, for purposes of responsibility and accountability towards the public whose health will be impacted by the medicines contained on the list. Again, international cooperation and consolidation of data on quality of medicines can be successfully used to increase affordability and accessibility.

A regulatory overview of existing patent legislation will have to consider "pre-qualification" of certain medicines, without having to re-subject them to the vigorous qualification processes by SAHPRA to allow for registration in the South African health market.

International agreements with existing international authorities such as the United States' FDA, the Europe Medicines Agency or the UK Medicines and Healthcare Products Regulatory Agency must be pursued and implemented to fast-track essential medicines to allow for quick access to, and availability of, these life-saving medicines. Existing regulatory barriers in patent legislation and even the draft South African

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National Intellectual Property Policy will have to be removed and supported by a revised National Drug Policy.

SAMA again supports the recommendation of the YCEMP<sup>74</sup> in this regard, i.e. the essential development of national and international norms to protect essential medicines within free trade agreements, supported by trilateral cooperation between the World Health Organization, World Trade Organization, and World Intellectual Property Organization, excluding agreements like TRIPS that facilitate high-income countries' domination of intellectual property protection (through free trade agreements that include provisions to enable intellectual property protection and even allows for "ever greening" principles exacerbating such protection, as well as allowing for exclusive patents on biological drugs lasting a minimum of 20 years).

It has become imperative that all stakeholders come together to develop a more balanced and inclusive approach to IP rights trade agreement negotiations, specifically in regard to access to medicines. The recently developed multilateral body of the WTO, WHO, and World Intellectual Property Organization (WIPO) Trilateral Cooperation is an ideal forum to bring together stakeholders to develop best practices in intellectual property rights provisions coherent with already established WTO rules and resolutions passed through the WHO and WIPO.<sup>75</sup>

As it stands, the South African Patent Act to some extent provides leniency in terms of the regulation of patents to the pharmaceutical industry, but adoption of TRIPS also provides for leniency where public health is at stake in terms of restricting patents – the State can restrict patentability to protect human health (i.e. public health) or provide compulsory licensing where a drug is not sufficiently available. It also provides for parallel imports – the same medicine can be important from more than one country if it is manufactured by more than one country (which would enhance price negotiation ability). It is the SAMA's suggestion that the leeway so provided should in the interim be utilised until international co-operation on "patentless" essential medicines can occur.

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<sup>74</sup> Jarvis, Jordan: The Lancet Youth Commission on Essential Medicines Policies, 29 February 2016. Available at: <http://www.unsgaccessmeds.org/inbox/2016/2/29/0c87t0dtsq8u5k6rcrci4ttc8d2sw7q>

<sup>75</sup> Ibid

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Current patents in South Africa favour the private sector pharmaceutical companies in developing and producing new medicines and provide these companies with a monopoly in the market. When selling patented drugs, these companies can determine their price. Therefore patented drugs are markedly more expensive than generic drugs. The current impact of intellectual property protection laws can be clearly detected in relation to medicines for tuberculosis, as opposed to first line antiretroviral whose prices have plummeted as a result of generic competition. For example, the drug linezolid, which has been used in treating drug-resistant TB is marketed by Pfizer at an unaffordable price of almost R700 per tablet, while a generic version manufactured in India can be sold for R10. South Africa cannot import this cheaper option because of Pfizer's patent. Options to facilitate access to these generic options must be implemented in respect of medicines used to treat diseases with a high prevalence in South Africa.

It is also true that international pharmaceutical companies developing drugs do not necessarily do so for diseases specific to South Africa. If they are to be severely restricted in terms of price, they will also not be incentivised to do so, which will in turn result in South Africa having less access to innovative drugs. However, this may incentivise a more effective domestic pharmaceutical industry.

It is SAMA's submission that, for the Ministry of Health to be fully successful in determining prices as per the Medicines and Related Substances Control Act and as suggested in the White Paper (as a single purchaser), the Patent Act will initially (whilst international developments are awaited) have to be drastically revised to restrict patents and allow for implementation of the exceptions (flexibilities) allowed in TRIPS (as clarified by DOHA) on a large scale. It is SAMA's view that intellectual property rights cannot be upheld in isolation from the public's right to affordable medicines.

Currently a failure to utilise TRIPS to its fullest extent is a cause of high medicine costs rather than enhancing the availability of affordable generic medicines. The SAMA further supports the proposed amendments to legislation published in the Draft National Policy on Intellectual Property published by the Department of Trade and Industry in September 2013 to the extent set out below, revising those particulars that support patent protection.

To reduce medicine prices it would be essential for government to reach a balance between quality, affordability and availability during the initial stages of NHI development. The viability of the various private sector components in the supply chain will have to be protected.<sup>76</sup> “If manufacturers are forced to lower the price of their medicines too far, they may simply choose not to register or sell their products in South Africa. This may result in particular medicines becoming unavailable, but it could open up the door to generic competitors. If all manufacturers are forced to sell below cost, price controls that are too restrictive may result in no access at all. The dangers of over-regulation are thus very clear.”<sup>77</sup>

The White Paper foresees that the State will continue to provide essential medicines. In procuring these medicines the State will have to be cautious about the manner in which these medicines are obtained – care must be taken to involve local manufacturing insofar as possible (and simultaneously create employment opportunities) with the necessary quality insurance in terms of products manufactured, and continued availability of medicines must be ensured. It is furthermore imperative that medicines be provided without delay – the slow-turning wheels of the State’s prolonged tender processes may seriously hamper availability in situations of need. By allowing for parallel importing and executing its existing legislative prerogatives to engage in compulsory licencing, the State will be able to immediately fulfil its promises in this regard.

The current pharmaceutical industry involves legal, scientific, technical, fiscal and financial aspects. In order to step up their production capability, countries like South Africa need to tackle challenges on a variety of fronts. These range from research and development to exploring the full utilisation of the Trade Related Aspects of Intellectual Property Rights (TRIPS) flexibilities, tax and tariff policies, drug regulatory and registration systems and, of course, building infrastructure.<sup>78</sup>

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<sup>76</sup> Section 27: Health and Democracy, “Access to essential medicines” Chapter 14. Available at <http://www.section27.org.za/wp-content/uploads/2010/04/Chapter14.pdf>

<sup>77</sup> Ibid

<sup>78</sup> Lopes, C, Executive Secretary of the UN Economic Commission for Africa. <http://mgafrica.com/article/2015-02-17-manufacturing-pharmaceuticals-in-africa-the-untapped-opportunity-that-could-save-countless-lives>

Local manufacturing of pharmaceutical products in Africa has increased (Egypt and Tunisia produce most of their national requirements for essential medicines, Morocco has 40 pharmaceutical industrial units supplying 70% of domestic demand and exporting 10% of their production, significant production capacity is being developed and enriched in Tanzania, Kenya, Uganda, Ethiopia, Ghana, and Nigeria, and Mozambique has recently commissioned an ARV plant with the help of Brazil). Africa also hosts some of the leading global innovators and generic manufacturers – demonstrating that Africa is producing medicines that meet international standards.<sup>79</sup>

SAMA submits that South Africa should enhance and increase its manufacturing capacities accordingly, and consider the possibilities of effective intra-African trade opportunities to expand economies of scale.

#### **10.7 Medical practitioners, their contracting under NHI and the HPCSA**

According to the White Paper, the “planning, development, provisioning, distribution and management of human resources will be further improved to meet the needs of the population” (paragraph 20). To better utilise the available human resources for health in the country, there will be strengthening of contracting of private practitioners at the primary health care level and there will be contracting of accredited private sector providers at higher levels of care such as private hospitals and specialists (paragraph 21). (Emphasis added.) The White Paper however considers fee-for-service (FFS) and medical schemes’ payment thereof as one of the contributors to escalating costs in the healthcare system and also states that the “threat of medico-legal action has propelled the over-servicing of patients to unprecedented levels” (paragraph 71).

Paragraph 181 states that in the next phases of implementation, private providers at the PHC level will be contracted and reimbursed through a capitation model where appropriate instead of a FFS as it is happening currently. Paragraph 228 states that a range of health professionals working in the private sector will be engaged through innovative contractual arrangements to contribute to addressing the human resources gap.

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<sup>79</sup> Ibid

“An essential step in strengthening PHC and ensuring integrated services is the contracting of private health practitioners to render services” (paragraph 176) but contracting will also require a strong regulatory framework for determining the costs for health services and the tariffs that should be charged (paragraph 179). (Emphasis added.) General practitioners are envisioned to form part of multidisciplinary practices and those practising individually will have to be part of referral networks (paragraph 127) in specific areas.

Very few general practitioners were contracted under the NHI pilot sites roll-out, although the White Paper enunciates the estimated numbers of patients so served. SAMA notes the Minister of Health’s explanation to Parliament in this regard with regret – namely that the government failed to attract private doctors to work at clinics in NHI districts because their “greed was standing in the way”.<sup>80</sup>

General practitioners in established private practices have pointed out that practice cost studies emphatically indicated that the running costs of their practices, including payment to locums while they have to attend NHI clinics, definitively hamper their ability to contribute their services to these clinics at the suggested contract rates available for pilot sites.

In light of the foregoing, any capitation model in terms of a regulatory price regime set by the NHI (also with reference to paragraph 335 where the White Paper expressly states that the Minister and the NHI Fund will determine its own pricing and reimbursement systems) will have to be economically viable for these general practitioners to be enticed to enter into contracts based on such regime.

“GPs also expressed concerns about the capacity of government to pay on time. Basic contractual parameters must be set to avoid perverse incentives and to incentivise practices financially to ensure an adequately competitive market. The contract must strengthen user power and allow choice of provider. Rural areas may need large contract adjustments to attract more doctors.”<sup>81</sup>

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<sup>80</sup> <http://www.bdlive.co.za/national/health/2014/03/06/doctors-too-greedy-for-nhi-says-motsoaledi>

<sup>81</sup> Moosa, Luiz and Carmichael (2012). *Introducing a national health insurance system in South Africa: A general practitioner’s bottom-up approach to costing*. South African Medical Journal. 102(10): 794-797

Another concern is the patient volumes to be set in the proposed contracts (paragraph 334 of the White Paper) and whether such volumes would impede quality one-on-one patient service.

It is SAMA's submission that sufficient detail on all the above-mentioned concerns is needed before a comprehensive view in this regard can be submitted on behalf of its general practitioner members.

Any determination of fees for NHI services by medical practitioners must drastically improve on the later retracted 2012 Tariff Guideline published by the Health Professions Council of South Africa (HPCSA) and gazetted in September 2012 for public comment, in terms whereof doctors were to be remunerated at 5% less than a comparable 2003 income, whereas the Consumer Price Index (CPI) inflation (i.e. the cost of living) has increased by 55% since 2003, and medical schemes contribution inflation has increased by 119%.

### **Conclusion – price regulation:**

The SAMA agrees with the following statement: "Although individual price item regulation may produce savings to health systems, it is no guarantee that the overall cost of rendering health services would come down. Depending on the implications of various forms of price regulation, it may cause costs to increase (e.g. when certain services are not available anymore or when patient numbers or age increase). Price regulation without consideration of health outcomes, the availability of services, utilisation and costs in other parts of the social security system may not be rationally related to the agreed end-objective of all health regulation, namely progressive realisation of access to healthcare for all."<sup>82</sup>

## **10.8 Tax law**

### **10.8.1 Value Added Tax**

South African legislation exempts essential foodstuffs from VAT, but regardless of their essentiality or not, all medicines available in the private sector are subject to 14% VAT.

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<sup>82</sup> Klinck, E: "Law in Practice: Legal Frameworks and Price Regulation: Where are we Going? 3 September 2012, Opinion: Medical Chronicle. Available at: <http://www.medicalchronicle.co.za/law-in-practice-legal-frameworks-and-price-regulation-where-are-we-going/>

Prescription drugs with high therapeutic value and over-the-counter supplements are taxed in the same manner. Although the argument exists that those who cannot afford it have access to medicines in the public sector and are not affected by VAT, it must be remembered that South Africans using the public health sector are faced with problems such as the unavailability of medicines in State hospitals and clinics and are forced to buy their medicines from private pharmacies. Issues with transport, long distances, long queues and waiting times in respect of public health facilities also result in people rather making use of community pharmacies or dispensing doctors for their health needs, and are subjected to VAT payments in the process.

It is SAMA's recommendation that VAT on essential medicines should be scrapped to facilitate equitable access to these medicines.

In the alternative, selective concessions on VAT can be allowed in the manner as recently done by the Ukraine<sup>83</sup> – since March 2015 the Ukraine allowed State procurement of certain medicines through international organisations such as the WHO, UNICEF and other highly reputable institutions, dramatically reducing corruption on procurement, followed by an adoption of legislation to establish temporary exemption from VAT and import duties on the following selected transactions:

- import of medicines and medical devices on the customs territory of Ukraine and first supply of such medicines and devices,
- first supply of medicines by Ukrainian producers of medicines and medical devices, and,
- Supply (transfer) of medicines and medical devices to final consumers (patients).

The above exemption applies solely when medicines and medical devices are imported and/or supplied on the basis of agreements with qualified international

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<sup>83</sup> CMS Cameron McKenna, May 2015: Ukraine cancelled VAT and additional import duty on certain medicines. Available at: <http://www.lexology.com/library/detail.aspx?g=0ee161a7-cdff-4dd4-bf47-eb5e6f6e6c48>

procurement agencies and shall apply until March 31, 2019, and provides an interesting and workable example for consideration.

### **10.8.2 Import duties**

Importation of active pharmaceutical ingredients (APIs) and raw materials used to manufacture APIs is done from countries such as India. APIs are the building blocks of all medicines. The costs of APIs make up about 70 – 80% of the cost of generic drugs – this can be even higher for ARV medicines. Import duties thus have the potential to contribute directly towards increasing the cost of locally manufactured medicines and can make it more difficult for local generic companies to compete with foreign generic companies. [53]

SAMA recommends that any forthcoming NHI legislation take cognisance of these facts and exempt at least essential medicine component imports from import duties.

### **10.8.3 The Consumer Protection Act, regulations and medical devices**

Product liability legislation is another area of concern in respect of NHI that is not addressed in the White Paper. With reference to the 2011 breast implant scandal in France, women in a number of countries instituted legal action for damages against the French company Poly Implant Prothese and thereafter also against the regulatory body in France, TUV Rheinland, (with similar functions as that of the soon-to-be established SAHPRA). The French court of first instance as well as its appeal court found that TUV Rheinland was liable for damages to 1700 victims of defective breast implants, because they did not fulfil their obligations to carry out site-inspections or audits of the products made out of industrial grade silicon, i.e. neglected to fulfil its duties as regulatory body.

Similar liability of SAHPRA will occur in terms of the recent regulations on the registration of medical devices for human or animal use, requiring licenses for these products and activities, which strengthens its legal liability, as well as the Consumer Protection Act (CPA) that provides for a no-fault liability system for damage caused by consumer good, through a statutory implied warrant of quality similar to that of UK law.

In the context of supplying medical devices, and in terms of section 54 of the CPA , service providers like doctors supplying implants to patients during surgery may have to remove and replace defective devices without charge to the patient.

It is SAMA's contention that NHI regulatory development must consider the risks inherent to the supply of these goods and services and insure that adequate insurance is in place to deal with product liability.<sup>84</sup>

### **10.9 Pharmaceutical and health care innovations**

NHI regulatory development will have to keep track with pharmaceutical and healthcare innovations and how they will impact on current legislation. Technological developments like microchip modelling for clinical trials and digestible sensors (looking like a pill and transmitting patient information to doctors) will require new regulations throughout the entire lifecycle of the new product – including storage, transportation and distribution.<sup>85</sup>

### **10.10 Dispensing licences**

With reference made to the concession granted in relation to holders of dispensing licenses in October 2013, provided that the holders of such licenses pay the annual fee, to remain valid until suspended or revoked by the Director-General of Health (i.e. indefinitely), SAMA notices the contrast in respect of licenses to manufacture or to act as a wholesaler or distributor of medicines only being valid for five years, as well as patent rights existing for 20 years. It is SAMA's submission that these contradictory time periods should be somehow aligned when NHI is implemented.

Section 22C of the Medicines and Related Substance Act and various Health Professions Council acts should be reviewed to ensure that the dispensing provisions align with the changing health provision platform. The fee-for-service environment as well as a shortage of skills have resulted in medical doctors dispensing medication and pharmacists prescribing medication. It is important to note that once NHI is

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<sup>84</sup> <http://www.nortonrosefulbright.com/knowledge/publications/125329/keeping-abreast-of-product-liability-risks-for-defective-medical-devices-the-pip-story>

<sup>85</sup> Ford, K. Presentation at the DHL annual conference, 20 October 2015 – “The Changing Face of Regulatory Control”. Available at: <http://www.pharmacos.co.za/events-and-expos/1676-moving-pharma-logistics-forward-within-regulatory-controls>

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implemented, pharmacy-based diagnosis and treatment will pose huge risk for moral hazard. (Please see side-bar comment.)

Indications on their authority to prescribe medicines can be gained from the scope of practice descriptions from certain health professionals, but any medicines to be prescribed must in the first instance be listed in the schedules to the Medicines Act. The practice is that the HPCSA and MCC jointly decides on these lists for various health professions but seems to have been lacking in the promulgations of the draft scope of practice for clinical associates in May 2015, stating that clinical associations may prescribe “medicines for common and important conditions according to the primary health care level Essential Drugs List (EDL) and up to schedule IV, except in emergencies when appropriate drugs of higher schedules may be prescribed. The prescription must contain the name of the supervising registered medical practitioner. In the case of drugs not on the EDL the prescription must be countersigned by a registered medical practitioner.

These regulations will be problematic to pharmacists who are presented with prescriptions written by Clinical Associates. [53]

Progress has been made regarding nurses’ authorisation to prescribe, but the necessary interaction with the Medicines Control Council to enable scheduling of the process has not been finalised. [53]

The above-mentioned discrepancies will have to be urgently addressed prior to NHI implementation.

### **10.11 Protection of Personal Information Act**

In this Act “personal information” is defined broadly as information relating to identifiable, living natural (or juristic) persons, concerning their race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth. Significantly, such information also includes a person’s medical history and biometrics. The bodies identified may handle such information (lawful processing) under stringent conditions stipulated in the Act, and subject to the

rights of the individual being protected, which conditions include the principles of accountability, lawfulness, minimalism, consent, justification and objection. Further safeguards include security, data subject participation and correction of personal information. In addition, there is a prohibition on the processing of special personal information such as “the religious or philosophical beliefs, race or ethnic origin, trade union membership, political persuasion, health or sex life or biometric information” of an individual. The prohibition relating to an individual’s health or sex life does not apply to processing by certain exempt categories: medical professionals, healthcare institutions or facilities or social services (for the purposes of treatment, care or administration), insurance companies or medical schemes (for the purposes of assessing risk to the company or scheme), and a host of other bodies.

The Act has significant implications for the healthcare sector. It bolsters the privacy provisions in the common law, the Constitution and the National Health Act. It does so by requiring the adoption, by public and private bodies, of security measures on the integrity and confidentiality of personal information in their possession or control. This is to be achieved by taking appropriate and reasonable measures to prevent the loss of, and unlawful access to, such information. Breaches are to be visited with both penalties under the act, as well as civil claims for damages resulting from negligent disclosure of personal information. A notable exception is the processing of such information “solely for the purpose of journalistic, literary or artistic expression to the extent that such an exclusion is necessary to reconcile, as a matter of public interest, the right to privacy with the right to freedom of expression”. It thus appears to sanction the disclosure of medical records, provided it can be established that it would be in the public interest.

In his statement in the Department of Health Annual Report 2013-2014, the Deputy Minister of Health, Dr J Phaahla, MP, said the following on 2 September 2014:

“The eHealth strategy for the public health sector for 2012/13-2016/17 was approved by the Minister on the 09th July 2012. In 2013/14, the Normative Standards Framework for eHealth was developed and approved. The eHealth Strategy provides the roadmap for achieving a well-functioning national health information system with the patient located at the centre. The strategy also seeks to ensure that the Integrated

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National Patient-Based Information System will be based on agreed upon scientific standards for inter-operability, which improves the efficiency of clinical care, produces the indicators required by management, and facilitates patient mobility.”

SAMA cautions that, specifically with reference to the eHealth strategy for the public sector, any implementation of NHI along the lines of data collection envisaged by the Deputy Minister and also specified in the White Paper must be scrutinised against the provisions of the POPI Act – any contravention of this Act by the State would not only attract severe penalties but undermine the public’s trust in the NHI systems.

### **10.12 Conclusion**

It is essential that the NHI be harmonised with the necessary legal changes that must give effect to the successful implementation thereof. Gradual changes will provide stability and the effective provision of the resources needed to enable transitional arrangements until the system is fully operational. Legal changes should be phased in by providing different operation dates for various sections of new or changed legislation, allowing sufficient time to plan for additional responsibilities, functions and resources needed to give effect to the legislation.

## 11. NHI FROM A GOVERNANCE PERSPECTIVE

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### 11.1 Concept and scope

Governance within the NHI health system ought to mirror generally accepted global governance principles; the applicable concepts in this regard are addressed below. An earlier definition of governance in the health sector describes this concept simply as “governance undertaken with the objective to protect and promote the health of people”.<sup>86</sup> The WHO has since evolved this definition into the following aspects:

- *Intelligence and oversight*  
Ensuring the generation, analysis and use of intelligence on health system performance.
- *System design*  
Ensuring a fit between strategy and structure.
- *Policy guidance*  
Defining goals, formulating sector strategies and technical policies.
- *Collaboration and coalition building*  
Influencing action on social determinants of health and ensuring “joined up government”.
- *Regulation*  
Designing regulation and incentives, and ensuring they are enforced fairly.
- *Accountability*<sup>87</sup>

According to the WHO’s Health Systems Governance for Universal Health Coverage Action Plan<sup>88</sup> governance for universal health coverage applicable to NHI broadly involves:

- (a) Setting strategic direction and objectives,

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<sup>86</sup> USAID, March 2013. The eManager. Management Strategies for Improving Health Services. How to Govern the Health Sector and its Institutions Effectively. Available at: [http://www.lmgforhealth.org/sites/default/files/eManager\\_How%20to%20Govern%20the%20Health%20Sector\\_4.11.13\\_FINAL.pdf](http://www.lmgforhealth.org/sites/default/files/eManager_How%20to%20Govern%20the%20Health%20Sector_4.11.13_FINAL.pdf)

<sup>87</sup> Goudge, J. “Governance for UHC”, February 2014. The Centre for Health Policy and Systems Research, WITS School of Public Health. Available at: [www.econrsa.org/system/files/workshops/presentations/2014/governance\\_for\\_uhc\\_jane\\_goudge.pdf](http://www.econrsa.org/system/files/workshops/presentations/2014/governance_for_uhc_jane_goudge.pdf)

<sup>88</sup> © World Health Organization 2014, Department of Health Systems Governance and Financing, available at [www.who.int](http://www.who.int)

- (b) Making policies, laws, rules, regulations and decisions,
- (c) Raising and deploying resources to accomplish the strategic goals and objectives set,
- (d) Overseeing and making sure that the strategic goals and objectives are accomplished.

### **The importance of governance**

Although the NHI has a huge focus on public need and funding, the vital importance of effective and efficient governance, its effectiveness and impact, cannot be neglected – the NHI system will have to function properly to ensure that the envisaged services can be delivered, and to ensure that government, health institutions and health professionals can be held accountable to the public in accordance with their responsibilities.

“The problem with the lack of concern for basic governance principles in healthcare delivery is that well-intentioned spending may have no impact. Priorities cannot be met if institutions don’t function and scarce resources are wasted. Bribes, corrupt officials and mis-procurement undermine healthcare delivery in much the same way they do for police services, courts and customs whose functions become compromised by the culture of poor governance and corruption.”<sup>89</sup>

The effectiveness of government, and specifically the efficiency of its role in producing healthcare services, would therefore have to form the core of a successful NHI system in South Africa. The WHO describes governance as a “political process that involves balancing, competing influences and demands”<sup>90</sup> that includes:

- maintaining the strategic direction of policy development and implementation,
- detecting and correcting undesirable trends and distortions,
- articulating the case for health in national development,

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<sup>89</sup> Lewis, M. Governance and Corruption in Public Health Care Systems. Centre for Global Development, January 2006. Available at:

<http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.542.2159&rep=rep1&type=pdf>

<sup>90</sup> <http://www.who.int/healthsystems/topics/stewardship/en/>

- regulating the behaviour of a wide range of actors - from health care financiers to health care providers, and,
- establishing transparent and effective accountability mechanisms.

Good governance will have to reach beyond the traditional realm of the health system to include other sectors of society in a participatory and inclusive manner, both nationally and internationally.

Although “good governance” is a widely accepted and supported term, there is a difference between governance as a concept or phenomenon (how decisions are made) and *normative policy advice* (how decisions should be made and implemented, i.e. *good governance*). A majority of health system’s research literature continues to identify five areas in which governance can affect health systems: transparency, participation, accountability, integrity (i.e. management and anti-corruption measures) and policy-making capacity.<sup>91</sup>

The 2014 *International Framework: Good Governance in the Public Sector* was developed jointly by the Chartered Institute of Public Finance and Accountancy (CIPFA) and the International Federation of Accountants ® (IFAC®).<sup>92</sup>

The Framework’s diagram below illustrates how the various principles for good governance in the public sector relate to each other. These principles will be equally applicable to governance within the NHI. Principles A and B permeate implementation of principles C to G. The diagram also illustrates that good governance is dynamic, and that an entity as a whole should be committed to improving governance on a continuing basis through a process of evaluation and review.

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<sup>91</sup> Greer, SL & Mendez, CA. Universal Health Coverage: A Political Struggle and Governance Challenge. [Am J Public Health](#). 2015 Nov;105 Suppl 5:S637-9. doi: 10.2105/AJPH.2015.302733. Epub 2015 Jul 16

<sup>92</sup> The full Framework is available on the CIPFA and IFAC websites, [www.cipfa.org](http://www.cipfa.org) and [www.ifac.org](http://www.ifac.org)



The core, high-level principles characterizing good governance in the public sector set out above bring together a number of interrelated concepts. Principles C to G are linked to each other via the “plan-do-check-act” cycle.<sup>93</sup>

The Framework emphasises that, for good governance (as envisaged in the White Paper), both the governing bodies and the individuals working for NHI entities must try to achieve their entity’s objectives while acting in the public interest at all times (which all involved in NHI will strive to do), consistent with the requirements of legislation and government policies, avoiding self-interest and, if necessary, overriding a perceived organisational interest. Acting in the public interest implies primary consideration of

<sup>93</sup> The “Plan-Do-Check-Act Cycle,” also called the Deming Cycle, is an iterative management process organizations typically use for the control and continuous improvement of processes and products. Available at the International Organization for Standardization’s website [www.iso.org/iso/home.html](http://www.iso.org/iso/home.html)

the benefits for society, which should result in positive outcomes for service users and other stakeholders. It therefore requires<sup>94</sup>:

- A. Behaving with integrity, demonstrating strong commitment to ethical values, and respecting the rule of law** The entities described in the White Paper (see “Governance in terms of the White Paper” below) will be accountable not only for how much they spend, but also for how they use the resources under their stewardship. This includes accountability for outputs, both positive and negative, and for the outcomes they have achieved. These entities will be accountable to legislative bodies for the exercise of legitimate authority in society. This makes it essential that each entity as a whole can demonstrate the appropriateness of all of its actions and has mechanisms in place to encourage and enforce adherence to ethical values and to respect the rule of law.
- B. Ensuring openness and comprehensive stakeholder engagement** Since the envisaged NHI entities are established and run for the public good, their governing bodies (on both provincial and national level) should ensure openness in their activities. Clear, trusted channels of communication and consultation should be used to engage effectively with all groups of stakeholders, such as individual citizens and service users, as well as other institutional stakeholders.

In addition to the overarching requirements for acting in the public interest in principles A and B, achieving good governance in NHI will also requires effective arrangements for:

- C. Defining outcomes in terms of sustainable economic, social, and environmental benefits** The long-term nature and impact of many of the State’s responsibilities in terms of NHI mean that it should define and plan outcomes and that these must be sustainable. The government and other authorities down the NHI chain must ensure that its decisions

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<sup>94</sup> Ibid

further the specific entity's purpose, contribute to intended benefits and outcomes, and remain within the limits of authority and resources. Input from all groups of stakeholders, including citizens, service users, and institutional stakeholders, is vital to the success of this process and in balancing competing demands when determining priorities for the finite resources available.

**D. Determining the interventions necessary to optimize the achievement of the intended outcomes**

NHI must achieve its intended outcomes by providing a mixture of legal, regulatory, and practical interventions. Determining the right mix of interventions is a critically important strategic choice that the State and NHI governing bodies will have to make to ensure they achieve their intended outcomes. These entities need robust decision-making mechanisms to ensure that their defined outcomes can be achieved in a way that provides the best trade-off between the various types of resource inputs while still enabling effective and efficient operations. Decisions made need to be reviewed continually to ensure that achievement of outcomes is optimised.

**E. Developing the entity's capacity, including the capability of its leadership and the individuals within it**

The entities described in the White Paper will need appropriate structures and leadership, as well as people with the right skills, appropriate qualifications and especially mind-sets, to operate efficiently and effectively achieve their intended outcomes within the specified periods. These bodies must ensure that it has both the capacity to fulfil their own mandate and to assure that there are policies in place to guarantee that an entity's management has the operational capacity for the entity as a whole. Because both individuals and the environment in which an entity operates will change over time, there will be a continuous need to develop the

entity's capacity as well as the skills and experience of the leadership of individual staff members.

**F. Managing risks and performance through robust internal control and strong public financial management**

The governing bodies of NHI entities need to ensure that the entities they oversee have implemented - and can sustain - an effective performance management system that facilitates effective and efficient delivery of planned services. Risk management and internal control are important and integral parts of a performance management system and crucial to the achievement of outcomes. They consist of an ongoing process designed to identify and address significant risks involved in achieving an entity's outcomes.

A strong system of financial management is essential for the implementation of public sector policies and the achievement of intended outcomes, as it will enforce financial discipline, strategic allocation of resources, efficient service delivery, and accountability.

**G. Implementing good practices in transparency, reporting, and audit to deliver effective accountability**

Accountability is about ensuring that those making decisions and delivering services are held accountable for them, although the range and strength of different accountability relationships vary for different types of governing bodies. Effective accountability is concerned not only with reporting on actions completed, but also ensuring that stakeholders are able to understand and respond as the entity plans and carries out its activities in a transparent manner. Both external and internal audit contribute to effective accountability.

Whether the essential principles listed above will be effectively implemented and sustained during the roll-out of NHI remains an open question, given the varied and complex root causes for the problems underlying the current health system in South

Africa, requiring the collective efforts of all the role-players in the system and sufficient resource capacity for implementation.

### **NHI governance challenges**

The current difficulties in the South African health systems are well known: The public sector is plagued by corruption (discussed in detail within the chapter on Corruption), poor management on various levels (aggravated by a lack of accountability), a notable lack of implementation of existing policies, regulations and guidelines, and a lack of proper evaluation and monitoring. The private sector, on the other hand, suffers from seemingly unfettered cost and fee increases resulting in a real threat that medical scheme contributions will become unaffordable. Underscoring these issues are the inequalities between the private and public systems *per se*. Further challenges include the weakened exchange rate, South Africa's quadruple burden of disease, a serious shortage of medical practitioners, and other health care workers, evolving technology and research and vast geographical distances. Such a constantly changing and evolving health environment requires a flexible yet well-developed and refined governance system capable of self-evaluating, improving and adjusting with the tide of change.

SAMA is concerned with NHI's capacity to meet these challenges. Although the governance objectives set out in the White Paper are laudable, the focus should not remain only on making sweeping changes, but also include a realistic evaluation processes to measure the effect (and thus successful implementation) of such changes, constantly ascertaining their viability and sustainability.

### **Governance in terms of the White Paper**

The White Paper provides a basic summary of its foreseen governance structures in sections 11 to 15 and promises the improvement of management and governance of health facilities at PHC and hospital levels by strengthening same "in terms of structure, powers, delegation, financial management and accountability" (section 11). The OHSC Inspectorate will "ensure compliance with norms and standards" and the Ombud will "enforce accountability and impose corrective measures where necessary" (section 12). The Operation Phakisa programme aims at improving quality of health

services in PHC facilities and will later extend to public hospitals to have their “quality strengthened” as well (section 13). A safe and conducive environment will be established by “good quality public health infrastructure complete with bulk services” and a “consistent maintenance plan” (section 14). NHI fund creation will be coupled with the establishment of “functional governance and accreditation structures and purchasing systems, risk mitigation systems, health technology assessment as well as systems for monitoring and evaluation systems (section 15).

The SAMA’s concern is that the various governance principles outlined in the White Paper remain ideological and that the necessary implementation and evaluation aspects to effect these ideologies in practice remain vague and undefined.

The White Paper contains an abundance of well-known fact statements on what is necessary to enhance effectiveness of healthcare, amongst others including a number of foreseen governance strengthening principles:

- Strengthening PHC services is critically dependent on improved management at facility (clinics and community health centres) and district levels (section 182);
- “In addition to strengthening management capacity (e.g. through improving managers’ skills and upgrading information systems), there will be a need to delegate greater management responsibilities to the district level in the early phases so that the necessary decisions related to service delivery can be made and managers can be held accountable for their performance” (section 183), however, “... it may not be feasible in the early phases to delegate management to individual PHC facilities” and “appropriate delegations and management functions will be developed” (section 184) “as the system matures”.
- The PHC re-engineering vision of integrated comprehensive services “would best be promoted through co-ordination and management of these services at the district level” (section 185) and “functioning Clinic Committees” with developed guidelines will be established (section 186).
- There will be District Health Management Offices to manage district health services (section 187) and Central Hospitals are to be governed by “appropriately constituted Boards (section 206) – “The composition, role and

function of the Boards will be amended in line with the objectives of the NHI, including ensuring that they have greater oversight responsibilities. These boards will have a delegated oversight responsibility of all the functions of the hospital and represent the interest of the users of the facility and affected stakeholders.” Central hospitals are considered a “national resource” and, irrespective of the province in which they are located, must provide health services to the entire population” (section 201). “Their management will have full delegations and decision making powers including control over financial management, human resource management, infrastructure and technology, as well as planning and decision making” (section 203) and they will have cost centres, responsible for “managing meaningful units of business activities” (section 204). These functional business units will in turn be “disaggregated into smaller units with the lowest cost centre level being a ward or out-patient clinic” (section 205).

- “All these reforms will necessitate central hospitals becoming a competence of the national sphere of government which will require new governance structures” (section 207).
- Similarly, “the roles, functions and responsibilities of management and governance structures for the district, regional, tertiary and specialised hospitals will have to change” and hospitals will be contracted to “render quality health services in accordance with the norms and standards as determined by the Office of Health Standards Compliance (OHSC) and in line with benefits as determined by the NHI Benefits Advisory Committee (section 208)”. Challenges in respect of the OHSC are addressed elsewhere in this document.
- Strengthened management “with more decision making space in critical management domains” is considered “vital in the areas of facility management, cost centre management, and management and maintenance of essential equipment and infrastructure” (section 209). In terms of minimum competency requirements all managers will be “required to have a health management qualification” (section 210). Delegated authority assigned to each category of hospital will be commensurate with the capacity to exercise the appropriate responsibilities and functions that can be delegated and delegations afforded

to these hospitals will be in line with the Public Finance Management Act and Public Service Act (section 211).

- “As the NHI matures, hospitals will be authorised as semi-autonomous entities to provide services funded by the NHI Fund. They should be capable of providing quality services, operating as viable units with capacity to utilise their available resources. Hospitals will be required to assume increasing degrees of managerial autonomy in preparation for NHI but also to improve the efficiency and effectiveness of public hospital services in general” (section 212).
- Governance of public hospitals will be enhanced through increased levels of autonomy and appropriate oversight by hospital boards (section 213) and these boards “will be strengthened in order to improve the governance of hospital management and staff in line with good corporate governance”.
- NHI promises benefits such as “improved accountability on the use of public funds through appropriate governance mechanisms and transparency in performance reporting” (section 109) and the White Paper recognises that a “massive reorganisation of the health system would be required to create a new platform for service provision and health care financing”. Such reorganising “may require legislative changes, rearrangements of functions, responsibilities and relationships within the three spheres of government pertaining to governance, concurrency, financing and delivery of health services” (section 152).

Ambitious projects for quality improvement, with accompanying good governance and management ideologies suggested in the White Paper includes the implementation of National Quality Standards for Health, in-house provision of essential health support services such as laundry and security, the measuring of patient satisfaction through the OHSC, the implementation of a Patients’ Rights Charter (sections 219 – 224), the structuring of a NHI Fund under the auspices of a National Health Commission (to be supported by a Management Team and Stakeholder Representative Forum – section 421) and a Risk Management Framework for the NHI (section 382).

The SAMA is concerned that decentralisation to district level was first proposed in the 1997 White Paper on transformation of health services. Almost 20 years after this proposal, decentralisation to district level has not been implemented. It is very

important that the NDoH review why decentralisation to districts has not yet happened. If success of NHI depends on decentralisation, barriers to such must be addressed urgently.

In the establishment of the above-named structures, care must be taken to address conflict of interest issues when developing regulative frameworks, specifically with a focus on good governance. Autonomous decision structures must be protected by legislation.

### **The role of existing associations and institutions, and institution building**

The SAMA admires the White Paper's all-encompassing approach to the various components mentioned, as well its acknowledgment of the important role of good governance in the achievement of its goals. However, rather than only focusing on new institutions such as the OHSC, the positive role to be played by existing institutions with highly-valued knowledge resources such as professional associations like the SAMA, universities and research facilities should not be ignored, nor underestimated, in the planning of NHI. The NHI Fund will have to assess various health interventions and manage their provision, and have to access knowledge and expertise on the effectiveness, cost-effectiveness and feasibility of these interventions if it plans to be successful.

The SAMA commends the NDoH for establishing the new National Public Health Institute of SA. Hopefully this institution will consolidate data, generate activities, such as collection and analysis of survey data, and perform vital registration and surveillance of diseases. In conjunction with the expertise required, some functions essential to delivering on NHI are not yet actively addressed by any existing or planned institutions, for example:

- On the knowledge management level: systematically assessing health system outcomes and relating these outcomes back to inputs. Although the SA Medical Research Council routinely provides data, there are delays in relating these outcomes back to inputs.

- On the decision-making level: actively managing public opinion and engaging the public in the NHI process.<sup>95</sup>

Thailand's success with universal healthcare is *inter alia* attributed to the good governance achieved through its development of institutional capacity. Institutions were established that could function as knowledge brokers and performed the vital governance functions at the data-generation, knowledge-management and decision-making levels required by a universal healthcare system. These institutions included, amongst others, the Thai Health Promotion Foundation, the Health Systems Research Institute (an autonomous agency generating evidence in support of government policy decisions), a Health Insurance System Research Office to monitor the effects of universal health care system reforms, and a Health Intervention and Technology Adjustment Programme (HITAP), to assess interventions and new technologies.

"Thailand's experience shows that evidence-based platforms matter and that, over the longer term, capacity to generate evidence and translate it into policy must be institutionalised. The South African system does not yet have this capacity to the degree required for effective universal health care."<sup>96</sup>

NHI can therefore not afford to neglect intimate co-operation with existing stakeholders, which would also specifically include those in the private sector such as the South African Medical Device Industry Association (SAMEDI), for example, at least until SAHPRA is fully functioning.

### **Independent Medical Practitioner Council**

Another institution that is clearly needed within the NHI context, with reference to the institutional building mentioned above, is an Independent Medical Practitioner Council. Not only will such a Council assist in the efficacy of key regulators through its own registration and quality control processes of medical practitioners, but its existence has become imperative in light of the acute deficiencies identified in respect of the HPCSA, as pointed out in the executive report of the Ministerial Task Team that was appointed to investigate this organ of State. These deficiencies were also mentioned

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<sup>95</sup> Goudge, *supra*.

<sup>96</sup> Goudge, *supra*

during the recent sessions of the Health Market Inquiry, referring to the irregularities and maladministration of the HPCSA being the source of its failure to protect patient rights.

The Independent Medical Practitioner Council will furthermore assist with the necessary expertise on the transparent price and ethical tariff determination processes for purposes of NHI implementation. It is the SAMA's submission that price information systems that would allow health-care resources to be utilised optimally cannot be ignored within the NHI system – policy makers cannot accurately determine the extent of prices and their influence on viable cost estimations without such information.

Furthermore, as identified in the White Paper, the regulatory bodies will be responsible for registration and licensure of health professionals, a separate IMDC will be able to focus on medical doctors and clinical associates ensuring that the quality and scope of practice covers national needs.

The SAMA strongly supports the establishment of an independent Medical Practitioner Council for the reasons mentioned above. Such a structure would be contextually appropriate within the South African framework.

### **Federal structure, decentralisation and intergovernmental relationships**

The Constitution of South Africa requires all three spheres of government to adhere to principles of co-operative government and collective efforts.<sup>97</sup> Health services are one of the concurrent competencies applicable across national and provincial governments. Provincial government can therefore pass provincial legislation on health services but is still responsible for implementation of national health legislation and policy.<sup>98</sup> Local government is responsible for municipal and environmental health functions. The National Assembly may pass legislation on functional areas of concurrent competence and to prescribe minimum norms and standards.

In terms of the Constitution healthcare is also a “federal” matter – each province individually decides, within its available budget, how to allocate resources to health

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<sup>97</sup> Section 41, *Constitution of the Republic of South Africa*, 1996

<sup>98</sup> Schedule 4 of the Constitution

care. The Constitution also makes emergency medical services an exclusive provincial competency.

Currently, Provincial Departments of Health have a budget allocated from Provincial Treasury, who in turn receive their budget from National Treasury. It is important to note that, apart from some specific earmarked grants, there is no flow of money between the National Department of Health and the Provincial Departments of Health. The ambitious changes to these processes that will have to follow in terms of NHI implementation, as set out in the White Paper, will have to be exceptionally carefully governed and controlled.

A focus on an improvement of the relationships between the three spheres of government will be essential to NHI governance. Well-fostered relationships between local government and central government on a political level regarding NHI implementation will provide the governance basis for the success thereof. Specific detail on constructive intergovernmental relationships must be provided, not only relating to NHI but also in regard to other influencing factors such as education and economic development – interrelated cooperation on all these aspects will be crucial for successful NHI governance.

It is noted that the moving of central hospitals to the national sphere (section 410 of the White Paper) must be facilitated by changes in the National Health Act and regulations for the government and management of these hospitals that still need to be promulgated. The SAMA can thus only provide a preliminary comment on the matter, supporting the concept of this movement on the basis that it should allow for more effective governance and cost savings.

There is however criticism levelled against similar structures than those proposed in the White Paper. “Brazil’s federal structure and the decentralised nature of the SUS makes it difficult to track and monitor the financial flows which in turn makes accountability diffuse and difficult. Despite continuous upgrading, existing information systems do not permit accurate identification of how resources are allocated within the context of SUS, nor how expenditures are executed and services are provided at the health unit level. Information is lacking regarding how much SUS as a whole (including

the federal, state and municipal governments) spends on hospital and primary care. The levels of efficiency in health service provision are not systematically documented”.<sup>99</sup> The importance of the openness and transparency necessary to effect good corporate governance in a universal health care system, and the importance of accurate record keeping, are emphasised through these detected failures, and should be considered a warning in terms of the current inefficiencies already plaguing the health system in South Africa.

Criticism is also levelled about the fact that governance at grass-roots level is not properly addressed in the White Paper. “If health is to be truly recognised as a human right, the contribution of health committees, which include *representation from community members to ensure full and meaningful participation is crucial in ensuring health needs are met*. Thus the scant mention of health committees as important contributors to primary healthcare planning and implementation, and a lack of state funding to support them are of concern”. Community organisations and volunteers who have a historically vested interest in the health needs of their communities through well-established community health forums will resist a top-down management approach.<sup>100</sup>

The structure of District Health Councils requires important consideration in this regard – a semi-autonomous council with a board selected in part by local authorities would have more independence from the municipal political processes.<sup>101</sup>

### **Public-private partnerships**

It is of concern to the SAMA that the White Paper does not provide detail on private-public partnerships and co-existence between the private and public sectors, nor on the governance of these relationships.

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<sup>99</sup> Couttolenc, B, La Forgia, G and Matsuda, Y. Brazil: raising the quality of public spending and resource management in the health sector. 1 September 2007. Available at: [http://www.worldbank.org/en/topic/health/research/all?count\\_exact=Brazil&qterm=&teratopic\\_exact=Public+Sector+Development](http://www.worldbank.org/en/topic/health/research/all?count_exact=Brazil&qterm=&teratopic_exact=Public+Sector+Development)

<sup>100</sup> Stinson, K, People’s Health Movement in South Africa, 18 December 2015. Available at:

[http://www.groundup.org.za/article/nhi-white-paper-good-and-bad\\_3611/](http://www.groundup.org.za/article/nhi-white-paper-good-and-bad_3611/)

<sup>101</sup> Health Systems Trust, South African Health Review 2014-2015

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For example, given that a significant number of international life sciences manufacturers have a presence in South Africa through direct manufacturing facilities, distribution operations, or licensing agreements, and noting the foreseen NHI-necessitated growth in local pharmaceutical manufacturing, transparency of information of the government's intentions in this regard is needed to ensure public trust in these activities, taking place alongside NHI. The ambitious Ketlaphela project comes to mind - which intends to manufacture active pharmaceutical ingredients in South Africa by 2017 and which is currently seeking international technology and investment partners. The manufacture of APIs (active pharmaceutical ingredients) in South Africa via Ketlaphela could potentially add another competitor to the market and increase South Africa's ability to supply increasing domestic and global supply. The governance of these and similar international relationships must be regulated to the extent that they complement NHI implementation.<sup>102</sup>

In the foreword to the 2013-2014 Annual Report of the Department of Health the Director-General of Health wrote, with reference to public-private partnerships, that the Department continued with the planning phase of seven PPP projects namely, Dr George Mukhari, Chris Hani Baragwanath Academic, new Limpopo Academic, King Edward VIII Academic, Nelson Mandela Academic, and the new Mpumalanga Tertiary, Tygerberg Academic hospital. Feasibility studies (first drafts) for Chris Hani Baragwanath Academic and new Limpopo Academic Hospitals have been presented by the respective Transactional Advisors to steering committees. The Department is reviewing the current feasibility studies and investigating a more affordable and appropriate model to be considered for implementation to the current hospital projects. Biovac Institute is still mandated to source and supply good quality EPI vaccines on behalf of the provincial departments on health. The partnership is in effect until 2016.

It is the SAMA's submission that continuance of the above projects as well as newly envisaged public-private partnerships will have to be subjected to a lot more public scrutiny to be accepted alongside NHI development.

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<sup>102</sup> Suthakaran. World Journal of Pharmaceutical Research. Vol 5, Issue 1, 2016. Available at [www.wjpr.net](http://www.wjpr.net)

## The political character of governance

It has been argued that politics and governance have been undervalued as key drivers for universal health coverage.<sup>103</sup>

“Universal health coverage has become a rallying cry in health policy, but it is often presented as a consensual, technical project. It is not. A review of the broader international literature on the origins of universal coverage shows that it is intrinsically political and cannot be achieved without recognition of its dependence on, and consequences for, both governance and politics. On one hand, a variety of comparative research has shown that health coverage is associated with democratic political accountability. Democratization, and in particular left-wing parties, gives governments particular cause to expand health coverage. On the other hand, governance, the ways states make and implement decisions, shapes any decision to strive for universal health coverage and the shape of its implementation.”<sup>104</sup>

The fact that universal health coverage and thus the NHI is expensive and redistributive makes it a contentious issue in health politics. It further adds additional contentious issues such as the access to and availability of medicines and the regulating of prices in respect of the contracting of private practitioners. “It is unwise to assume that UHC goals are entrenched in the countries that have broadly achieved them, to overstate the influence of health ministries or advocates committed to UHC, or to overstate the degree of consensus among governments that have adopted them on paper. If any generalisation about UHC holds, it is that democratisation promotes it.”<sup>105</sup>

Governance influences the adoption of universal health care – a well-crafted policy can promote political survival by biasing policymaking towards groups who defend universal health care. “Policies create politics” after all.<sup>106</sup> Without political support a redistributive policy such as NHI will have less chances of implementation. The SAMA therefore warns that the altruistic obligation to commit to NHI as set out in the White Paper must be considered a binding obligation rather than a resource for political influence.

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<sup>103</sup> Greer & Mendez, *supra*.

<sup>104</sup> Ibid

<sup>105</sup> Ibid

<sup>106</sup> Ibid

## **Human resource requirements to improve governance**

For successful governance processes the skills levels of those employed in the system will be of the utmost importance. Decentralization will demand proper leadership from managerial teams, competencies and skills in the following areas will have to be improved to allow for effective decision-making and accountability: Communication and technical writing skills, analytical abilities (applied to specific context), skills in budgeting techniques, the ability to plan and manage human resources (supervision, analysing workloads, ensuring staff composition and performance commensurate with needs), procurement management skills, the capacity to monitor and improve service delivery, understanding the need and methods to monitor and evaluate, and an inherent willingness to serve and co-operate.<sup>107</sup>

## **Conclusion**

In the words of the World Bank's Patrick Osewe, leadership and governance in terms of the NHI specifically relates to the following: "It is about the role of the government in health and its relation to other actors whose activities impact on health. This involves overseeing and guiding the whole health system, private as well as public, in order to protect the public interest".<sup>108</sup>

The WHO's Action Plan mentioned above specifically acknowledges that, in regard to universal health care goals such as those in the NHI, "moving closer to this goal requires the needed health services to be *available, of good quality and affordable*, which in turn requires attention to all the various components of a health system including infrastructure, medicines and medical products, health workers, health information and health systems financing. *Governance and leadership is critical, relevant to all of these components as well as to the interactions between them*".

The SAMA is of the opinion that the NHI requires the continued and sustainable establishment of strong governance mechanisms in all the areas of concern highlighted above – without which the NHI system will not be viable.

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<sup>107</sup> Health Systems Trust, South African Health Review 2014-2015

<sup>108</sup> World Bank representative, 8 December 2011. Presentation at NHI Conference.

## ADDENDUM A (comprehensive analysis of NHI White Paper key selected sections)

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This is a section by section analysis of the NHI white paper.

### **Chapter 3:**

Contracting in patient numbers, due to unemployment and escalating medical scheme introduction. This is largely due to hospi-centric care in lieu of cost-effective primary healthcare. This has also created entitlement mentality amongst patients who feel they need their PHC needs attended to by medical specialists.

**Paragraph 68:** *'High costs in the private health sector also contribute to high costs of labour in the public sector as the public sector attempts to match the high salaries in the private sector.'*

This is not applicable to GPs as government reimbursement through FPD is better than medical aid reimbursement. Over the last few years government has been able to recruit from private GPs due to competitive remuneration resulting in contracting of the GP market.

According to the Council for Medical Schemes 2015 Annual report, benefits paid to general practitioners have not increased despite increase in burden of disease. It should be noted that the dearth of a GP is a serious risk for the country as the profession is no longer lucrative. This will result in demand for the Specialist, international migration, or complete shift into non-health sector or cooperate health care. This will further reduce number of PHC foot soldiers.

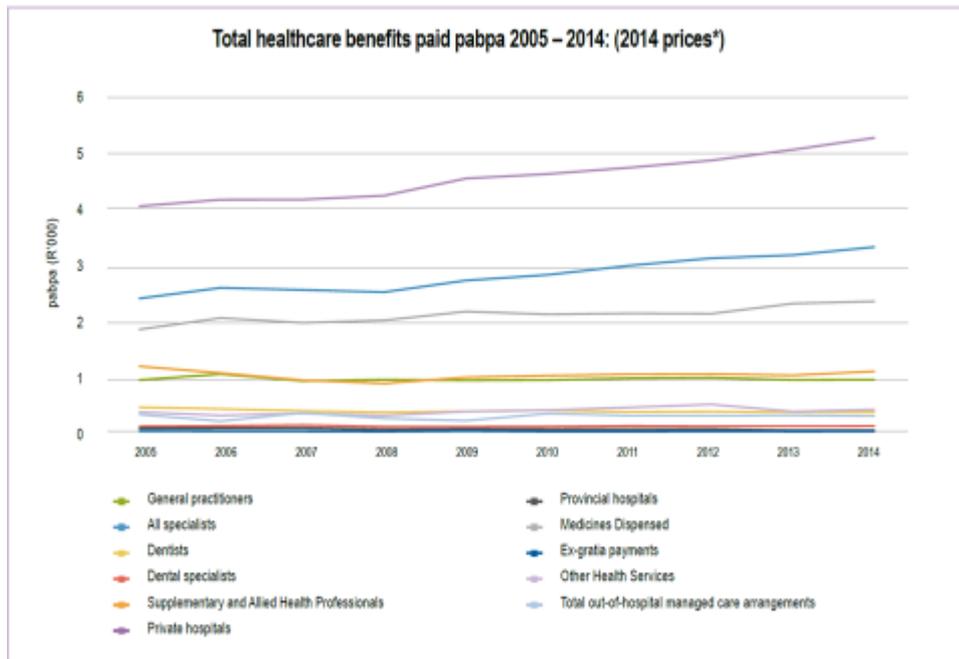


Figure 4: Total Health Expenditure in Medical Scheme Benefits: CMS report (2015)

**Paragraph 67:** 'Furthermore, the private health sector is characterised by:

- a) Exorbitant costs due largely to a fee- for-service model;
- b) Imbalance in tariff negotiations between purchasers and providers;
- c) Small and fragmented risk pools in each medical scheme, where there is limited cross subsidy between the young and old, the sick and healthy, as well as the rich and poor'.

The above is an example of poor implementation of regulations and non-harmonious regulatory framework, that is:

- Lack of understanding of the health market by the Competition Commissioner and ruling that prohibited fair and transparent negotiation of prices.
- Introduction of insurance products which undermine solidarity principle
- Failed implementation of mandatory enrolment

**Paragraph 158:** *'PHC will be the heart-beat of NHI. The PHC services include health promotion, disease prevention, curative (acute and chronic clinical) services, rehabilitation and palliative services'.*

**Paragraph 159:** *'PHC starts in the communities and is the first level of contact with the health system by individuals, the family and community. In addition, multidisciplinary and networks of practices in the private sector will form part of the first level of contact? Facility based services offered at community clinics and Community Health Centres (CHC's) and multidisciplinary practices will conform to the Ideal Clinic model. An Ideal clinic is a health facility that possesses the following characteristics'.*

**Paragraph 127:** *'The point of entry to accessing health services will be at the primary health care level with referrals to higher levels of care by providers at the PHC level. PHC services will be delivered by accredited integrated teams of providers or networks structured as multidisciplinary practices of a wide range of health care professionals such as medical practitioners, dentists, nursing professionals, pharmacists, audiologists, optometrists, physiotherapist and oral health practitioners amongst others. Those who practice as individual practitioners **will have to be part of referral networks**. The PHC providers will serve a catchment population that takes into account geographic, demographic and epidemiological profiles of the community'.*

SAMA welcomes the inclusion of referral networks as this will ensure that patients can be referred; this will ensure service access in the absence of multidisciplinary practices.

The HPCSA's ethical rule number 8 should be amended to allow integrated practice with professions not registered under HPCSA such as Nursing and Pharmacy Council

**Paragraph 162:** *'During the first phase of implementation, piloting of these activities was undertaken and lessons have been learnt. In taking these lessons forward, a fourth stream has been added to the three that were in the Green Paper on NHI. Hence, the four streams of PHC reengineering that are being implemented are...'*

The piloted contracting model was primarily **contracting in** of GPs which is day to day activity of government that is employing health care professionals. It remains unknown how the private practitioner will be engaged. This is an area that South Africa is

uninformed about and piloting **contracting out** of services to GPs and Specialist will provide valuable information on the models to be used.

**Paragraph 163.** *‘The Municipal Ward-based Primary Health Care Outreach Teams (WBPHCOTs) form a pivotal part of South Africa’s PHC re-engineering strategy. The outreach team will be led by a nurse and linked to a PHC facility. The CHWs will assess the health status of individuals in the households. They will also provide health promotion education, identify those in need of preventive, curative or rehabilitative services, and refer those in need of services to the relevant PHC facility. If implemented well, the WBPHCOTs will be a game changer’.*

Ward based PHC outreach implies that the functional units for NHI will be wards. SAMA supports ward based health care as the level of accountability and implementation is at the community level. For WBPHC to work the teams must include GPs/PHC doctors.

GP involvement at the ward level increase community participation and access to doctor based services. The GP can play a leadership role in coordinating care of patients in the wards, oversight into clinical governance and quality assessment and improvement.

**Paragraph 177:** *‘Outcomes will be measured and monitored through a performance management framework and will be in accordance with agreed upon performance standards. Eventually performance management will cover public health outcomes in a specified catchment population. For this model to be successful the clinic settings and environment must comply with the Ideal Clinic model specifications’.*

Performance management framework must be consultative and SAMA doctors must be consulted to ensure that indicators are appropriate and feasible.

**Paragraph 178:** *‘Contracting of general practitioners to provide PHC services at clinics located within the pilot districts was implemented in the 2013/14 financial year. Over 302 general practitioners have been contracted since. Available data indicates that 152 contracted general practitioners are providing services 260 PHC facilities in eight*

*pilot districts. Preliminary data indicates that for the 2014/15 financial year, approximately 34,330 patients received services delivered through these general practitioners contributing to the reduction in waiting times and improving access to needed services for the catchment populations served'.*

**Paragraph 179:** *The general practitioner contracting model has provided a platform for expanding implementation to include other health care professionals such as audiologists, optometrists, speech therapist, physiotherapists and occupational therapist amongst others. The contracting also requires a strong regulatory framework for determining the costs for health services and the tariffs that should be charged. This will influence the cost of health service delivery and the ability of the NHI to sustainably contract with all accredited providers.*

The **contracting in** of GPs is similar to employment of GPs by the state. Different logistics are involved in **contracting out**. Transparent and inclusive /consultative cost determination of health services is imperative. Prices must be reviewed annually.

SAMA recommends the establishment of Pricing Commission. A strong regulatory framework is required to ensure no gaming by the funder.

**Paragraph 180:** *'Contracting for pharmaceutical services will also be undertaken to facilitate improved access for patients that have been stabilised. This will be achieved through determining medicine collection points in the community such as schools, churches and community Pharmacies'.*

Community GP practices must be included as collection points particularly for high risk patients **i.e. those poorly controlled on chronic treatment, risk of drug to drug interactions, non-adherent, teenagers, mental health etc.**

**Paragraph 181:** *'In the next phases of implementation, private providers at the PHC level will be contracted and reimbursed through a capitation model where appropriate instead of a FFS as it is happening currently'.*

**Paragraph 335:** *'The NHI Fund in consultation with the Minister will determine its own pricing and reimbursement mechanisms. Providers who wish to contract with the NHI Fund must comply with the stipulated pricing and reimbursement mechanisms.'*

This will be an uninformed phase and can be disastrous unless government tests it in the pilot phase.

**It is very important that the cost be determined to inform the reimbursement model be evidence-based (practice cost-studies), transparent, negotiated, realistic and sustainable. Capitation fee determination, is very complex and need to take into consideration geographic variation, burden of disease, size population.**

The proposed methodology in paragraphs 351 to 354 will be inappropriate for GP practices. The health expenditure in the public sector often does not include overhead costs. The private sector has to bear overhead costs such as administration, capital expenditure, administrative costs and marketing. The proposed methodology is unacceptable and unconstitutional.

### **Paragraph 331 (Accreditation of Providers by NHI Fund)**

*'Health service benefits to which the population is entitled will be delivered by public and private providers that have been accredited and contracted by the NHI Fund. The accreditation process will require providers to firstly meet the minimum quality norms and standards and be certified by the OHSC, and where relevant by the appropriate statutory professional council, which will continue to register and license professionals in line with national health legislation as shown **Figure 5**'.*

### **SAMA Comment on the 'RESYST' box (paragraph 330)**

NHIF must involve the doctor and SAMA will represent their members in implementing the activities stipulated.

**Paragraph 332:** *'Accreditation by the NHI Fund will be based on the health needs of the population and will require provider compliance with specific information and performance criteria. One of the criteria for accreditation of a provider to be eligible for*

*purchasing of services by the NHI Fund will be the routine submission of specified information. This will include the following information for each patient:'*

Where applicable must be added as length of stay and discharge summaries cannot be provided in ambulatory primary health care

**Paragraph 354** *'To deal with any potential adverse effects of capitation funding<sup>49</sup>, there will be routine monitoring of provider practices, particularly in relation to the use of treatment protocols and clinical guidelines for key diagnoses and referral patterns. This will include both peer review at the district level and monitoring by the NHI Fund through analysis of diagnosis, treatment and referral information'.*

The performance standards must be predetermined, and assessment be objective.

**Paragraph 335.** *'The NHI Fund in consultation with the Minister will determine its own pricing and reimbursement mechanisms. Providers who wish to contract with the NHI Fund must comply with the stipulated pricing and reimbursement mechanisms'.*

**This statement is unconstitutional, undemocratic, unconstitutional, draconian, totalitarian, dictatorial and unacceptable.**

**Paragraph 336:** *'Performance will be monitored and appropriate sanctions will be applied where there is deviation from contractual obligations. The contracts will also stipulate the reimbursement strategy that will be applied. Contracts will be reviewed on a regular basis taking into account health system priorities, epidemiological changes and provider performance. The performance of the contracted providers will be monitored and evaluated by the Performance Monitoring Unit of the NHI Fund'.*

SAMA must be involved in negotiating contracts. Sanctions should also apply to public sector too. Hence need for transparent and publication of performance indicators for scrutiny by public.

**Paragraph 339:** *'The EDL guidelines are the most extensive treatment guidelines available in South Africa, and have been developed through a process of evidence review and consultation. The overall approach guiding choices of what is included in the guidelines is evidence-based with extensive peer review. In making these choices, principles that are considered include:'*

The methodology for developing guidelines must be in accordance with international standards of guideline development. PMB treatment algorithms are outdated.

**Paragraph 342:** *'The NHI Fund will establish Clinical Peer Review Committees with transparent and accountable processes to mitigate the potential impact of perceived inflexibility of treatment...'*

**Paragraph 340:** *'The guidelines are reviewed and updated over a three-year cycle to take account of new technology and evidence. These guidelines cover 80 percent of the most prevalent conditions in South Africa. However, they focus on conditions that could require drug therapy at some stage (given that the focus was on drawing up guidelines to accompany the EDL). Thus, conditions that require purely surgical procedures are not included. In addition, anaesthesia, treatment of malignancies, oral health outside of hospitals and optometry represent a gap in the current guidelines. The EDL guidelines will form the basis of the treatment guidelines for the NHI, along with those developed by the Department of Health. The treatment algorithms that have been developed for PMB conditions in terms of the Council for Medical Schemes regulations should be reviewed to assess if they can be used to complement the EDL and Department of Health Treatment Guidelines.'*

The NHI information system must interphase with all existing electronic records systems.

Paragraph 74: *'According to the CMS 2014 Annual Report<sup>13</sup>, the total cost of prescribed minimum benefits (PMBs) for the schemes included in this analysis amounted to R53.7 billion. For these same schemes, R102.2 billion was paid from the risk pool for all benefits including PMBs. This means PMBs consume more than 50% of the schemes expenditure (constituting 52.5% of the total risk benefits), as opposed to the 47.5% paid to non-PMB related conditions. Prior to the 2010 CMS circulars<sup>14</sup> on PMBs, the crude estimates indicated that in 2008 PMBs consisted of 35% of the risk pool benefits paid for by medical schemes. The cost of PMBs is mainly driven by amongst others:*

*c) The increased prevalence of chronic conditions and disease burdens which are provider driven and where it is mandatory for schemes to reimburse'*

- This is due to crowding of benefits

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- Increased prevalence of disease and improved detection through screening