STRATEGIC PLAN

2015/16 - 2019/20

OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care

Office of Health Standards Compliance

Improving the quality of healthcare in South Africa

STRATEGIC PLAN

For the Fiscal Years 2015/16 to 2019/20

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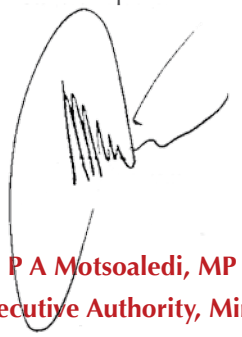
FOREWORD BY THE MINISTER OF HEALTH

This Strategic Plan for the years 2015 to 2020 has been developed by the Office of Health Standards Compliance (OHSC). It represents the understanding and aspirations of the Board of the OHSC to ensure that through their considered and responsible actions, they can together with the staff of the Office as it grows into maturity over the coming years to make a real difference to the quality and safety of healthcare delivered through all health establishments in South Africa, and to definitely shift the provision of health services towards the interests and legitimate expectations of the users of our healthcare services.

In doing this, we are cognisant of the powers vested in the Office by the National Health Amendment Act, 2013 (Act No. 12 of 2013) and of the expectations and trust placed in the Office by the public and all those who speak for them; while not forgetting the honest and dedicated efforts on the part of the many thousands of healthcare workers who strive every day to do the best they can for their patients and communities.



Dr P A Motsoaledi, MP
Executive Authority, Minister of Health

OHSC CHAIRPERSON'S FOREWORD AND INTRODUCTORY NOTE

Access to quality health care for South Africans reflects the constitutional obligations contained in the Bill of Rights. In carrying out its mandate and function for the Medium Term Strategy Framework (MTSF) period, the OHSC's vision is to contribute to safe and quality health care by reducing avoidable mortality, morbidity and harm within health establishments through reliable and safe health services; and improving the availability, responsiveness and acceptability of health services for users.

Protecting and Promoting health and safety

The National Health Amendment Act, 2013 (Act No. 12 of 2013) provides for quality requirements and standards in respect of health services provided by health establishments in both the public and private health sectors, in order to promote and protect the health and safety of the users of health services and thus contribute to improved outcomes.

Improving responsiveness of health services to the users

According to World Health Organisation (WHO) responsiveness covers how and how well the health system meets the legitimate expectations of the population and includes the elements of dignity, confidentiality, autonomy, prompt attention, social support, basic amenities, and choice of provider. Developing and sustaining such responsiveness in the health sector through effective monitoring, certification and enforcement of legislated norms and standards is the OHSC's role and responsibility, including the "manner in which users are accommodated and treated" in accordance with Section 47 of the National Health Act, 2003 (Act No. 61 of 2003).

Earlier preparatory work was done by the OHSC within the National Department of Health (NDoH) towards the establishment of the OHSC as a Schedule 3A public entity. The new independent OHSC has existed in law since the National Health Amendment Act (NHAA) was proclaimed by the President on 2nd September 2013. In January 2014, the Minister of Heath, Dr. Aaron Motsoaledi appointed the first OHSC Board for a three year term of office, and an interim Chief Executive Officer (CEO) was appointed for the period April 2014 to July 2015. In August 2015 an Acting CEO was appointed and appointments to the OHSC Executive Team and to all approved units of the entity are continuing to be made.

The OHSC's Strategic Plan is guided by the Strategic Planning and the MTSF. This revised Strategic Plan for 2015-2020 heralds a new phase in cooperating and strengthening relationships with health sector and other partners to facilitate and support the implementation of norms and standards at all levels of care. Strengthening health systems for the achievement of the Sustainable Development Goals, National Development Plan Goals, National Health Insurance (NHI) and the National Service Delivery Agreement outcomes and outputs is critical going

forward.

The process of establishing an efficient office is an ongoing and evolving process. Communication with internal and external role players regarding their engagement and participation is essential and the OHSC is in the process of creating platforms to further engage staff and build strong, competent and dynamic teams.

I would like to thank the OHSC Management and staff for their cooperation, hard work and support in setting up the OHSC. I would especially like to express my appreciation and support to the Minister of Health, Dr Aaron Motsoaledi, the Director-General, Ms Malebona Matsoso and the NDoH officials.

I also wish to extend my heartfelt gratitude and acknowledge the previous OHSC Board for the remarkable job and dedication during its term of office:

a) Professor Laetitia Rispel – OHSC Deputy Chairperson

b) Dr. Zameer Brey

c) Professor Sabiha Yusuf Essack

d) Ms. Thembeka Gwagwa

e) Mr. Martin Kuscus

f) Advocate Sammy Lebala SC

g) Ms. Josephine Mabotja

h) Professor Ethelwynn Stellenberg

i) Professor Gert Van Zyl

j) Professor Stuart Whittaker

The final acknowledgement is to my fellow Board members who will be serving on this Board until December 2019 and are part of this important journey:

a) Professor Ethelwynn Stellenberg

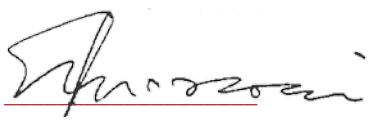
b) Professor Stuart Whittaker

c) Mr. Abdul Kariem Hoosain

d) Dr. Bandile Masuku

e) Ms. Audrey Montshiwa

f) Mr. Bada Pharasi

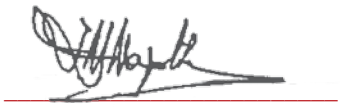


Professor Lizo Mazwai
Chairperson of the Board

OFFICIAL SIGN-OFF

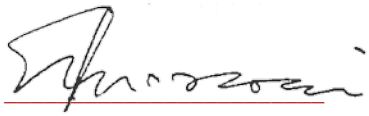
It is hereby certified that this OHSC revised Strategic Plan:

- Was developed by the management of the OHSC under the guidance of the OHSC Board;
- Takes into account all the relevant policies, legislation and other mandates relevant to the Office; and
- Reflects the strategic outcome oriented goals and objectives which the OHSC will endeavour to achieve over the period 2015 to 2019.



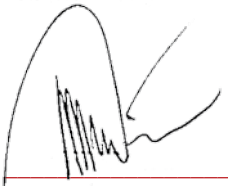
Mr. J. Mapatha
Chief Financial Officer
Date: 31/01/2017

Mr. Bafana Msibi:
OHSC Acting CEO
Date: 31/01/2017



Professor Lizo Mazwai:
OHSC Chairperson
Date: 31/01/17

Approved by:



Dr P.A Motsoaledi, MP
Executive Authority, Minister of Health
Date: 6/3/2017

PART A

STRATEGIC OVERVIEW

PART A: STRATEGIC OVERVIEW

1. OHSC MANDATE

"Protect and promote the health and safety of users of health services by:

- Monitoring and enforcing compliance by health establishments with norms and standards prescribed by the Minister in relation to the national health system; and
- Ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner"

This mandate contributes to two distinct but interdependent regulatory outcomes. These are:

- Reductions in avoidable mortality, morbidity and harm within health establishments through reliable and safe health services; and
- Improvements in the availability, responsiveness and acceptability of health services for users.

2. OHSC VISION

Safe and Quality Healthcare for all South Africans

3. OHSC MISSION

We act independently, impartially, fairly and fearlessly on behalf of the people of South Africa in guiding, monitoring and enforcing health care safety and quality standards in health establishments

4. OHSC VALUES AND PRINCIPLES

Our values are informed by the South African Constitution and Batho Pele Principles:

"Human dignity; freedom and the achievement of equality; and that people must come first"

"To protect and promote the health and safety of health services users"
implies that we:

1. Act as the champion of the public and of healthcare users so as to restore credibility and trust;
2. *Respect healthcare users and their families as well as healthcare staff;*
3. *Push for effectiveness in achieving health system change and social impact;*
4. *Strive for excellence, innovation and efficiency in our operations;*
5. *Are truthful, fair and committed to intellectual honesty;*
6. *Practice transparency but respect confidentiality;*
7. *Achieve the highest standards of ethical behaviour, teamwork and collaboration; and*
8. *Promote professionalism, compassion, diversity, and social responsibility.*

5. OHSC REGULATORY PRINCIPLES

Five principles guide the daily operations and regulatory decisions of the OHSC in line with good regulatory practice and enable evaluation of its performance as a regulator.

Principle 1: Regulation must foster greater accountability

Regulation must set explicit benchmarks for regulated entities against which they can be measured objectively and those in charge can be held accountable for compliance. Regulators are also accountable for their regulatory decisions and the achievement of regulatory outcomes.

Principle 2: Regulation must be clear and transparent

Regulation should be clear, specific and explicit about the obligations placed on regulated entities and the reasons for these obligations. Regulatory decisions (or summaries thereof) should be published and subject to public scrutiny. Adequate relational distance between the health establishment subject to regulation and the regulator must ensure the necessary autonomy for it to make decisions in line with its mandate

Principle 3: Regulation should be targeted

Regulation should target the problem or risk it has been established to address and regulatory outcomes should identify clearly the 'end-result' of the regulatory intervention while minimising any unintended consequences that may undermine the effectiveness of regulation.

Principle 4: Regulatory interventions should be proportionate

Regulatory interventions should be proportional to the regulatory problem or risk that they seek to address, and the minimum necessary to achieve objectives, being only one of a range of ways of achieving policy objectives. Regulation should avoid overly punitive approaches and resultant compliance-driven responses by regulated entities. Regulation should further avoid undue crisis-based response which may undermine the regulatory programme.

Principle 5: Regulation should be applied consistently and yield reliable decisions

Regulatory and enforcement processes and procedures should be consistent to ensure that decisions are reliable and rigorous, where internal rules govern regulatory processes and that staff are trained and capable of administering regulation in a consistent manner.

6. LEGISLATIVE AND OTHER MANDATES

6.1. Legislative Mandates

As part of overall health system strengthening to address and improve health service delivery, improving quality is fundamental in improving South Africa's current poor health outcomes. Better quality of care will restore patients' and staff confidence in the public and private health care system.

Quality in the health system can be defined as getting the best possible results with the available resources. A number of governing acts, regulations and policies influence the quality of healthcare in South Africa, including the following:

6.1.1. Constitution of the Republic of South Africa, Act No.108 of 1996

Underpinning the entire health system are the constitutional imperatives enshrined in the Bill of Rights. Specifically, Section 27 of the Constitution guarantees everyone the right of access to healthcare services, including reproductive health services and emergency medical treatment. The Constitution further requires the State to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right.

The realisation of socio-economic rights has been tested multiple times by the Constitutional Court in relation to housing, social assistance and health rights. In the majority of these decisions, the Constitutional Court examined the reasonableness of government measures in realising these socio-economic rights (James, 2012). Put differently, the Courts focused on whether government had sufficient plans and policies in place to fulfil the obligations set out in the Bill of Rights. The regulation of the quality of health services charts a path for all health establishments to comply with policy priorities and minimum standards of care. In this manner, the regulation of quality contributes directly to government's progressive realisation of its constitutional obligations.

The constitutional imperatives set out in the Bill of Rights cannot be achieved without the collective efforts of all spheres of government. Hence, Section 41 of the Constitution requires all three spheres of government to work cooperatively to secure the wellbeing of the people of the Republic, and to preserve the peace, national unity and indivisibility of the Republic. This principle of cooperative government is particularly important in health services, which are a functional area of concurrent competence across national and provincial governments as defined in Schedule 4 of the Constitution.

National government is responsible for developing and monitoring policies, legislation and norms and standards for the health sector. Provincial government can discharge their constitutional obligations by passing provincial legislation in the area of health services, but remain responsible for the implementation of national policy and legislation, while local government is responsible for municipal and environmental health functions. Section 44

of the Constitution gives the National Assembly the authority to pass legislation with regard to functional areas of concurrent competence and to prescribe minimum norms and standards.

6.1.2. The National Health Act, 2003 (the Act)

The Act re-affirms the constitutional rights of users to access health services and just administrative action. As a result, Section 18 allows any user of health services to lay a complaint about the manner in which he or she was treated at a health establishment. The Act further obliges MECs to establish procedures for dealing with complaints within their areas of jurisdiction. Complaints provide useful feedback on the areas within health establishments that do not comply with prescribed standards or pose a threat to the lives of users and staff alike.

The Act provides the overarching legislative framework for a structured and uniform national healthcare system. It highlights the rights and responsibilities of healthcare providers and healthcare users, and ensures broader community participation in healthcare delivery from a health facility level up to national level. With respect to the sections now being amended, although never promulgated, the Act provided for the creation within the NDoH of an OHSC with provincial Inspectorate units. The OHSC as then envisaged would advise on health standards, carry out inspections and monitor compliance, report on non-compliance, issue or withdraw a certificate of compliance, and advise on strategies to improve quality and included an Ombud.

6.1.3. The National Health Amendment Act (2013)

Chapter 10 of the National Health Act relating to the OHSC was repealed in its entirety (and other minor changes were enacted) through the promulgation of the National Health Amendment Act No 12 of 2013, which replaced the previous provisions (that had never been brought into effect) with a new independent entity, the OHSC.

The Objects of the Office are reflected in the Act as being:

To protect and promote the health and safety of users of health services by:

1. *Monitoring and enforcing compliance by health establishments with norms and standards prescribed by the Minister in relation to the national health system; and*
2. *Ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner"*

In terms of the Act the OHSC must:

- **Advise the Minister** on matters relating to the determination of norms and standards to be prescribed for the national health system and the review of such norms;
- **Inspect and certify** health establishments as compliant or non-compliant with prescribed norms and standards, or where appropriate and necessary, withdraw such certification;
- **Investigate complaints** relating to the national health system;
- **Monitor indicators of risk** as an early warning system relating to serious breaches of norms and standards and report any breaches to the Minister without delay;
- **Identify areas and make recommendations for intervention** by a national or provincial department of health or a health department of a municipality, where it is necessary, to ensure compliance with prescribed norms and standards;
- **Recommend quality assurance and management systems** for the national health system to the Minister for approval;
- **Keep records** of all its activities; and
- **Advise the Minister** on any matter referred to it by the Minister.

In addition the OHSC may:

- **Issue guidelines** for the benefit of health establishments on the implementation of prescribed norms and standards;
- **Publish any information relating to prescribed norms and standards** through the media and, where appropriate, to specific communities;
- **Collect or request any information relating to prescribed norms and standards** from health establishments and users;
- **Liaise with any other regulatory authority** and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority in respect of (i) matters of common interest; or (ii) a specific complaint or investigation; and
- **Negotiate cooperative agreements with any regulatory authority** in order to (i) coordinate and harmonise the exercise of jurisdiction over health norms and standards; and (ii) ensure the consistent application of the principles of this act.
- **OHSC enforcement powers given the mandate and functions** (would be investigated and communicated to the Board by TA legal advisor).

6.1.4. The Protection of Personal Information Act (PoPI) (2013)

The purpose of the PoPI Act is to ensure that all South African institutions conduct themselves in a responsible manner when collecting, processing, storing and sharing another entity's personal information by holding them accountable should they abuse or compromise personal information in any way.

The PoPI legislation basically considers personal information to be "precious goods" and therefore aims to bestow upon owners of personal information, certain rights of protection and the ability to exercise control over:

- when and how to share information (requires individual consent);
- the type and extent of information individuals choose to share (must be collected for valid reasons);
- transparency and accountability on how your data will be used (limited to the purpose) and notification if/when the data is compromised;
- providing individuals with access to personal information as well as the right to have personal data removed and/or destroyed should individuals so wish;
- who has access to personal information, i.e. there must be adequate measures and controls in place to track access and prevent unauthorized people, even within the same company, from accessing your information;
- how and where personal information is stored (there must be adequate measures and controls in place to safeguard personal information to protect it from theft, or being compromised);
- the integrity and continued accuracy of personal information (i.e. personal information must be captured correctly and once collected, the institution is responsible to maintain it).

6.1.5. Promotion of Access to Information Act No. 2 of 2000(PAIA)

Section 32(1)(a) of the Constitution of the Republic of South Africa Act, No. 108 of 1996 (hereinafter referred to as "the Constitution") provides that everyone has a right of access to any information held by the state and any information held by another person that is required for the exercise or protection of any rights. PAIA gives all South Africans the right to have access to records held by the state, government institutions and private bodies.

The following are the objectives which PAIA seeks to achieve:

- To ensure that the state takes part in promoting a human rights culture and social justice;
- To encourage openness and to establish voluntary and mandatory mechanisms or
- procedures which give effect to the right of access to information in a speedy, inexpensive and effortless manner as reasonably possible;
- To promote transparency, accountability and effective governance of all public and private bodies, by empowering and educating everyone to understand their rights in terms of PAIA so that they are able to exercise their rights in relation to public and private bodies,
- To understand the functions and operation of public bodies; and
- To effectively scrutinise, and participate in decision making by public bodies that affects their rights.

6.1.6. Other Acts relevant to the delivery of health services

From the National Health Act which has been amended, the identified acts would have influence the OHSC mandate and functions and they include:

Medical Schemes Act No. 131 of 1998	Provides for the regulation of the medical schemes industry to ensure consonance with national health objectives.
Medicines and Related Substances Act No. 101 of 1965	Provides for the registration of medicines and other medicinal products to ensure their safety, quality and efficacy. The Act also provides for transparency in the pricing of medicines.
National Health Laboratory Service Act No. 37 of 2000	Provides for a statutory body that provides laboratory services to the public health sector.
Health Professions Act No. 56 of 1974	Provides for the regulation of health professions, in particular medical practitioners, dentists, psychologists and other related health professions, including community service by these professionals.
Pharmacy Act No. 53 of 1974	Provides for the regulation of the pharmacy profession, including community service by pharmacists.
Nursing Act No. 33 of 2005	Provides for the regulation of the nursing profession.
Allied Health Professions Act No. 63 of 1982	Provides for the regulation of health practitioners such as chiropractors, homeopaths and others, and for the establishment of a council to regulate these professions.
Dental Technicians Act No. 19 of 1979	Provides for the regulation of dental technicians and for the establishment of a council to regulate the profession.
Hazardous Substances Act No. 15 of 1973	Provides for the control of hazardous substances, in particular those emitting radiation.
Foodstuffs, Cosmetics and Disinfectants Act No. 54 of 1972	Provides for the regulation of foodstuffs, cosmetics and disinfectants, in particular, setting quality and safety standards for the sale, manufacturing and importation thereof.
Occupational Diseases in Mines and Works Act No. 78 of 1973	Provides for medical examinations of persons suspected of having contracted occupational diseases, especially in mines, and for compensation in respect of those diseases.
Human Tissue Act No. 65 of 1983	Provides for the administration of matters pertaining to human tissue.

6.1.7. Entity Specific Legislation applying to health establishments and the OHSC as relevant

The following Acts of Parliament are pertinent to the OHSC mandate and administrative compliance functions and they include:

Public Finance Management Act no 29 of 1999	Regulates financial management in the national government and provincial governments
Basic Conditions of Employment Act No. 75 of 1997	Provides for the minimum conditions of employment that employers must comply with in their workplaces.
Occupational Health and Safety Act No. 85 of 1993	Provides for the requirements that employers must comply with in order to create a safe working environment for employees in the workplace.
State Information Technology Act No. 88 of 1998	Provides for the creation and administration of an institution responsible for the State's information technology system.
Child Care Act No. 74 of 1983	Provides for the protection of the rights and well-being of children.

Public Service Act No. Proclamation 103 of 1994	Provides for the administration of the public service in its national and provincial spheres, as well as for the powers of Ministers to hire and fire.

The following Acts of Parliament are pertinent to OHSC administrative compliance

- Promotion of Administrative Justice Act No. 3 of 2000
- Labour Relations Act No. 66 of 1996
- Compensation for Occupational Injuries and Diseases Act No. 130 of 1993
- The Division of Revenue Act No. 7 of 2003
- Skills Development Act No. 97 of 1998
- Preferential Procurement Policy Framework Act No. 5 of 2000
- Employment Equity Act No. 55 of 1998
- The Competition Act No. 89 of 1998
- The Copyright Act No. 98 of 1998
- The Patents Act No. 57 of 1978
- The Merchandise Marks Act No. 17 of 1941
- Consumer Protection Act No 68 of 2008

6.2 Policy Mandates

6.2.1. National Policy on Quality (2007)

A focus on quality assurance and quality improvement is not a new concept. A National Policy on Quality in Healthcare was initially developed for South Africa in 2001 and revised in 2007. The policy identifies mechanisms for improving the quality of healthcare in both public and private sectors. It highlights the need to focus capacity-building efforts and quality initiatives on health professionals, communities, patients and the broader healthcare delivery system NDoH,

Hence, the objectives of the National Policy on Quality were to:

- improve access to quality healthcare;
- increase patients' participation and the dignity afforded to them;
- reduce underlying causes of illness, injury, and disability;
- expand research on treatments specific to South African needs and on evidence of effectiveness;
- ensure appropriate use of services; and
- reduce errors in healthcare.

6.2.2. Batho Pele and the Patient's Rights Charter

In addition to health-specific policies and legislation, Batho Pele principles govern all public services including healthcare delivery. Batho Pele, a Sotho translation for "People First", is an initiative to get public servants to be service-oriented, to strive for excellence in service delivery, and to commit to continuous service delivery improvement. Batho Pele sets out eight principles to enhance the delivery of public services (Republic of South Africa, 2007). These include obligations on public agencies to:

- Regularly consult with customers;
- Set service standards;
- Increase access to services;
- Ensure higher levels of courtesy;
- Provide more and better information about services;
- Increase openness and transparency about services;
- Remedy failures and mistakes; and
- Give the best possible value for money

The specific commitment of the health sector to this basic policy of government was the development and extensive promulgation of the "Patient's Rights Charter" which is re-iterated in the National Core Standards (NCS). This specifies that the most critical rights of patients are to be respected and upheld, including the rights of access to basic care and to respectful, informed and dignified attention in an acceptable and hygienic environment. Patients should be empowered to make suitably informed decisions about their health, and to complain if they have not received decent care. The Patients' Rights Charter specifies that the universal health rights of patients are to be respected and upheld, including the rights of access to healthcare by users and to be treated respectfully

6.2.3. National Core Standards for Health Establishments in South Africa

The "NCS for health establishments in South Africa" have gone through successive phases of development based on input from the numerous stakeholders involved in the process as well as extensive use in the field, and have since formed the basis for proposal on norms and standards to be prescribed in law. The document was finally approved by the policy-making body (the National Health Council) and issued by the Minister in February 2011.

This set of standards was based on the existing policy environment and tailored to South Africa's healthcare context, while also reflecting international best practice and a strong evidence base. The purpose of the NCS has been to:

- "develop a common definition of quality care which should be found in all health establishments in South Africa, as a guide to the public and to managers and staff at all levels;
- establish a benchmark against which health establishments can be assessed, gaps identified and strengths appraised; and
- provide for the national certification of compliance of health establishments with mandatory standards."

A subset of these standards, focusing on six critical areas of most concern to patients, has been prioritised throughout the public health system. These areas are:

- Values and attitudes
- Waiting times
- Cleanliness
- Patient and staff safety and security
- Infection prevention and control
- Availability of medicines and supplies

6.2.4. National Health Insurance (NHI)

In order to address previous historical inequities and to ensure universal coverage for all South Africans, government adopted on NHI as the means to transform the health system and grant all citizens access to good quality health services irrespective of their socio-economic status. NHI is based on the principles of universal coverage, right of access to basic health care and social solidarity. These principles are intertwined with the concept of equity. In August 2011, the NDoH released the Green Paper on NHI (Government Gazette Vol 554. No 34523, 12 August 2011) for public comment and in December 2011, the NDoH convened an NHI conference with international experts to draw lessons from developed and developing countries in developing an approach for universal coverage for South Africa.

NHI as proposed by the NDoH is not just a new financing mechanism for the health system but a system for ensuring solidarity in the delivery of good quality services, accessible to all South Africans. An effective and well-functioning health quality system with effective implementation of set standards and norms is therefore essential for the successful execution application of NHI.

In facilitating and supporting overall health systems strengthening, the NDoH is focusing on key enablers of improved delivery including the completion of the Human Resources Strategy, re-engineering of primary health care, improved governance and a focus on re-building and rehabilitating the dilapidated infrastructure. On the other hand, there is a focus on the issue of costs and affordability of private healthcare; and the recognition that the requirement for and right to quality care and the need for monitoring and enforcement of this is pertinent to both public and private sectors.

The Green Paper as well as subsequent policy pronouncements proposes that certification by the OHSC with respect to quality norms and standards will be a prerequisite in the future for accessing funding from the NHI fund. A White paper on NHI was published for public comments in December 2015.

6.2.5. National Development Plan

In June 2011 the National Planning Commission released its Diagnostic Report which set out South Africa's achievements and shortcoming since 1994. It identified a failure to implement various policies and an absence of broad partnerships as the main reasons for slow progress, and set out nine primary challenges:

a. Too few people work;

b. The quality of school education for black people is poor;

c. Infrastructure is poorly located, inadequate and under-maintained;

d. Spatial divides hobble inclusive development;

e. The economy is unsustainable resource intensive;

f. The public health system cannot meet demand or sustain quality;

g. Public services are uneven and often of poor quality;

h. Corruption levels are high; and

i. South Africa remains a divided society.

The NDP aims to eliminate poverty and reduce inequality by 2030. Nineteen years into democracy, South Africa has made a number of gains on the economic front, in particular on its macro-economic policy. However, health challenges are more than medical. Behaviour and lifestyle also contribute to ill-health. To become a healthy nation, South Africans need to make informed decisions about what they eat, whether or not they consume alcohol, and their sexual behaviour, among other factors.

The NDP Vision 2030 states that a health system that works for everyone and produces positive health outcomes is not out of reach. It is possible to:

a. Raise the life expectancy of South Africans to at least 70 years;

b. Ensure that the generation of under-20s is largely free of HIV;

c. Significantly reduce the burden of disease; and

d. Achieve an infant mortality rate of less than 20 deaths per thousand live births, including under-5 mortality rate of less than 30 per thousand.

The NDP Chapter on Health, Priority 2 on "strengthening the health system", includes the role of the OHSC as the independent entity mandated to promote quality by measuring, benchmarking and accrediting actual performance against standards for quality. The OHSC will be responsible for ensuring that standards are met in every sphere and at every level. Specific focus will be on achieving common basic standards in the public and private sectors.

6.2.6. Regulated Norms and Standards

Proposed norms and standards to be regulated were published by the Minister of Health for comment in February 2015 as per Section 90 (b) and (c) of the National Health Act as amended. The comments received from the public were considered by the OHSC and constructive comments incorporated into the proposed norms and standards. The proposed norms and standard were further reviewed in 2016 and were re-published for public comments in January 2017. These proposed norms and standards are intended to apply to the following categories of health establishments:

- Public sector hospitals set out in the regulations relating to the categories of hospital as per notice in Gazette No. 35101;
- Public sector clinics;
- Public sector community health centres;
- Private sector acute hospitals; and
- Private sector primary health care clinics or centres.

The norms and standards regulations applicable to other categories of health establishments contemplated in the Act will be developed by OHSC for advice and recommendation to the Minister to prescribe specific norms and standards for such categories.

The proposed norms and standards to be prescribed are in large part informed by the "*National Core Standards for Health Establishments"* published in 2011 after approval by the National Health Council. The OHSC has undertaken a process of extensive consultation since 2013 in order to correct errors, clarify ambiguities, ensure measurability and better align the framework of Domains and Sub-domains as areas of risk. Significant new health system policy developments over the preceding few years have also resulted in the need to update the standards, as is standard practice with respect to standards. This has included those standards relevant to patient experience of care, Primary Health Care (PHC), governance and management of hospitals and clinics, strengthening clinical safety and health programmes including infection prevention and control, the introduction of anti-microbial resistance as an area of risk, and updating the areas of environmental health, infrastructure, equipment and medicine management. The proposed norms and standards to be prescribed have been reviewed by (the International Society for Quality in Healthcare (ISQUA)) in relation to principles of norms and standards for quality care in the health sector.

These future regulations will articulate the level of quality and safety expected from health establishments and set out objective benchmarks against which they will be measured in terms of the powers given to the Office to monitor, certify and enforce such compliance and to monitor early warning indicators of risk indicating a breach of norms and standards. They will also inform the exercise of the powers of the Ombud placed within the Office to investigate complaints relating to breaches of these norms and standards. The proposed regulations are "performance-based" and place an obligation on all health establishments to comply with the prescribed criteria as well as to meet the intent of the standard.

As mandatory standards they are designed to meet criteria for good regulatory practice in that they are risk-based with a focus on different types of risk (physical, health, reputational and financial); consistent with the objectives of the Act; targeted in that they solve the right problem; reliably measureable; and legally enforceable. They derive in large part from existing national policies or legislation but may go beyond these where the health or safety of users requires this. The cost of implementation is considered to be proportionate to the benefits; this also means however that there are standards that may, within the existing under-resourced healthcare environment, be difficult for some health establishments to achieve but which are directly linked to patient rights, basic care needs and patient safety. These are still proposed for regulation even though this may result in additional resource requirements for the health system. Standards and norms that do not meet all criteria for mandatory or regulated standards but are considered important as enablers of quality and safety provisions may still be published by the Office as guidelines.

These norms and standards proposed for regulation do not specify targets (quantitative norms) or precise indicators of risk as no reliable benchmarks (or policies where relevant) yet exist as a basis for this. They do specify the requirement to report on current parameters for quantitative norms and for indicators of risk; the inspection process will gather data on this which will then be used by the OHSC to make recommendations and advise the Minister on targets for norms to be prescribed and for reporting on risk as per the OHSC's legislated functions (s79 (1) (a) and (d) the NHAA).

The proposed norms and standards regulations also do not specify the measurement criteria and tools to be used to determine compliance, nor the guidance to be issued by the Office.

6.2.7. Procedural Regulations

The procedural regulations which have since been promulgated by the Minister and published in the Gazette on 13 October 2016 guide the exercise of powers conferred on the Office, the Board, the CEO, the Ombud and the Inspectors by the Amendment Act. The regulations elaborate on the form of details, procedures and processes to be followed by the Office.

Areas covered in these Regulations are:

- Collection of information from health establishments and the designation and duties of the person in charge;
- Inspectors and inspections including their appointment, training, experience and conduct and the inspection approach and process including notice and additional inspections;
- Entry and search of premises including procedures to obtain prior consent or the application for a warrant, if required;
- Processes of certification, renewal and suspension;
- Compliance notice, enforcement process including formal hearing, revocation of certificate, fines or referral to prosecuting authority, appeals, and reporting;
- Complaints handling, investigation and the resolution procedures, lodging of complaints, their screening, investigation and reporting, and time frames; and
- General provisions regarding the prescribed forms to be used (listed in schedule 1)

The procedural regulations are applicable to all categories of health establishments as per the NHA.

The provision for a formal hearing (and the process) before revocation of a certificate of compliance or imposition of a fine is not explicitly authorised by or contained in the Act. However, as these are drastic actions they cannot be done without following due progressive process, and a hearing ensures compliance with the rules of natural justice. The provision for a formal hearing could have been provided for in the NHAA, but providing for it in procedural regulations is not felt to render them or the relevant section *ultra vires*.

While the regulations speak about a notice of inspection to be handed to the establishment, this is done on arrival at the site thus rendering the inspection effectively unannounced in line with recognised best practice to protect the health and safety of users. Administrative justice provisions for the person in charge of a health establishment

are ensured through the annual distribution of the inspection strategy indicating the proportion of establishments to be inspected that year and the procedures, without providing the names of such establishments.

6.3. Relevant Court Rulings

There are no current court actions or rulings regarding the OHSC, its establishment and operations.

6.4. Planned Policy Initiatives

A proposed enforcement policy has been developed by the Office to give effect to the prescribed procedural regulations, and will be published for comments before it is gazetted in a final form. The policy will guide the exercise of the enforcement action by the Office against persistently non-compliant health establishments.

7. SITUATIONAL ANALYSIS

7.1. Performance Delivery Environment

The Performance delivery environment in the context of a regulator is influenced by the policy and legislative provisions outlined above, as well as by the actual situation pertaining on the ground and the responses and initiatives being implemented to address challenges and reinforce successes.

7.1.1. The Quality Challenge

In healthcare as in many other sectors, it has been recognised that while major strides had been made in improving access to services over the previous 15 years, the quality of that access was widely perceived to be inadequate. Improving the quality of healthcare thus became a key objective, reflecting in large part the widespread dissatisfaction with the acceptability or patient experience of health care especially in the public sector, the perceived levels of harm to patients, and the unaffordable costs and persisting inequities apparent in previously disadvantaged areas and between public and private sectors.

These concerns were confirmed by the results of a national audit of all public sector healthcare facilities conducted in 2011 and 2012, showing very low levels of compliance with standards in the 6 identified priority areas or basic critical requirements.

Other identified health sector organisational problems include:

a) Unacceptable poor quality and unsafe health services.

b) High levels of inequality in per capita health expenditure between public and private sectors.

c) Public health system with poor outcomes or return on investment in the context of:

- Under resourced/overburdened public health sector.
- A fragmented health system; and
- Poor leadership and management at different levels of care.

d) Fragmented health information management system characterised by lack of standardisation and poor measurement of outcomes; and

e) Increasing public discontent and frustrations with the health system based on their experiences.

Some of the critical underlying causes for this situation were seen to lie in a mismatch between resources and workload or frankly inadequate resources; and the inadequate knowledge, experience and skills of many managers and staff. A further important underlying reason for this situation was the weak accountability mechanisms with few consequences for poor (or good) care, exacerbated by the semi-federal public system with a multitude of different standards being practiced across the country, and the largely unregulated situation in the private sector.

7.1.2. Health Reform Efforts and Implications for Quality

The NDoH has been implementing a large number of initiatives for reform of the healthcare sector and as a preparation for the implementation of NHI with a focus on ensuring that the public health sector can deliver on key expectations and requirements, including that for quality. This also reflects that the role of the OHSC as the regulator of quality is to remain an objective guide and assessor of performance.

Initiatives of relevance to the work of the Office range from the development of staffing norms for hospitals and clinics; processes to rehabilitate health infrastructure and improve its maintenance; the review of structures and systems to strengthen governance, oversight and management and the recruitment of managers of hospitals (and later clinics); the introduction of better controls on the acquisition and use or over-use of resources; and a major focus on clinic management and service delivery. All of these aspects are already directly reflected in the NCS and the regulations published for comment; this focus on improved delivery is essential if improved levels of compliance and of the health and safety of users are to improve.

A key area of relevance in ensuing improved quality and safety are the many initiatives directed towards improving the knowledge and skills base of managers, whether through appropriate formal training, seminars, mentoring and collaborative efforts, health worker motivation and e-learning; as well as operational research and documentation of best practice. These efforts tie in directly with the function of the Office in proving guidance on norms and standards and are one of the most critical success factors

The socio-political and economic situation and its relationship with healthcare resourcing is of critical importance in the work of the Office, as without improvements in efficiencies, reductions in budgets allocated to health and an escalation in costs can lead to reduced levels of quality and safety. This is a further reason for the urgent establishment of external monitoring and regulation as envisaged in the NHAA, as a critical mechanism to offer some protection to patients and users in such a situation.

The overall economic situation and the funding of public services will also influence the timing and level of introduction of revenue to be raised by the OHSC for services rendered in terms of the legislative provisions to this effect.

7.1.3. Mock Inspections and Findings

The OHSC set up within the NDoH as a precursor to the new regulator has since late 2011 been doing “mock” or training inspections of public sector institutions. The total number of validated inspection results for health establishments by March 2016 was 1386 or over 35% of all public healthcare establishments, sufficient for an analysis of the challenges being faced and the rationale for the existence of the regulator.

This analysis shows large deficits as well as variations in the quality of health services**:**

- Between health establishments and types of health establishment, in particular showing a problem with clinics, which are a cornerstone for NHI
- Between provinces, where persistent inequities are still apparent
- In the functionality of supply and support systems at all levels
- In the degree of individual responsibility and accountability (managerial, clinical) for delivering basic quality care and ensuring respect for users of health services

7.1.4. Envisaged Impact

The two core health sector aims in which quality is seen as playing a major role are those of improving outcomes and thus impacting on life expectancy as well as on the achievement of the millennium development goals (MDGs), and the move towards universal quality healthcare coverage (UHC), widely known by its local name of National Health Insurance or NHI.

The contribution of improved quality in achieving better outcomes would be seen through an improvement in the implementation of defined best practice guidelines, resulting from availability of needed inputs and the reliable implementation (at all times, in all places, for all patients) of identified processes and practices, especially those designed to reduce unintended harm to patients and thus reduce avoidable mortality and morbidity.

The contribution of improved quality to universal healthcare coverage would be in the first place through improving the acceptability or patient experience of care and thus impacting on the critical element of utilisation, patient choice and the acceptance of the needed social solidarity for cross-subsidisation between richer and poorer segments of the user population. In addition, improved quality will be necessary to assure the public in general that the improved level of resources to flow into healthcare will be effectively and efficiently used.

7.2. Organisational Environment

The organisational environment of the Office itself is critical if it is to effectively use its powers to influence the desired changes in healthcare delivery but over which it has no direct control. The evolution of the OHSC up to the point of the formal appointment of the Board in early 2014 has extended over 7 years and has created a foundation both internally in terms of inspectors and the work they do and externally in terms of knowledge and awareness across the health system itself. The establishment of a new independent organisation brings with it both a key strength in that its work will become institutionalized and more objective and focused, as well as the challenge of setting up of completely new structures and systems, and attempting to meet public expectations for immediate impact while still in the phase of growth and development itself.

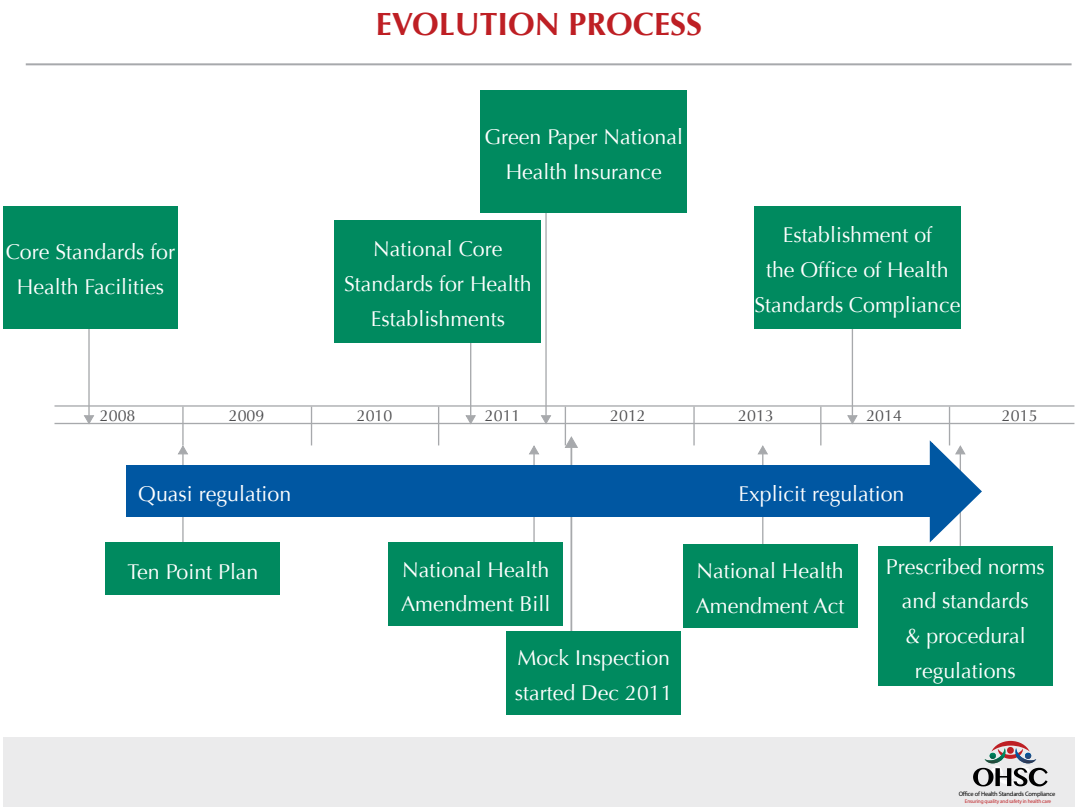
7.2.1. Historical Evolution

The Cluster: Office of Standards Compliance (OSC) in the NDoH drove the development and implementation of policy and guidelines for quality assurance and improvement in the health system and took forward the legislative preparation for the OHSC as outlined in the table below. The transition to the independent regulator is now complete under the oversight of the Board.

Table 1: Historical Evolution

YEAR	STANDARDS AND AUDIT TOOLS	LEGISLATION AND REGULATION
2008	First draft of national standards and basic measurement tool; piloted in 27 facilities.	National Health Act (2003) outlines "OHSC" within NDoH.
2009	Refinement through a working group of stakeholders. Identification of "6" priorities as sub-set Initial quality improvement projects and workshops.	Policy decision to establish independent "quality management and accreditation body",
2010	2nd national pilot of revised tool and further refinement and use Finalisation of "NCS for Health Establishments in South Africa".	Bill outline approved by National Health Council: mandatory standards and norms, external certification, Ombud function,
2011	Publication of NCS. Baseline audit of all facilities using sub-set of tools (contracted). Self-assessments used as a basis of QI,	Bill gazette for public comment; approved by Cabinet; certified by law advisors. Inspectors appointed.
2012	Baseline assessments used by national "facility improvement teams", 3rd revision of audit tools. National inspections by OSC.	Bill to National Assembly, National Council of Provinces, Inspector training through mock inspections , Preparation for Office.
2013	583 Mock inspections carried out by team of 27 inspectors; development of procedures. Complaints data base operational. Work on revision of NCS.	Detailed Business case, signed off by Ministers of Health and Public Service and Administration; submitted to Minister of Finance. National Health Amendment Act promulgated 2nd September 2013. Advertisement for the Board.
2014	Proposed regulations developed for submission to Minister. 480 inspections and 60 re-inspections conducted Revised tools and guidance developed	Board inaugurated 29 January 2014. OHSC listed as public entity as per letter from MOF of 6 May 2014. CEO appointed on interim basis from 1st April 2014
2015	Procedural Regulations and the proposed Norms and Standards to be prescribed published for public comments	National Health Amendment Act
2016	Procedural Regulations promulgated in October 2016	National Health Amendment Act
2017	Proposed norms and standards re-published for public comments	National Health Amendment Act

Diagram 1: Evolution of Process



7.2.2. Establishment of the OHSC

A detailed business case and staffing structure relating to the establishment of the OHSC was approved by the Minister of Health in June 2013 and by the Minister of Public Service and Administration in August 2013. This document has formed a basis for this Strategic Plan and of ongoing Operational Planning.

From 2011 to 2013, extensive preparatory work was done by the OHSC within the NDoH to prepare for the establishment of the future public entity. The new OHSC as a juristic person has existed in law since the National Health Amendment Act (NHAA) was proclaimed by the President on 2nd September 2013. With the appointment of the Board, the Accounting Authority of this new body when is in place. The Board can carry out its functions, employ staff and incur expenditure. Additionally, by notice in the Gazette published by the Minister of Finance on 23rd May 2014, the OHSC has been listed as a Section 3A Public Entity.

An interim CEO was appointed by the Board and the Minister by secondment from the NDoH effective 1st April 2014 to 31 July 2015 with full delegation of powers from the Board. The process of appointing a new CEO was started by the Board immediately upon the expiry of the secondment period for the interim CEO, however, the recruitment process was not successful. An Acting CEO was appointed in August 2015. The process of appointing an Ombud was finalised by the Minister of Health in June 2016.

The initial transition phase for the Office to operate independently from the NDoH was governed by a Memorandum of Agreement signed between the NDoH and the Office enabling provision of support and services to the Office while the Office continued with recruitment of staff and development of policies and systems set up. The new entity became essentially independent by the start of the 2015/16 financial year.

7.2.3. Strengths, Weaknesses, Opportunities and Threats (SWOX)

The OHSC undertook a SWOT Analysis in the context of achieving the mandate of the future entity and the results are reflected below in Table 2:

Table 2: SWOT Analysis

STRENGTHS	WEAKNESSES
▪ Legislative authority: new health sector public entity to regulate health standards and compliance ▪ Independent Board and Ombud reporting directly to the Minister of Health ▪ Cross-sectoral mandate (public and private sectors) ▪ Form legal status - Entrenched in national policy/ manifesto/act of parliament –legal status ▪ The power to develop and influence regulations ▪ Cross-sectional, diverse and experienced board ▪ Clear policy mandate role within NDP for the office	▪ Limited powers to enforce compliance ▪ Lack of early warning system in the sector currently ▪ Limited resourcing (staff & office space) ▪ Inadequate infrastructure (location, offices etc.) ▪ Inadequate IT systems ▪ Relative younger regulatory entity compared to existing ones ▪ No power in absence of regulations ▪ Absence of revenue collection model
OPPORTUNITIES	**THREATS**
▪ The public clamour for better quality health for all South Africans ▪ A safe & efficient Health system ▪ Use power of regulation to change management of services and staff ▪ Favourable context and clear expectation role within NDP ▪ Policy mandate –NDP –NHI- advocacy ▪ Bring the private and public sector together on health standards compliance	▪ Real or perceived undue interference from stakeholders ▪ Resistance from establishments or authorities not willing to comply ▪ Concurrent powers and regulatory overlap with other regulators – disagreements potential ▪ Legacy perceptions as part of the NDoH ▪ High public expectations of the office ▪ Compromised perception of not being independent ▪ Perceptions on non-independence from the NDoH ▪ Imbedded bureaucracy and accountability to National Treasury and oversight bodies ▪ Other legal and regulatory developments (PoPI, PAIA)

7.2.4. Strategies

The broad strategies adopted by the Board of the OHSC during its first year in operation are designed to achieve the legislative mandate and the Strategic Goals it has set for the entity.

They are:

a) Prioritize those establishments that are the weakest and serve the most disadvantaged users in order to shift the system towards safer care, while still recognizing excellence wherever it is found;

b) Use a progressive and developmental approach to enforcement in order to enhance change at different levels of the system;

c) Use the power of information and communication, ranging from awareness and guidance through monitoring, analysis, reporting and publication, as a strategic tool to influence decisions and behaviour;

d) Create and effectively use platforms for interaction with key user, provider and leadership groups to foster collaborative efforts towards improved outcomes; and

e) Develop the capacity of staff and those who work directly with the Office as agents of change through training, rigorous control of the quality of outputs and ongoing learning.

7.2.5. Regulatory Response

The enabling legislation setting up an independent regulator of the norms and standards and enforcing compliance, the OHSC, was promulgated in September 2013 after a two-year parliamentary process. This is a critical input for both the external performance environment as well as the internal organisational environment of the OHSC itself.

The Board during its first year in office discharged its responsibility to advise the Minister through the tabling of two (2) sets of regulations: Procedural Regulations setting out how the Office will function and the obligations on health establishments and the set of prescribed "norms and standards" that will both place an obligation on all health establishments to ensure quality and safety of care as well as give powers to the Office to monitor, certify and enforce such compliance. In addition, the norms and standards will enable the Office to monitor early warning indicators of risk indicating a breach of norms and standards, and empower the Ombud placed within the Office to investigate complaints relating to breaches of norms and standards, either as acts or omissions.

Following publication for comment in February 2015, the regulations were reviewed to incorporate constructive comments. The Procedural Regulations were promulgated in October 2016 and the proposed norms and standards have since been reviewed and were re-published for public comments in January 2017.

In addition, certification of compliance with these norms and standards will be a pre-requisite for the future process of "accrediting" health establishments to deliver defined services and receive payment for these, through the NHI fund linked to the move towards universal healthcare coverage. This will mean the need for close collaboration between the regulator and the fund in order to meet common goals.

These revised NCS in the form of the prescribed norms and standards will stand at the heart of the work of the Office with the aim:

"To guide, monitor and enforce the control of critical risks to the health and safety of users by means of the required systems and relevant supportive structures within different types of healthcare establishments, in accordance with the South African legislative and policy context, in order to provide safe quality services to the citizens of South Africa."

7.2.6. Regulatory Good Practice and Risk Mitigation

Based on principles of good regulatory practice, an assessment of risks to the implementation of these principles has been developed and the mitigating factors identified are addressed in the specific programme plans below:

Table 3: Principles of good regulatory practice and risks to their implementation

REGULATORY PRINCIPLES	RISK	ROOT CAUSE	MITIGATION
Principle 1: **Regulation must foster greater accountability** **(Set explicit benchmarks for objective measurement to hold those in charge accountable. Regulators also accountable)**	HEs do not respond to OHSC reports and findings for improvement OHSC reputation challenged OHSC does not impact on situation	Expectations unclear Results contested (objectivity, accuracy) Accountability linked to authority / decision making which lies elsewhere	Explicit standards, tools and guidance linked to outcomes and policy directions Objective and fair measurement apparent Reports and recommendations target correct people OHSC evaluates and communicates decisions and outcomes
Principle 2: **Regulation must be clear and transparent** **(Clear, specific and explicit obligations and reasons; summary decisions published, necessary autonomy for decisions)**	Obligations regarded as confusing, unfair and contradictory Decisions contested based on interpretation, intent, secrecy Selection of HEs or recommendations / sanctions (seen as) biased	Intent not clear, attribution not clear, Unclear roles and no policy coordination Potential for selection, inspection or recommendation bias	Clear and specific obligations and rationale in guidance and application Detailed tool and regulatory algorithm out of hands of individual inspectors Publication of methodology, criteria and procedures and strict internal monitoring Publication of findings after reasonable time to correct
Principle 3: **Regulation should be targeted** **(Target problem or risk 'end-result'; minimise unintended consequences)**	Real problems not identified (type I error) Unintended consequences (malicious compliance, wrong guidance on resources or procedures, opportunity cost of regulation) Scope creep No impact on quality and safety demonstrated	Measurement or EW tools not focused on outcomes and risks to these Tools unable to distinguish gaming Tools not validated Impact not evaluated	Careful design and validation of tools in terms of focus and methods Ongoing evaluation of impact

REGULATORY PRINCIPLES	RISK	ROOT CAUSE	MITIGATION
Principle 4: **Regulatory interventions should be proportionate** **(Proportional to problem or risk; minimum necessary as one of mechanisms in this; avoid punitive approach and compliance-driven response; avoid crisis-based response)**	High resource and opportunity cost of achieving compliance – too demanding / unrealistic / duplicated Managers / good staff driven out of public health sector by fear OHSC reactive not proactive; poor planning	Poorly designed / excessive tools Impatience, frustration or poor judgment leads to unduly punitive approach	Careful review of tools and burden Formal health system policy dialogue Agreements with other regulators to reduce regulatory burden Specific criteria and procedures for inspectors and other staff ensure supportive / phased approach Regular evaluation Criteria guide risk-based inspections
Principle 5: **Regulation should be applied consistently and yield reliable decisions** **(Processes consistent and decisions reliable and rigorous; staff trained and capable).**	Inconsistent decisions lead to loss of credibility Allegations or perceptions of undue influence / fraud undermine authority	Poorly trained or undisciplined inspectors Ambiguous tools, poor quality control	Decisions consistent, rigorous and reliable Tools and guidance clear Staff trained and constantly monitored

7.2.7. Service Delivery Model

In support of the objectives of the OHSC, the service delivery model consists of three functional processes.

The essential features of the OHSC as provided for in the legislation are as follows:

- The OHSC is a juristic person funded by money appropriated by Parliament and by fees for services provided and has been listed as a Schedule 3A national public entity in terms of the PFMA;
- The OHSC is governed by a Board, the members and chair of which have been appointed by the Minister; and which is the accounting authority of the OHSC in terms of the PFMA;
- The Minister also appoints the Ombud who is responsible for the investigation of complaints by health service users and holds office for a non-renewable term of seven years;
- Although the Ombud is appointed by the Minister, s/he uses staff seconded by the OHSC. Parliament will earmark specific funding for the Ombud to create conditions for the impartial and independent exercise of these functions;
- The Board appoints the CEO of the OHSC, in concurrence with the Minister of Health. The CEO may serve for a maximum of two five-year terms and is responsible for the administration of the Office and the discharge of its functions. The CEO is the head the Office; and
- The CEO is charged with appointing suitably qualified inspectors to undertake monitoring and certification of health establishments. The Act sets out in some detail the powers and functions of inspectors.

As the sector quality overseer and regulator, the OHSC will lead the much-needed improvement in health service quality, change in public healthcare management, and institution of core health standards in public and private service providers. This move will lay the groundwork for the rollout of the NHI initiative. The OHSC is empowered

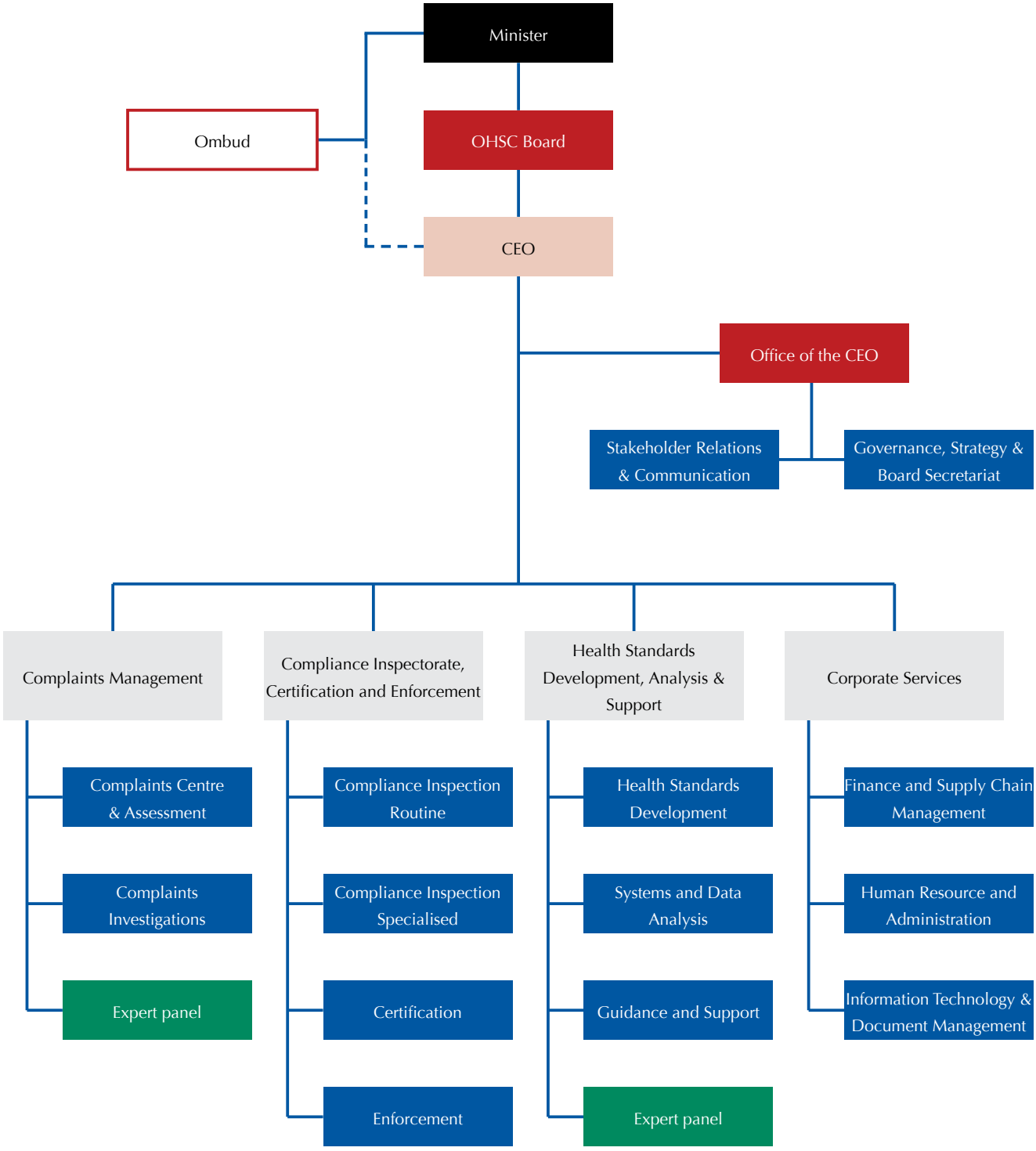
to monitor and enforce health standards in all health establishments throughout country including both private and public hospitals and clinics. This is an important step in addressing what many perceive to be large-scale failings in certain health establishments where care and access to proper health care services is wholly deficient.

7.2.8. Staff Establishment and Recruitment

The Board of the OHSC approved the macro-structure of the Office (shown below) which reflects the implementation of the legislated functions of the OHSC and was approved by the Minister of Health in June 2014 as per the provisions of the National Health Amendment Act.

This OHSC structure will be phased in over a number of years in accordance with the development of capacity and the availability of funds.

Diagram 2: OHSC organisational structure



Recruitment of executives and senior managers and initial staffing of all units to enable full functionality will increase slowly over the MTEF period.

7.3. Institutional Partnerships

In terms of the National Health Amendment Act of 2013, the OHSC fulfils its mandate of protecting and promoting the safety of users of health services by monitoring health establishments through the collection of key data through on-site inspections as well as annual reporting, and developing and maintaining an early warning system which serves to alert the authorities to the existence of conditions that poses a risk to safety and quality standards. In today's world of complexity, limited resources and rapid pace it is almost impossible to do anything alone. This is especially true in the health sector where constantly there are challenges that make it difficult to imagine OHSC providing its services without strong institutional partnerships. An earlier stakeholder analysis highlights the most critical partners and also now reflects the "arm's length" relationship of an independent regulator with the entities it regulates including the authorities who manage and oversee them.

Two primary categories of stakeholders are the most critical:

- Health establishments that are subject to regulation by the OHSC. Within this broad category, managers and rank and file staff members may be further differentiated. The "head offices" or "relevant authorities" of health establishments – for example, provincial health departments and private hospital groups, are also included in this primary stakeholder category; and
- Users of health establishments whose safety is to be protected and promoted by the OHSC, and their families

In addition to these primary stakeholder categories, there is an array of smaller stakeholders that vary in terms of their influence on and attitude to the matter of regulating health establishments. These can be broadly categorised as:

- **Organisations that influence and have an interest in health service provision.** These would include professional associations and trade unions of health workers, associations of hospitals, academic and training institutions in the health field, and certain types of NGOs;
- **Organisations that have an influence on and represent the interests of healthcare consumers.** These would include mass-based civil society structures (such as trade union federations, political parties and faith-based communities), NGOs that focus on health rights and advocacy, and consumer bodies;and
- **Organisations that are primarily interested in the effective and fair regulation and oversight of healthcare services.** These would include Parliament, the NDoH, other regulators, such as the Nursing Council, Health Professions Council of SA, Pharmacy Council, Council for Medical Schemes, and accreditation authorities.

There are also stakeholders, such as the mass media, which span these categories:

The partnerships definitely are not yet well established as this is a new state entity that has just been set up. These partnerships however have one thing in common: *the common goal of ensuring that the ultimate benefit is that of the user of the health services.* If these partnerships are to be successful, and have both clear mutually agreed upon objectives and calculated risks as intended, it is in the interest of the OHSC that such partnerships will clearly meet the following criteria:

- That they are clear, specified, realistic and purposeful shared goals;
- That clearly delineated and agreed roles and responsibilities are maintained;
- They have distinct benefits for all parties in an environment of transparency; and
- There is equality of participation and meeting the agreed obligations.

7.4. Description of the Strategic Planning Process

This revised Strategic Plan reflects extensive inputs obtained from the Board in relation to their vision for the OHSC, as expressed in a number of meetings and recommendations from Board Committees. The OHSC has itself consulted widely on its goals, objectives and proposed regulations and as such had revised the initial Strategic Plan for alignment of the programmes to the mandate as opposed to the initial plan which followed the structure. The review of the plan was also informed by the delays with the promulgation of the norms and standards regulations, which will set the Office to be able to implement some of the critical objectives contained in this plan, including the inspection of private sector health establishments and certification of compliant health establishments. This has necessitated the postponement of implementation of these critical objectives and planned targets to the 2018/19 financial year as this is the year in which the Office anticipates to have promulgated norms and standards regulations.

This revised plan also captures extensive inputs received over the past few years in relation to the challenges experienced with the implementation of the initial Strategic Plan and the audit outcomes which also informed the need for the review of the initial plan and re-tabling in Parliament together with the Annual Performance Plan for 2017/18. The performance information programmes had since been reduced from five (5) to four (4). The Office of the CEO and Corporate Services programmes have been merged to form one (1) programme, namely Administration. The purpose of the merger is to cater for the three (3) core business programmes with support from the administration programme.

The work of the Office, especially in relation to the inspection and complaints functions, and preparatory work done on technical drafting of future regulations and prescribed norms and standards, has also been very relevant in this review process to ensure that this Strategic Plan is informed by the mandate as per the NHA and that the strategic outcome oriented goals follow the mandate in terms of the agreed programme performance information.

The Office is expected to deliver on its mandate within the broader resource constraints faced by most organs of government. In this regard, in revising the Strategic Plan and the targets over the MTEF period, the Office had to strike a balance and trade-offs between the budget allocation as communicated by the National Treasury, and its ability to meet its strategic objectives. The Office largely relies on the human capital to be able to deliver on the key mandates of compliance inspections and complaints investigations. In light of this, the current budget allocation allows the Office to operate with half of the total staff complement in its establishment, and this necessitated that the Office should review the anticipated targets over the MTEF period.

7.5 Strategic Outcome Oriented Goals of the OHSC

The OHSC has the following 4 Strategic Outcome Oriented Goals within its mandate:

Goal 01	Publicly demonstrate responsiveness and accountability as an effective and efficient high-performance organisation
Goal statement	The OHSC is an effective and efficient high-performance organisation that is responsive and publicly accountable
Indicator	Auditor General's annual findings rating

Goal 02	Inspect Health Establishments (HEs) for compliance with quality norms and standards
Goal statement	Health establishments comply with norms and standards for health and safety of users and provision of quality, compassionate and responsive care.
Indicator	Number and % of HEs certified as complying with quality standards

Goal 03	Patient and community complaints regarding poor care and situations of concern are investigated and responded to
Goal statement	The public is protected through ensuring that poor care and situations of concern are investigated and responded to
Indicator	Number and % of user and community complaints investigated and responded to within six months

Goal 04	Progressively improve the quality and safety of healthcare through effective communication and collaboration with users, providers and other relevant stakeholders
Goal statement	Communicate and work with users, providers and other relevant stakeholders through written agreements of collaboration and information sharing to enhance quality and compliance.
Indicator	Number of public awareness initiatives executed

PART B

STRATEGIC OBJECTIVES

PART B: STRATEGIC OBJECTIVES

8. STRATEGIC GOALS AND OBJECTIVES

The OHSC has **19 Strategic Objectives** aligned with the **4 Strategic Goals** (Outcomes) as per table below:

Table 4

GOALS	OBJECTIVES
1. Publicly demonstrate responsiveness and accountability as an effective and efficient high-performance organisation.	1.1. Establish a fully functional Office suitably staffed to execute the mandate and goals of the OHSC 1.2. Accredit inspectors after successfully completing approved training course 1.3. Implement good governance, oversight and accountability through appropriate delegations, including financial management and compliance to PFMA requirements 1.4 Leverage the technology of the IT system to meet the needs of the OHSC and to deliver OHSC services more efficiently. 1.5 Create public, provider and stakeholder awareness about the roles and powers of the OHSC. 1.6 Support the mandate and objectives of the OHSC through Memorandum of Understanding (MOUs) with relevant regulators or other organisations
2. Inspect Health establishments (HEs) for compliance with quality norms and standards	2.1. Inspect regulated (public and private) health establishment for compliance with prescribed norms and standards at least every 4 years 2.2. Certify HEs that are compliant with prescribed norms and standards. 2.3 Effect enforcement action against persistently non-compliant HEs 2.4 Publish information about compliance status of HE with norms and standards
3 Patient and community complaints regarding poor care and situations of concern are investigated and responded to.	3.1. Create an accessible mechanism to lodge complaints with the OHSC 3.2. investigate and respond to complaints or concerns about non-compliance with norms and standards effectively 3.3. Issue findings and recommendations about complaints of non-compliance with prescribed norms and standards within six months 3.4. Communicate and monitor recommendations made by the Ombud
4. Progressively improve the quality and safety of healthcare through effective communication and collaboration with users, providers and other relevant stakeholders	4.1. All HEs regulated by prescribed norms and standards to submit annual returns before the end of March each year for purposes of monitoring and inspections 4.2. Recommend norms and standards for different types of HEs for submission to the Minister for promulgation 4.3. Provide guidance on compliance with norms and standards for regulated HEs 4.4. Monitor early-warning reports of situations of potential risk from HEs or users to prioritise inspections.

9. PROGRAMME 1: ADMINISTRATION

9.1. Programme Purpose

To provide the leadership and administrative support necessary for the OHSC to deliver on its mandate and comply with all relevant legislative requirements

9.2 Strategic Objectives

Strategic Objective 1.1	**Establish a fully functional Office suitably staffed to execute the mandate and goals of the OHSC**
Objective statement	A functional OHSC with a budget and personnel to implement the OHSC mandate effectively is established
Indicator	% of funded staff appointed
Baseline (2015-16)	New indicator
Target (2015-20)	90%

Strategic Objective 1.2	**Accredit inspectors after successfully completing approved training course**
Objective statement	To formally accredit inspectors through staff training and development within the OHSC as part of overall training and staff development function
Indicator	% of compliance inspectors accredited
Baseline (2015-16)	New indicator
Target (2015-20)	100%

Strategic Objective 1.3	**Implement good governance, oversight and accountability through appropriate delegations, including financial management and compliance to PFMA**
Objective statement	To ensure good governance, oversight and accountability through appropriate delegations to Board and management governance structures and legislative compliance
Indicator	Auditor General's annual findings rating.
Baseline (2014-15)	New indicator
Target (2015-20)	Unqualified audit report

Strategic Objective 1.4	**Leverage the Information Technology to meet the needs of the OHSC and to deliver OHSC services more efficiently**
Objective statement	Specialised IT system for the OHSC is implemented
Indicator	% of IT systems uptime
Baseline (2015-16)	New indicator
Target (2015-20)	95%

Strategic Objective 1.5	**Create public, provider and stakeholder awareness about the roles and powers of the OHSC**
Objective statement	Activities are carried out to create public awareness on the mandate, roles and powers of OHSC
Indicator	Number of media and communication events and campaigns conducted annually
Baseline (2015-16)	New indicator
Target (2015-20)	18

Strategic Objective 1.6	**Support the mandate and objectives of the OHSC through Memorandum of Understanding (MOUs) with relevant regulators or other organisations**
Objective statement	MOUs with relevant regulators/other organisations to further the mandate and objectives of the OHSC to improve quality and safety and monitor implementation prior to annual ratification are signed.
Indicator	Number of MOUs signed annually with regulators/other organisations to protect and promote healthcare quality and safety
Baseline (2015-16)	New indicator
Target (2015-20)	10

9.3 Resource considerations

9.3.1 Trends in the numbers of key staff:

- The Administration programme comprises of staff in the Corporate Services division and the Office of the CEO.
- The programme will see an increase in the number of staff members in order to provide the necessary support to a growing organization in the MTEF period.

Table 5

PERSONNEL	2015/16	2016/17	2017/18	2018/19	2019/20
Management/Professionals (L11-L16)	**10**	**13**	**13**	**13**	**13**
Employees (L10 & below)	**11**	**13**	**16**	**16**	**16**
Interns	**-**	**3**	**8**	**8**	**8**

9.3.2 Trends in the supply of key inputs:

- The first OHSC Board was appointed in January 2014 and has assumed its oversight and policy-making role,
- An interim CEO was appointed from April 2014 until 31July 2015. The process for a long term appointment is ongoing, however, in an Acting CEO appointed in August 2015.
- The baseline allocation will be progressively increased to enable the organisation to meet its legislated mandate.

9.3.3 Expenditure trends

- The programme budget increases from R39.2 million in 2016/17 to R53.3 million in 2019/20 to enable the Office to meet its strategic objectives.
- The large budget items within the programme are:
  - The implementation of the approved Communications and Stakeholder Relations Strategy to increase the OHSC's brand visibility and public awareness. The Board and related costs to enable adequate corporate governance and oversight with required additional expertise as may be needed.
  - Support functions such as rental of office premises, audit costs, training and development, telephone, information technology maintenance, as well as advertising for both procurement and recruitment
  - Additional furniture and computer equipment for the new offices and additional staff members.

Programme 1: Administration Budget

Economic Classification			Medium-term estimates		
	Audited outcomes 2015/16	**2016/17**	**2017/2018**	**2018/19**	**2019/20**
CURRENT PAYMENTS	**24 466 722**	**30 313 336**	**45 552 236**	**48 033 181**	**50 102 394**
Compensation of employees	10 289 310	15 505 486	19 134 723	20 621 658	22 184 971
Goods and services of which:	14 177 412	14 807 850	26 417 513	27 411 523	27 917 423
Board fees and related costs	1 429 668	1 823 643	1 877 258	1 982 384	1 982 384
Travel,subsistence and accommodation	603 144	922 979	608 506	642 582	678 567
Training and development	742 980	1 321 000	900 000	950 400	950 400
Venues and facilities	27 290	533 875	160 000	168 960	178 422
Catering services	135 438	50 000	30 000	31 680	33 454
Legal fees	-	-	1 000 000	1 000 000	1 000 000
Consulting and professional services	5 151 907	1 099 500	1 352 362	1 428 094	1 490 327
Inventory and consumables	241 776	250 000	302 800	319 757	337 663
Advertising	1 162 452	800 000	600 000	633 600	633 600
Publications and marketing	283 998	2 450 000	2 450 000	2 587 200	1 855 554
Relocation expenses	49 412	250 000	800 000	300 000	300 000
Printing and stationery	467 749	400 000	560 000	591 360	624 476
Gain/(loss) from transfer of functions	27 134	-	-	-	-
Bank charges	57 331	20 000	60 000	63 360	66 908
Insurance	-	171 464	125 839	132 886	140 328
Water and electricity	184 648	300 071	316 875	334 620	353 359
Communication costs (telephone and data)	575 604	1 386 240	1 023 422	1 088 575	1 169 465
Operating lease	1 416 204	1 222 077	11 610 450	12 407 123	13 258 518
Security services	-	-	100 000	105 900	112 148
Cleaning services	65 411	-	340 000	359 040	379 146
Audit costs	814 872	1 500 000	1 500 000	1 584 000	1 672 704
Penalties and interest	5 884	-	-	-	-
Depreciation and amortisation	655 203	-	-	-	-
IT maitenance and support	79 308	307 000	700 000	700 000	700 000
PAYMENTS FOR CAPITAL ASSETS	**4 788 092**	**8 928 717**	**4 562 156**	**3 184 287**	**3 236 880**
Other machinery and equipments	775 933	3 540 000	816 596	716 002	786 444
Office furniture	1 207 898	-	1 000 000	300 000	100 000
Leasehold improvements	843 777	-	-	-	-
Software and intangible assets	462 359	4 248 717	2 055 560	1 413 285	1 550 436
Computer equipment	1 498 125	1 140 000	690 000	755 000	800 000
TOTAL	**29 254 814**	**39 242 053**	**50 114 392**	**51 217 467**	**53 339 274**

9.4 Risk management

Table 6

RISK NO.	RISK CONTEXT	RISK NAME	RISK DESCRIPTION	ROOT CAUSE	POTENTIAL CONSEQUENCE	MITIGATION PLAN
1	Financial Resources	Funding Flows	Lack of adequate funding	Slow economic growth leading to reductions in public funding	Some of the legislated mandates regarding coverage and frequency of inspections will not be achieved	OHSC will prioritise critical strategic objectives; phase in delivery
2.	Funding Source	Revenue generation	OHSC not using potential revenue streams	As a new regulator, the OHSC needs first to establish activity-based costs and procedures and assess impact on regulated establishments.	Slower attainment of full coverage and follow-up	Revenue model to be developed and approved
3.	Leadership	Vacant CEO position	Currently the CEO is an acting appointment for over a year	Unattractive salary package for the required skills and experience	Lack of stability and long term perspective	Board to make a submission to the Minister motivating for the approval of the regrading level of the position as commissioned by the Board
4	Reputational	Independence	Perception of not being independent Unrealistic expectations re scope, powers & capacity	Historic public perception about the public health sector lack of public knowledge given new entity Legal and constitutional provisions	Lack of trust and knowledge regarding OHSC's role to the public	Media and stakeholder campaigns; demonstrable independence and transparency in reports and recommendations
5	Regulatory effectiveness	Regulatory principles	Regulatory principles not fully implemented	Start-up phase and pressure of expectations lead to inadequate attention to detail	Erosion of credibility, legitimacy and effectiveness	Build regulatory principles into planning, monitoring and evaluation of work

RISK NO.	RISK CONTEXT	RISK NAME	RISK DESCRIPTION	ROOT CAUSE	POTENTIAL CONSEQUENCE	MITIGATION PLAN
6	Governance Risk	Board effectiveness	Board oversight role and capacity not clear	Recently established Board and Office requiring progressive clarity on roles	Lack of strategic leadership and oversight on the OHSC performance	Periodic evaluation and reflection on roles as OHSC evolves
		Informal roles and responsibilities	Start-up phase with no capacity means roles and responsibilities not formalized	Delegations and reporting lines not developed until capacity in place	Impaired supervision and reporting; poor functionality	Formalise roles and responsibilities as soon as capacity in place; strong focus on induction training, team building
7.	Financial Resources and revenue	Funding and revenue generation	Lack of adequate funding	Slow economic growth leading to reductions in public funding; new regulator not ready to quantify or raise revenue	Slower attainment of full coverage and follow-up	Revenue model to be developed and approved. Prevent waste and improve efficiencies
8.	Human resource capacity constraints	Staff recruitment and retention	Recruitment and retention of highly skilled and trained staff	Staff with extensive knowledge but heavy workload and expectation	Attrition may result from better prospects elsewhere Hard to recruit needed skills	Focus on performance management and recognition, working environment, career pathing. Contracting of core skills and support
9.	Technology	IT system	Full use of technology not enabled	Inadequate investment in IT system design and support	IT system not adequate for OHSC needs; not maximally used	Up-front investment; adequate internal capacity; training and monitoring

10. PROGRAMME 2: COMPLIANCE INSPECTORATE, CERTIFICATION AND ENFORCEMENT

10.1. Programme Purpose

To manage the inspection of health establishments in order to assess compliance with national health system's norms and standards as prescribed by the Minister, certify health establishments as compliant or noncompliant with prescribed norms and standards and take enforcement action against non-compliant health establishments.

10.2. Strategic Objective

Strategic Objective 2.1	**Inspect regulated (public and private) health establishment for compliance with prescribed norms and standards at least every 4 years**
Objective statement	Compliance with acceptable standards of quality and safe healthcare delivery in public and private sector HEs are monitored and inspected at least every four years, and relevant action is taken
Indicator	# and % of public sector clinics, CHCs and hospitals inspected annually by the OHSC
Baseline (2014-15)	10%
Target (2015-20)	20%
Indicator	# and % of private sector clinics, CHCs and hospitals inspected annually by the OHSC
Baseline (2015-16)	New indicator
Target (2018-20)	30%

Strategic Objective 2.2	**Certify HEs that are compliant with prescribed norms and standards**
Objective statement	HEs that comply with prescribed norms and standards receive certificate of compliance within 60 days of inspection
Indicator	Procedures for certification process developed and implemented
Baseline (2014-15)	New indicator
Target (2015-20)	Certification procedures
Indicator	% of compliant establishments certified by the OHSC within 60 days after the final inspection report
Baseline (2014-15)	New Indicator
Target (2018-20)	100%

Strategic Objective 2.3	**Effect enforcement action against persistently non-compliant HEs**
Objective statement	Enforcement action is taken against persistently non-compliant HE
Indicator	Procedures for timely enforcement action developed and implemented
Baseline (2014-15)	New indicator
Target (2015-20)	Enforcement procedures
Indicator	% persistently non-compliant health establishments for which enforcement action is initiated within 10 days from date of receipt of re-inspection or EWS report

Baseline (2014-15)	New indicator
Target (2018-20)	100%

Strategic Objective 2.4	Publish information about compliance status of HE with norms and standards
Objective statement	Information relating to compliance with norms and standards by HE is published annually
Indicator	# of reports on inspections conducted, remedial recommendations issued and compliance status of health establishments (annual inspection report)
Baseline (2014-15)	New indicator
Target (2015-20)	5

10.3. Resource considerations

10.3.1. Trends in the numbers of key staff:

- This is the biggest division driven by the staff numbers required to ensure on-the-ground coverage of all health establishments across the country.
- The progressive increase in budget allocation will enable an increase in the numbers of inspectors and thus increase the coverage achieved in public and private sectors, including initiating inspections of specialised hospitals, and ensuring enough resources are put into the follow-up and re-inspections needed in order to contribute to the objective of enhancing and enforcing compliance.
- Inspection coverage should be at 25% per year in terms of the legislated mandate but the capacity will have to be built up over time. It is envisaged that by the end of the MTEF period the number of inspectors would have increased to be able to achieve at least 20% coverage and still be able to sustain follow-up activities.
- Certification and Enforcement is dependent on the promulgation of regulations and the Inspectorate going through a full cycle of their work, so capacity can be built up over time.

Table 7

	2015/16	2016/17	2017/18	2018/2019	2019/2020
▪ Management/Professionals (L11 – L16)	**13**	**15**	**16**	**16**	**16**
▪ Employees (L10 & Below)	**42**	**43**	**47**	**47**	**47**

10.3.2. Trends in the supply of key inputs:

- The most critical input for this programme is the appointment of additional inspection teams to increase coverage of all types of institutions over time as well as conduct re-inspections and follow-up.
- Together with this comes all the requirements for these teams to function: travel costs and accommodation)

10.3.3. Expenditure trends

- Over the MTEF period, the budget will increase from R39 million in 2016/17 to R57.2 million in 2019/20
- The budget largely comprises of the staff numbers required to ensure on-the-ground inspection coverage of all health establishments across the country. In order to increase inspections coverage both in the public

and private sectors, consideration has been given to increasing the number of inspectors by progressively increasing inspection teams.

- In addition to compensation of employees, travelling, subsistence and accommodation, form a large portion of the budget which increases with the scope of inspections planned over the MTEF period.

Programme 2: Compliance Inspectorate, Certification and Enforcement Budget

Economic Classification			Medium-term estimates		
	Audited outcomes 2015/16	2016/17	2017/2018	2018/19	2019/20
CURRENT PAYMENTS	**30 492 386**	**39 429 532**	49 110 158	53 377 089	57 209 945
Compensation of employees	23 266 828	30 824 901	38 123 319	41 127 763	44 244 656
Goods and services of which:	7 225 558	8 604 630	10 986 839	12 249 326	12 965 289
Travel,subsistence and accommodation	7 010 867	8 283 120	10 624 936	11 837 156	12 500 037
Venues and facilities	4 530	196 602	100 000	105 600	111 514
Consulting and professional services	2 596	-	100 000	105 600	111 514
Advertising	31 698	-	-	-	-
Catering services	5 379	73 305	107 410	143 425	181 457
Inventory and consumables	90 799	51 603	54 493	57 544	60 767
PAYMENTS FOR CAPITAL ASSETS	**-**	**-**	**-**	**-**	**-**
TOTAL	**30 492 386**	**39 429 532**	**49 110 158**	**53 377 089**	**57 209 945**

10.4. Risk Management

Table 8

RISK NO.	RISK CONTEXT	RISK NAME	RISK DESCRIPTION	ROOT CAUSE	POTENTIAL CONSEQUENCE	MITIGATION PLAN
1	Financial Resources	Funding Flows	Low inspection and re-inspection coverage	Inadequate funding	High risk HEs not reached; scandals undermine credibility and reputation	Public awareness of phasing, early warning system, sampling with recommendations to relevant authority
2	Capacity constraints	Staff capacity	Inadequate numbers and skills of inspectors; low morale	Recruitment and retention of highly skilled and trained staff	Low morale, attrition,	Strong and supportive supervision and performance management; attention to travel procedures
3	Regulatory effectiveness	Regulatory measurement	Risks to quality and safety not correctly identified by inspections	Measurement and reporting tools inadequate to identify real problems	Loss of legitimacy and credibility of findings Litigation	Careful design, validation of tools and reports; ongoing evaluation

RISK NO.	RISK CONTEXT	RISK NAME	RISK DESCRIPTION	ROOT CAUSE	POTENTIAL CONSEQUENCE	MITIGATION PLAN
		Regulatory procedures	Clear, transparent and rigorous procedures to ensure consistency and reliability	Procedures not adequate, not implemented and monitored	Inconsistent decisions and possible undue influence undermine credibility	Rigorous procedures, staff and supervisory training, monitoring at all levels.
		Ethical conduct	Staff / inspectors not seen to adhere to ethical code	Low morale, poor staff engagement or supervision	Loss of legitimacy of decisions	Code of conduct embedded Ongoing staff development and supervision
		Compliance enforcement	Reports, compliance notices not implemented	Not clear or targeted in terms of priority or responsibility; not supportive	No improvement in compliance or in quality and safety; reputational loss	Supportive inspections, clear reports and actions including attribution of responsibility; formal feedback, re-inspections; ongoing monitoring
		Regulatory principles	Regulatory principles not fully implemented	Start-up phase and pressure of expectations lead to inadequate attention to detail	Erosion of credibility, legitimacy and effectiveness	Build regulatory principles into planning, monitoring and evaluation of work

11. PROGRAMME 3: COMPLAINTS MANAGEMENT AND OFFICE OF THE OMBUD*

11.1. Programme Purpose

To consider, investigate and dispose of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

(**Ombud functions integrated into Strategic objectives and indicators as functionally Ombud is located with the Office [NHAA S 81 (3) (b) and uses staff of the Office NHAA S 81 (3) (c), however funding is ring-fenced*]

11.2. Strategic Objectives

Strategic Objective 3.1	**Create an accessible mechanism to lodge complaints with the OHSC**
Objective statement	An accessible mechanism by which Complaints can be lodged with the OHSC is in place
Indicator	Fully functional Call Centre system for receiving complaints
Baseline (2014-15)	New Indicator
Target (2015-20)	Functional call centre

Strategic Objective 3.2	**Investigate and respond to complaints or concerns about non-compliance with norms and standards effectively**
Objective statement	Complaints regarding non-compliance with norms and standards are effectively investigated and responded to
Indicator	Procedures for receiving and managing complaints developed
Baseline (2014-15)	New indicator
Target (2015-20)	Procedures for receiving and managing complaints in place
Indicator	% of complaints lodged with the OHSC investigated and responded to within six months.
Baseline (2015-16)	New Indicator
Target (2015-20)	80%

Strategic Objective 3.3	**Issue findings and recommendations about complaints of non-compliance with prescribed norms and standards within six months**
Objective statement	Findings and recommendations relating to complaints of non-compliance with prescribed norms and standards are issued within 6 months
Indicator	System and procedures for investigation of complaints set up
Baseline (2014-15)	New indicator
Target (2015-20)	System set up and functional
Indicator	% of investigations finalised by the Ombud within 6 months from the lodgement date
Baseline (2014-15)	New Indicator
Target (2015-20)	80%

Strategic Objective 3.4	Communicate and monitor recommendations made by the Ombud
Objective statement	Ombud recommendations about complaints of non-compliance with prescribed norms and standards are communicated to OHSC for monitoring and follow up
Indicator	Procedures for communication and monitoring of Ombud recommendations set up and functional
Baseline (2014-15)	New Indicator
Target (2015-20)	System set up and functional
Indicator	% of Ombud recommendations monitored for implementation by health establishment within six months of tabling to OHSC
Baseline (2014-15)	New indicator
Target (2015-20)	80%

11.3. Resource considerations

11.3.1. Trends in the numbers of key staff:

- The staff under this programme comprises of the Complaints Management division and the Office of the Ombud.
- The National Health Amendment Act requires that the Ombud is funded through money appropriated by Parliament in order to ensure and protect the independence of this office. However, the OHSC will assist and support the Ombud's office. The layout of the budget therefore reflects this provision.
- The OHSC anticipates that with the promulgation of the regulations for the norms and standards, there will be an increase in the volume of complaints lodged with the Office.
- Provision has been made for additional staff members for the call centre, complaints assessments and investigations, which will further provide additional capacity for the proper functioning of the Office of the Ombud.
- Over time, ways of extending access to the Ombud through partnerships, and district-level agents will be developed and tested.

Table 9

	2015/16	2016/17	2017/18	2018/19	2019/2020
▪ Management/Professionals (L11 – L16)	2	6	9	9	9
▪ Employees (L10 & Below)	4	7	8	8	8

11.3.2. Expenditure trends

- The budget for this programme will increase from R12.9 million in 2016/17 to R16.9 million in 2019/20 over the MTEF period.
- The major expenditure for this programme is compensation of employees.
- The complaints call centre will be fully operational and staffed to receive complaints. The call centre will serve as one of the channels for the complaints system, including assessment and referral and communication with the Ombud regarding monitoring of the implementation of recommendations.

- The OHSC expects an increase in travelling and accommodation costs covering the volume of activities in all the provinces.

Programme 3: Complaints Management and Office of the Ombud

Economic Classification			Medium-term estimates		
	Audited outcomes 2015/16	2016/17	2017/2018	2018/19	2019/20
CURRENT PAYMENTS	**3 498 872**	**12 999 833**	14 769 975	15 835 475	16 955 628
Compensation of employees	3 033 971	10 792 811	12 479 195	13 450 011	14 470 178
Goods and services of which:	464 901	2 207 022	2 290 780	2 385 464	2 485 450
Travel,subsistence and accommodation	76 679	377 442	1 100 000	1 161 600	1 226 650
Venues and facilities	-	17 403	50 000	52 800	55 757
Catering services	-	95 436	100 780	106 424	112 384
Training and development	11 950	-	-	-	-
Consulting and professional services	375 801	-	400 000	422 400	446 054
Inventory and consumables	471.68	36 741	40 000	42 240	44 605
Operating lease (lease of equipment)	-	1 680 000	600 000	600 000	600 000
PAYMENTS FOR CAPITAL ASSETS	**-**	**-**	**-**	**-**	**-**
TOTAL	**3 498 872**	**12 999 833**	**14 769 975**	**15 835 475**	**16 955 628**

11.4. Risk Management

Table 10

RISK NO.	RISK CONTEXT	RISK NAME	RISK DESCRIPTION	ROOT CAUSE	POTENTIAL CONSEQUENCE	MITIGATION PLAN
1	Financial Resources	Inadequate funding for scale-up	Slow growth in Ombud capacity and reach	Establishment phase for Ombud; competing demands on OHSC budget	Loss of credibility given very high public expectation	Clear start-up plan and media communication
2	Capacity constraints	Complaint management and investigative capacity	Speed and scope of set-up of Ombud office too slow for public expectations	Start-up phase; highly level of skills required; ensuring access	Loss of credibility if initial systems are overwhelmed	Clear start-up plan and media communication; partnerships for leverage of existing institutions; expert panel
3	Reputational	Timeliness of findings	Ombud may struggle to conclude cases within 6 months	Overload of cases relative to capacity; selection too wide	Loss of credibility	Careful criteria for selection and communication of these; rigorous monitoring
		Acceptability of findings	Ombud findings and recommendations contested by complainants, public	Ombud processes flawed; public or complainant misunderstanding; expectation of compensation	Loss of credibility Legal challenge	Careful procedures for investigation and reporting

RISK NO.	RISK CONTEXT	RISK NAME	RISK DESCRIPTION	ROOT CAUSE	POTENTIAL CONSEQUENCE	MITIGATION PLAN
		Impact of findings	Ombud recommendations not implemented by HEs	Respondents perceive recommendations as unaffordable, impossible or unimportant	Loss of credibility, perception of bias	Strong monitoring of recommendations through prioritised inspections
		Use of findings	Ombud findings to complainants used for litigation	Expands access to justice but also facilitates position of lawyers	Spike in medico-legal cases leads to opposition to work of Ombud	
4	Governance Risk	Placement of Ombud	Relationship with OHSC unclear in terms of support and independence	Reporting lines and funding of Ombud separate but staff and support of Ombud through OHSC	Potential for duplication or disagreement	Clear protocols focussed on mutual advantage, formal and regular review and monitoring; advisory panel

12. PROGRAMME 4: HEALTH STANDARDS DESIGN, ANALYSIS AND SUPPORT

12.1. Programme Purpose

To provide high-level technical, analytical and educational support to the mandate of the Office in relation to the research, development and analysis of norms and standards; and support; capacity building and establishment of communication networks with stakeholders.

12.2. Strategic Objectives

Strategic Objective 4.1	**All health establishments obligated or regulated by prescribed norms and standards to submit annual returns before the end of March each year for purposes of monitoring and inspections**
Objective statement	All HEs obligated by prescribed norms and standards annually submit required data for analysis to determine the profile of each HE
Indicator	System for submission of annual returns by regulated health establishments set up and functional
Baseline (2014-15)	New indicator
Target (2015-20)	System set up and functional
Indicator	% of annual returns analysed within 60 days to determine the profiles of HE
Baseline (2014-15)	New indicator
Target (2018-20)	80%

Strategic Objective 4.2	**Recommend norms and standards for different types of HEs for submission to the Minister for promulgation**
Objective statement	Norms and standards for different types of HEs are recommended to the Minister for promulgation
Indicators	Number of norms and standards recommended to the Minister annually
Baseline (2014-15)	New indicator
Target (2015-20)	3

Strategic Objective 4.3	**Provide guidance on compliance with norms and standards for regulated HEs**
Objective statement	National, Provincial, district and municipal authorities and hospital groups (relevant authorities) that have completed the OHSC training of trainers programme
Indicators	# of relevant authorities responsible for support to health establishments that have received guidance on compliance with norms and standards
Baseline (2014-15)	New indicator
Target (2015-20)	14

Strategic Objective 4.4	**Monitor early-warning reports of situations of potential risk from HEs or users to prioritise inspections**
Objective statement	Appropriate action (reporting, inspection, investigation) is taken against HEs identified as high risk by early warning reports
Indicator	Fully functional surveillance system that reports on potential risks to compliance
Baseline (2014-15)	New indicator
Target (2015-20)	System set up and functional
Indicator	% of health establishments identified as high risk that are referred to the appropriate division/unit within OHSC
Baseline (2014-15)	New
Target (2015-20)	100%

12.3. Resource considerations

12.3.1. Trends in the numbers of key staff:

- The bulk of the staff in this division will be highly skilled individuals in the areas of standards development, data analysis, and guidance and training programmes.
- The appointments over the next 5 years will ensure that the expertise and information of the OHSC is used strategically to enhance quality and safety improvements in the health system through standard setting, business intelligence and knowledge management, as well as through contributing this knowledge to the development of competent and skilled OHSC staff and providing guidance to all regulated entities.

Table 11

	2015/16	2016/17	2017/18	2018/19	2019/2020
▪ Management/Professionals (L11 – L16)	**5**	**9**	**9**	**9**	**9**
▪ Employees (L10 & below)	**1**	**2**	**3**	**3**	**3**

12.3.2. Trends in the supply of key inputs

- Expertise and skills are the most critical input into this unit which is focused on quality not quantity. In addition, the OHSC may be required to look for strategic partnerships to be able to ensure this, as well as investing in staff development.

12.3.3. Expenditure trends

- The budget under this programme will increase from R8.8 million in 2016/17 to R12.9 million in 2019/20.
- The main budget item is the remuneration of employees in view of the division's plans to conduct a review of and/or develop new norms and standards, and measurement tools. This will also include additional work in terms of guidance, support and research at both national and provincial levels.
- The review of the norms and standards, coupled with guidance and support at national and provincial levels, necessitates budgetary provision for increased travelling and accommodation provisions

- Additional external technical expertise and input will also be required

Programme 4: Health Standards Design, Analysis and Support Budget

Economic Classification			Medium-term estimates		
	Audited outcomes 2015/16	2016/17	2017/2018	2018/19	2019/20
CURRENT PAYMENTS	**4 154 647**	**8 863 582**	**11 716 474**	**12 572 968**	**12 946 153**
Compensation of employees	2 888 816	7 521 959	9 424 254	10 152 384	10 922 337
Goods and services of which:	1 265 831	1 341 623	2 292 220	2 420 584	2 023 816
Travel,subsistence and accommodation	170 320	367 206	641 820	677 762	677 762
Venues and facilities	180 467	50 000	400 000	422 400	446 054
Inventory and consumables	7 147	-	-	-	-
Catering services	152 486	24 417	-	-	-
Consulting and professional services	755 411	900 000	1 250 400	1 320 422	900 000
PAYMENTS FOR CAPITAL ASSETS	**-**	**-**	**-**	**-**	**-**
TOTAL	**4 154 647**	**8 863 582**	**11 716 474**	**12 572 968**	**12 946 153**

12.4. Risk management

Table 12

RISK NO.	RISK CONTEXT	RISK NAME	RISK DESCRIPTION	ROOT CAUSE	POTENTIAL CONSEQUENCE	MITIGATION PLAN
1.	Capacity constraints	Skill recruitment and retention	Highly skilled staff hard to recruit and retain	Specialised skills very scarce in the market	Inability to produce expected outputs (standards, tools, reports) leads to OHSC not delivering on mandate	Ensure favourable working environment; seeks partnerships; use expert panels
3	Reputational	Early warning system	Early warning system does not correctly identify risk in time	Low reporting, inaccurate profiling of risk	Loss of credibility form public scandals not prioritised by OHSC	Media campaigns; focus on users and monitors but with clear roles and expectations
		Standards and tools	Standards and tools do not correctly identify risks to quality and safety or HEs most at risk	Poor design of standards and tools; slow scale-up of coverage of all types of HEs due to inability to monitor	Loss of credibility of OHSC	Careful design and validation of standards and tools; media campaigns on focus

RISK NO.	RISK CONTEXT	RISK NAME	RISK DESCRIPTION	ROOT CAUSE	POTENTIAL CONSEQUENCE	MITIGATION PLAN
4	Governance Risk	Scope of work	Work of HSDAS may be inadequate as support of OHSC core business	Inadequate skills and capacity relative to need; poor reporting and internal communication	Reduced efficacy and effectiveness of OHSC and Ombud monitoring, investigation and enforcement capacity	Organisation-wide planning and monitoring of HSDAS work; use of partnerships and contracted capacity

PART C

LINKS TO OTHER PLANS

PART C: LINKS TO OTHER PLANS

13. LINKS TO OTHER PLANS

There are no links to other plans or envisaged capital investments at this stage.

PART D

ANNEXURES

PART D: ANNEXURES

14. ANNEXURE 1: BUDGET PROGRAMME SUMMARY

OHSC Budget Programme Summary

SUMMURY BUDGET PER PROGRAM

DIVISION	Audited outcomes 2015/16	2016/17	2017/2018	2018/19	2019/20
CEO's office	5 874 012	12 402 743	12 335 087	13 097 779	12 897 804
Compliance Inspectorate, Certification and Enforcement	30 492 386	39 429 532	49 110 158	53 377 089	57 209 945
Complaints management	3 498 872	12 999 833	14 769 975	15 835 475	16 955 628
Corporate services	23 380 802	26 839 310	37 779 305	38 119 689	40 441 470
HSDAS	4 154 647	8 863 582	11 716 474	12 572 968	12 946 153
TOTAL	**67 400 719**	**100 535 000**	**125 711 000**	**133 003 000**	**140 451 000**

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