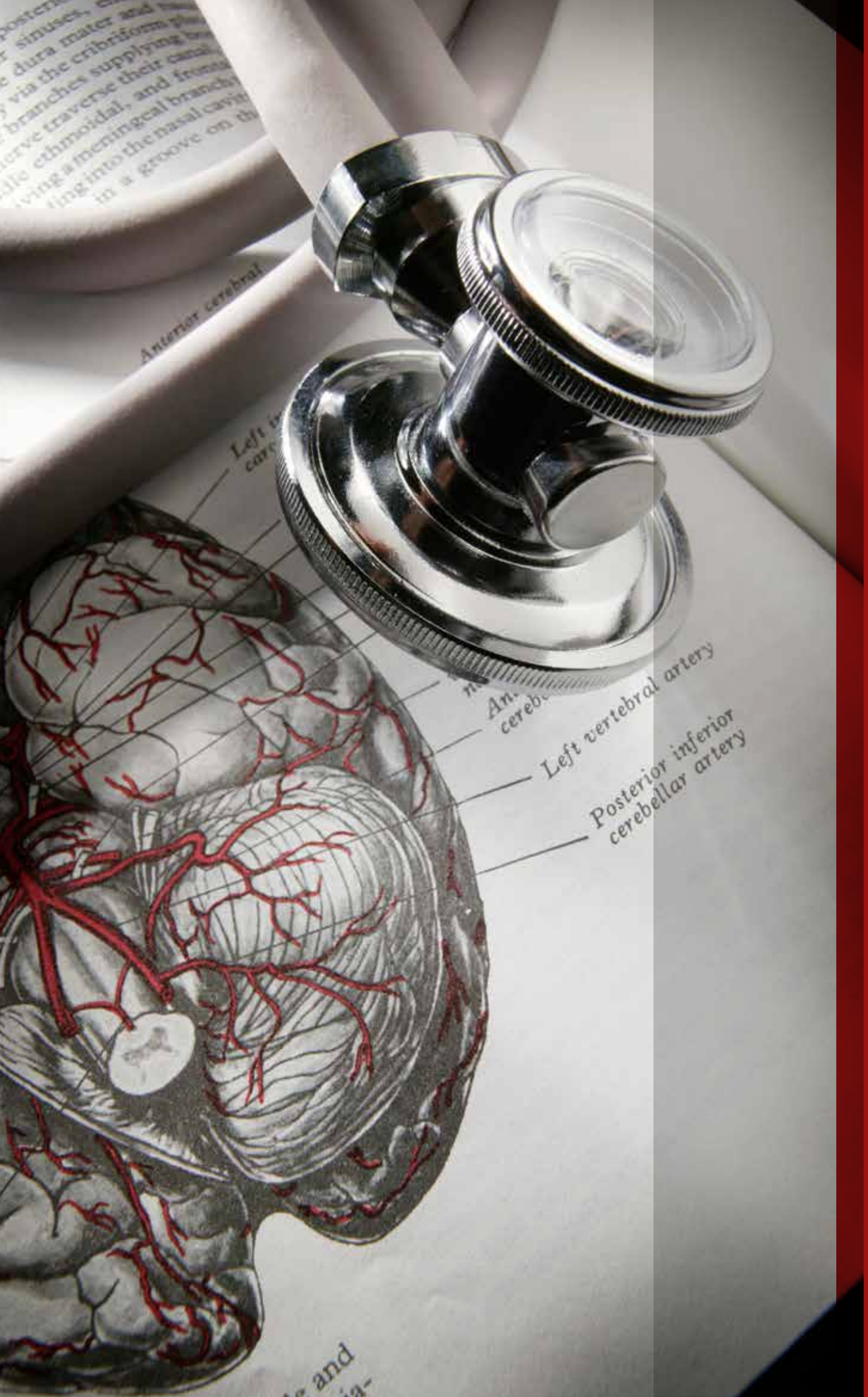
STRATEGIC PLAN

For the Fiscal Years 2015/16 to 2019/20

OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care


Anterior cerebral
Left vertebral artery
Posterior inferior cerebellar artery

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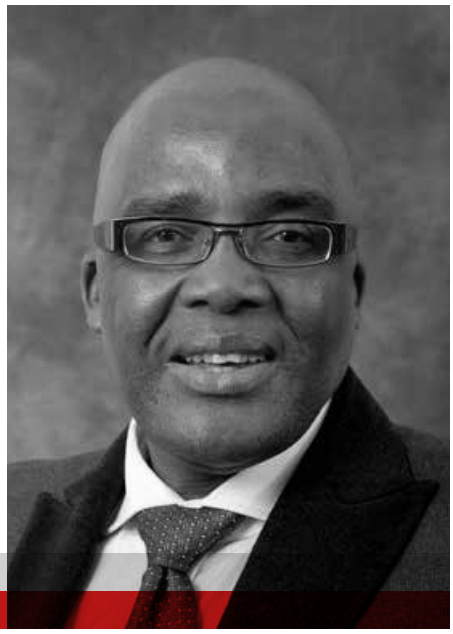


Foreword by the Minister of Health

This Strategic plan for the years 2015 to 2020 has been developed by the newly-established public entity, the Office of Health Standards Compliance. 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, 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 PA Motsoaledi

Executive Authority, Department 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, 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, 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" (National Health Act section 47).

Earlier preparatory work was done by the Office of Standards Compliance within the National Department of Health towards the establishment of the Office of Health Standards Compliance (OHSC) as a Schedule 3A public entity. The new independent OHSC has existed in law since the National Health Amendment Act (NHAA) was promulgated by the President on 2nd September 2013. In January 2014 the Minister of Heath, Dr. Aaron Motsoaledi appointed the first OHSC Board, and a Chief Executive Officer was appointed for the period April 2014 to July 2015. Appointments to the OHSC Executive Team and to all approved units of the entity are being made.

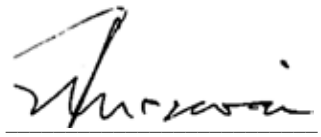
The OHSC's strategic plan is guided by the Strategic Planning and the Medium Term Strategic Frameworks (MTSF). This Strategic Plan for 2015-2020 heralds a new phase in cooperating and strengthening relationships with health sector and other partners to facilitate and support the implementation of norms and standards at all levels of care. Strengthening health systems for the achievement of the Millennium Development Goals, National Development Plan Goals, National Health Insurance and the National Service Delivery Agreement outcome 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 and 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 Motsoaledi, the Director-General, Ms Matsoso and the National Department of Health.

The final and most heartfelt acknowledgement and thanks is to my fellow Board members who are serving on this Board until January 2017 and are part of this important journey:

a) Professor Laetitia Rispel – OHSC Deputy Chairperson
b) Dr. Zameer Brey
c) Ms. Vuyiseka Dubula
d) Professor Sabiha Yusuf Essack
e) Ms. Thembeka Gwagwa
f) Mr. Martin Kuscus
g) Advocate Simmy Lebala
h) Ms. Josephine Mabotja
i) Professor Ethelwynn Stellenberg
j) Professor Gert van Zyl
k) Professor Stuart Whittaker



Professor Lizo Mazwai
Chairperson of the Board; Office of Health Standards Compliance

OFFICIAL SIGN-OFF

It is hereby certified that this OHSC 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 2020.

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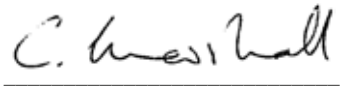
Chief Financial Officer (not yet appointed)



Dr. Carol Marshall:
OHSC CEO Interim
Date: 27 February 2015

Professor Lizo Mazwai:
OHSC Chairperson
Date: 27 February 2015

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:

- Act as the champion of the public and of healthcare users so as to restore credibility and trust;
- Respect healthcare users and their families as well as healthcare staff;
- Push for effectiveness in achieving health system change and social impact;
- Strive for excellence, innovation and efficiency in our operations;
- Are truthful, fair and committed to intellectual honesty;
- Practice transparency but respect confidentiality;
- Achieve the highest standards of ethical behaviour, teamwork and collaboration; and
- 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 National Department of Health of an Office of Standards Compliance with provincial Inspectorate units. The Office of Standards Compliance 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 Ombudsperson.

6.1.3 The National Health Amendment Act (2013)

Chapter 10 of the National Health Act relating to the Office of Standards Compliance 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 Office of Health Standards Compliance.

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 unauthorised 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.
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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; and
- The Merchandise Marks Act No. 17 of 1941

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 (National Department of Health).

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. 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 "National Core Standards for Health Establishments in South Africa" (NCS) 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 National Core Standards 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; and
- 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 National Health Insurance (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 National Department of Health 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 National Department of Health 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, and is critical in the progressive improvement of the public sector and in the partnerships and collaboration towards this end needed now and in the future.

The Green Paper as well as subsequent policy pronouncements proposes that certification by the Office of Health Standards Compliance with respect to quality norms and standards will be a prerequisite in the future for providers to be accredited and contracted by the NHI fund to render defined health services. A White paper on NHI is expected to be published shortly.

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;
f) Public services are uneven and often of poor quality
g) Corruption levels are high; and
h) 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 Office of Health Standards Compliance (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 have been signed the Minister of Health and published for comment as per Section 90(b) and (c) of the National Health Act as amended. These prescribed norms and standards are intended to apply to the following categories of health establishments at present:

- 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 will apply to other categories of health establishments contemplated in the Act, once the OHSC has advised the Minister in this respect and the Minister issues 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 OSC / OHSC has undertaken a process of extensive consultation since 2013 in order to 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 the 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 ISQUA

(the International Society for Quality in Healthcare) in relation to principles of Norms and standards for quality care 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 acts of omission or commission with respect to 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 guidance.

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 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. The procedural regulations require the Office to issue an inspection strategy and a plan outlining its approach.

6.2.7 Procedural regulations

The procedural regulations signed by the Minister and published for comment guide the exercise of powers conferred on the Office, the Board, the Chief Executive Officer, the Ombud and the Inspectors by the Amendment Act, which they elaborate on in the form of details, procedures and processes.

Areas covered in these regulations are:

- Collection of information from Health Establishments (HEs) 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, for laying 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 proposed 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 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 un-announced 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

At this point there are no planned policy initiatives on the part of the OHSC over and above the promulgation of the regulations outlined above.

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 indentified priority areas or basic critical requirements.

Other identified health sector organisational problems include:

a) Unacceptably 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; increasing numbers of medico-legal claims and resultant costs.

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 Department of Health has been implementing a large number of initiatives for reform of the healthcare sector and as a preparation for the implementation of National Health Insurance 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 Office of Health Standards Compliance 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 National Core Standards 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 collaboratives, 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 providing 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 Office of Standards Compliance set up within the Department of Health 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 December 2014 is 891 or over 20% 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 HE, 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; and
- 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 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 institutionalised 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.

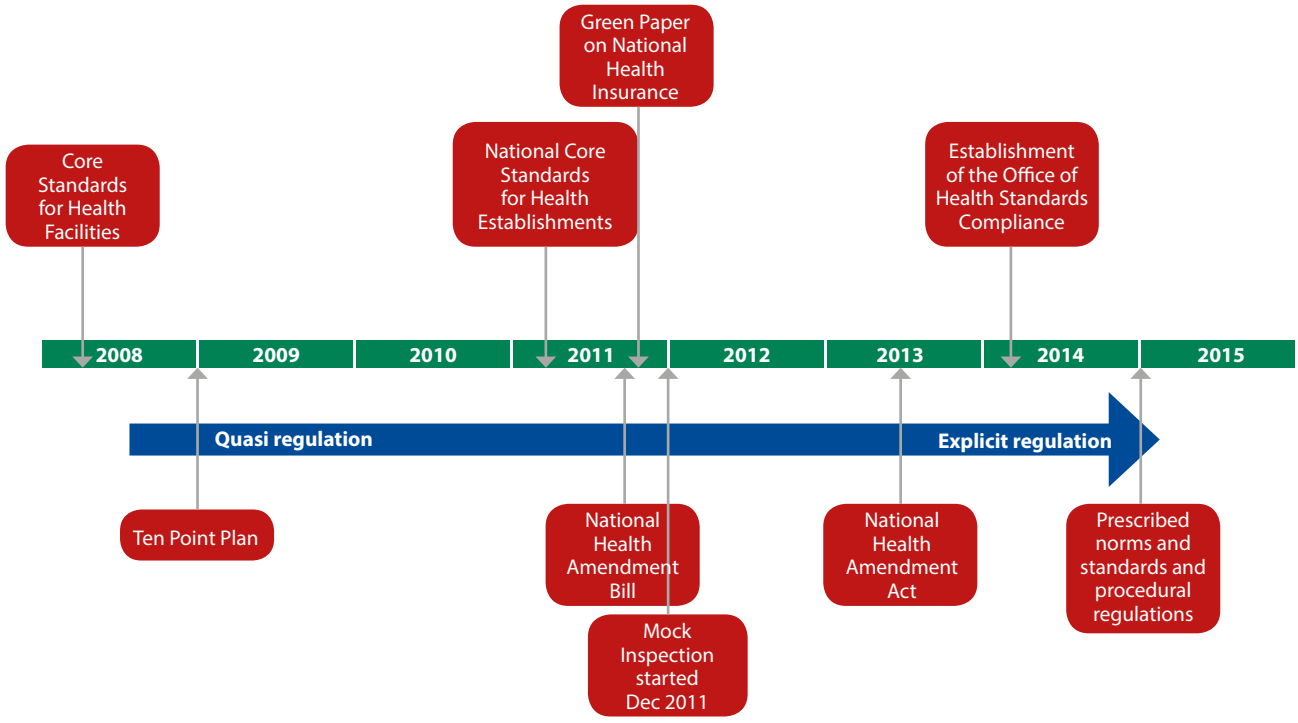
7.2.1 Historical Evolution

The Cluster: Office of Standards Compliance (OSC) in the National Department of Health (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 Office of Heath Standards Compliance (OHSC) as outlined in the table below. The transition to the independent regulator is now almost 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 "Office of Standards Compliance" within National DOH.
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 "National Core Standards 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

Diagram 1: Evolution of Process



7.2.1 Strengths, Weaknesses, Opportunities and Threats

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 Ombudsman 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 directly enforce compliance • Lack of early warning system in the sector currently • Limited resourcing (staff and budget) • 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 and 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 Department of Health • High public expectations of the office • Compromised perception of not being independent • Perceptions on non-independence from NDoH • Imbedded bureaucracy and accountability to National Treasury and oversight bodies • Other legal and regulatory developments (PoPI, PAIA)

7.2.3 Strategies

The broad strategies adopted by the Board of the Office of Health Standards Compliance 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:

1. Prioritise those establishments that are the weakest and serve the most disadvantaged users in order to shift the system towards safer care, while still recognising excellence wherever it is found;
2. Use a progressive and developmental approach to enforcement in order to enhance change at different levels of the system;
3. 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;
4. Create and effectively use platforms for interaction with key user, provider and leadership groups to foster collaborative efforts towards improved outcomes; and
5. 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.

7.2.4 Regulatory response

The enabling legislation setting up an independent regulator, the Office of Health Standards Compliance (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 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 will be promulgated, probably during the course of 2015.

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 National Health Insurance 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 "National Core Standards" 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.*"

7.2.5 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 ad findings with 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

Regulatory principles	Risk	Root cause	Mitigation
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
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

7.2.6 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 Public Finance Management Act (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 Chief Executive Officer (CEO) of the OHSC, in consultation with the Minister. 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 and accounting officer of the Office. An interim CEO has now been appointed; 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 National Health Insurance 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.

7.2.7 Establishment of the Office of Health Standards Compliance

A detailed Business case and staffing structure relating to the establishment of the Office of Health Standards Compliance was approved by the Minister of Health in June 2013 and by the Minister of the Public Service 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 Office of Standards Compliance within the NDOH to prepare for the establishment of the future public entity. The new Office of Health Standards Compliance (OHSC) as a juristic person has existed in law since the National Health Amendment Act (NHAA) was promulgated by the President on 2nd September 2013. With the appointment of the Board in January 2014, the Accounting Authority of this new body was put in place. The Board has already taken significant steps through its Committees to ensure the needed policies and controls are in place and that its core business is carried out effectively and efficiently and in accordance with the highest standards of governance. Additionally, by notice in the gazette published by the Minister of Finance on 23rd May 2014, the OHSC been listed as a Section 3A Public Entity.

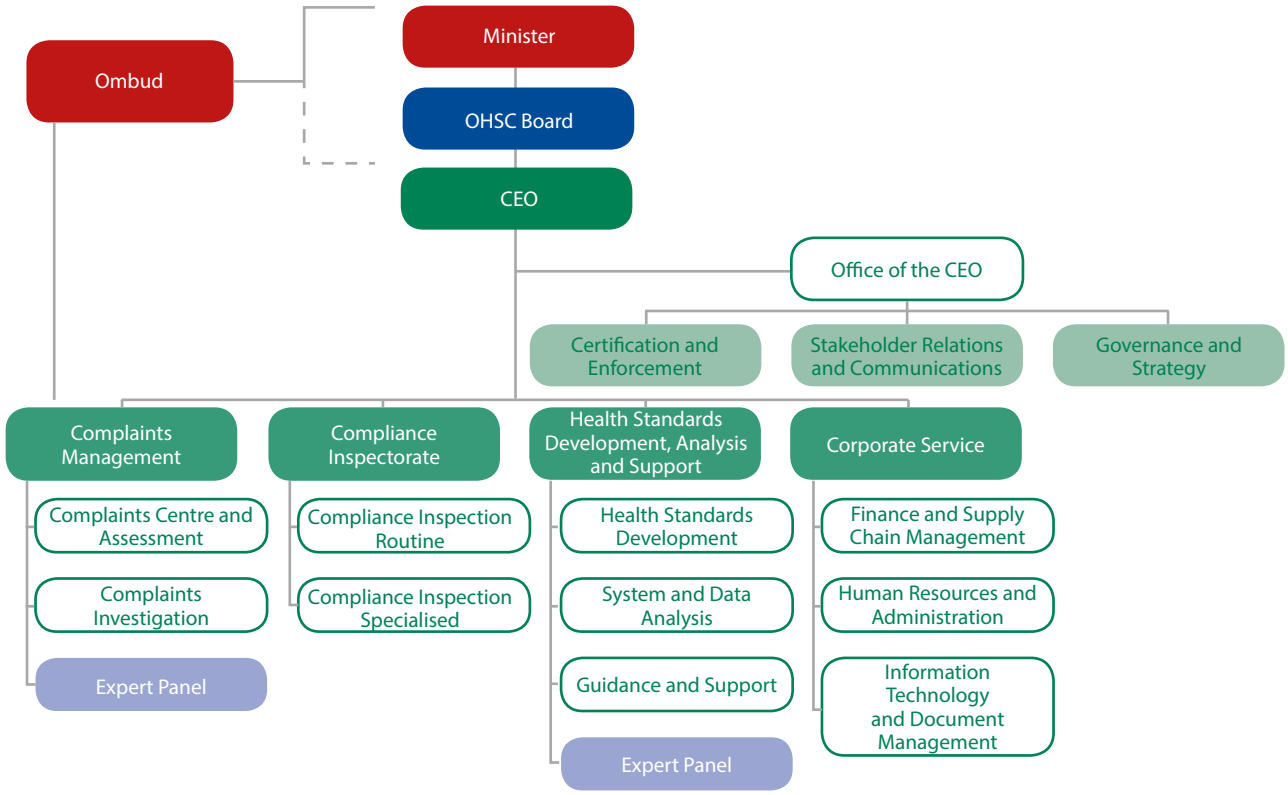
An Interim Chief Executive Officer has been appointed by the Board and the Minister by secondment from the NDoH effective 1st April 2014 – July 2015 with full delegation of powers from the Board. The process of appointing of an Ombud by the Minister of Health will be finalised by the Minister. The initial transition phase has been governed by a Memorandum of Agreement signed between the National Department of Health and the Office enabling provision of support and services to the Office while their staffs were being recruited and policies and systems set up. The new entity is anticipated to be essentially independent by the start of the new financial year in April 2015.

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 Executive and Senior managers and initial staffing of all units to enable functionality is expected to be completed by mid-2015 and numbers 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.

- **Organisations that are primarily interested in the effective and fair regulation and oversight of healthcare services.** These would include Parliament, the National Department of Health, 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 is still being 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 Strategic plan reflects extensive inputs obtained from the Board in relation to their vision for the OHSC, as expressed in a number of meetings they have already held since their inauguration on 29th January 2014. The OHSC has itself consulted widely on its Goals, Objectives and proposed regulations.

It also captures extensive inputs received over the past few years in relation to the drafting of the Business case for the future public entity.

The work of the Office of Standards Compliance in the National Department of Health, 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 process.

7.5 Strategic outcome oriented goals of the OHSC

The OHSC has four Strategic Outcome Oriented Goals in with its mandate as summarised below:

Goal 1	**Health Establishments (HEs) comply 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 2	**Patient and community complaints regarding poor care and situations of concern are heard and responded to**
Goal statement	The public is protected through ensuring that poor care and situations of concern are heard and responded to
Indicator	Number and % of complaints from users and communities that are responded to within 6 months

Goal 3	**The quality and safety of healthcare is progressively improved through effective communication and collaboration between the OHSC and users, providers and other entities**
Goal statement	The OHSC communicates and works with users, providers and other entities through written agreements for collaboration and information sharing to enhance quality and compliance.
Indicator	# Public awareness initiatives executed

Goal 4	**The OHSC is an efficient and effective high performing organisation that is responsive and publicly accountable**
Goal statement	The OHSC is inefficient and effective high performing organisation that is responsive and publicly accountable
Indicator	Auditor General Annual Findings Rating

PART B
STRATEGIC OBJECTIVES

8. Strategic Goals and Objectives

The OHSC has 23 Strategic Objectives aligned with the 4 Strategic Goals (Outcomes)

Goals	Objectives
1. Health establishments (HEs) comply with quality norms and standards	1.1 All HEs regulated by prescribed norms and standards are registered annually for purposes of monitoring and inspections
	1.2 Guidance is provided on compliance with norms and standards for regulated HEs
	1.3 Compliance with quality standards in regulated health establishments is monitored and inspected at least every 4 years
	1.4 Non-compliant HE are subjected to re-inspection or review within 6 months
	1.5 Health Establishments found to be compliant with prescribed norms and standards are certified.
	1.6 Enforcement action is effected with respect to persistently non-compliant health establishments
	1.7 An early warning system of potential situations of risk is implemented by HEs to prioritise inspections
2. Patient and community complaints regarding poor care and situations of concern are heard and responded to.	2.1 An accessible mechanism by which Complaints can be lodged with the OHSC is in place
	2.2 Complaints or concerns regarding non-compliance with norms and standards are effectively managed and disposed of
	2.3 Findings and recommendations relating to complaints of non-compliance with prescribed norms and standards are issued within agreed time frames
	2. 4 Recommendations made by the Ombud are communicated and monitored
3. The quality and safety of healthcare is progressively improved through effective communication and collaboration between the OHSC and users, providers and other entities.	3.1 Public, provider and stakeholder awareness on the roles and powers of OHSC is created
	3.2 Norms and standards for different types of HEs are consulted, developed and/or revised for submission to the Minister for promulgation
	3.3 Memoranda of Agreement to further the mandate and objectives of the OHSC are in place with relevant regulators or other organisations
	3.4 Information relating to compliance with norms and standards is published
	3.5 An Early warning system of potential situations of risk from users and other entities is in place to prioritise inspections
4. Efficient and effective high performing organisation that is responsive and publicly accountable.	4.1 A functional Office is set-up and suitably staffed in accordance with the mandate and goals of the OHSC
	4.2 Inspectors are accredited after successfully completing approved training course
	4.3 Financial management and PFMA requirements are complied with
	4.4 The IT system meets the needs of the OHSC

9. Programme 1: Office of the CEO

9.1 Programme Purpose

To provide the leadership, communication and regulatory functions required to carry out the mandate and functions of the OHSC as per the legislative requirements.

9.2 Strategic Objectives

Strategic Objective 1.5	Health Establishments found to be compliant with prescribed norms and standards are certified
Objective statement	Health Establishments found on inspection to be compliant with prescribed norms and standards are issued with certificates of compliance within 60 days of inspection
Indicator	System for certification of compliant instructions set up and functional
Baseline (2014-15)	New indicator
Target (2015-20)	System set up and functional
Indicator	% compliant establishments certified by the OHSC within two months of inspection by the OHSC
Baseline (2014-15)	New indicator
Target (2015-20)	100%

Strategic Objective 1.6	Enforcement action is effected with respect to persistently non-compliant health establishments
Objective statement	Enforcement action as regulated is taken with respect to persistently non-compliant health establishments
Indicator	System and procedures for timely enforcement action set up and functional
Baseline (2014-15)	New indicator
Target (2015-20)	System set up and functional
Indicator	% persistently non-compliant establishments for which regulated actions initiated within 6 months of inspection by the OHSC
Baseline (2014-15)	New indicator
Target (2015-20)	100%

Strategic Objective 2.4	Recommendations made by the Ombud are monitored
Objective statement	Recommendations relating to complaints of non-compliance with prescribed norms and standards are monitored and followed-up by the OHSC
Indicator	System and procedures for communication of 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 within six months of tabling to OHSC
Baseline (2014-15)	New indicator
Target (2015-20)	80%

Strategic Objective 3.1	Public, provider and stakeholder awareness on the roles and powers of OHSC is created
Objective statement	Activities are carried out to create public awareness on roles and powers of OHSC.
Indicator	Number of media and communication events and campaigns to increase awareness of the OHSC among public, providers and stakeholders carried out annually
Baseline (2014-15)	New indicator
Target (2015-20)	12

Strategic Objective 3.3	Memoranda of Agreement (MOAs) to further the mandate and objectives of the OHSC are in place with relevant regulators or other organisations
Objective statement	MOAs to further mandate and objectives of OHSC relating to improved quality and safety are signed with relevant regulators or other organisations and their implementation is monitored prior to annual ratification
Indicator	Number of MOAs with regulators to protect and promote quality and safety of care in place each year
Baseline (2014-15)	New indicator
Target (2015-20)	10

Strategic Objective 3.4	Information relating to compliance with norms and standards is published
Objective statement	Information relating to compliance with norms and standards is published
Indicator	No. of reports on inspections conducted, recommendations issued, and compliance status of health establishments
Baseline (2014-15)	New indicator
Target (2015-20)	5

9.3 Resource considerations

9.3.1 Trends in the numbers of key staff:

- All business units in the CEO's office will have key staff in place during the 2015/16 financial year to enable the Office to have the needed systems in place. Some outsourced support may be necessary in order to use full time staff resources more efficiently.
- 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.
- By 2018 the units will have grown to 14 posts with subsequent growth dependent on funding, with a particular focus on effective communication and stakeholder relations, including publication of OHSC compliance findings and recommendations.

Personnel	Existing	2015/16	2016/17	2017/18
Management (L11-L16)	(2)	6	6	7
Employees (L10 and below)	(0)	2	3	4
Interns				

9.3.2 Trends in the supply of key inputs:

- The Board was appointed in January 2014 and has assumed its oversight and policy-making role;
- A CEO has been appointed from April 2014 until July 2015, when a long term appointment will be made; and
- The baseline allocation will be progressively increased to enable the organisation to meet its legislated mandate.

9.3.3 Expenditure trends

- The CEO's budget increases from R11 Million in 2015/16 to R 13 Million in 2017/18 to enable the Office to meet its strategic objectives.
- The large budget items within the unit of the CEO are:
  - Advertising which represents 14% of the CEO's budget over the MTEF period which will be channeled for the media and communication on the OHSC;
  - The Board and Expert panel remuneration represents 11% the budget over the MTEF period to enable the adequate corporate governance and oversight with required additional expertise as needed; and
  - Travel and subsistence represents 6% of the budget to enable the staff within the unit to carry out the strategic objectives.

Programme 1: Office of the CEO Budget

	Medium term estimates		
CURRENT PAYMENTS	**2015/16**	**2016/17**	**2017/18**
Compensation of employees	**6,070,836**	**6,694,671**	**7,571,232**
Salaries and wages	6,070,836	6,694,671	7,571,232
Goods and services	**4,977,257**	**4,451,525**	**5,470,182**
Advertising	1,944,309	1,064,793	1,748,033
Assets < than the threshold (currently R5 000)	52,700	55,493	58,268
Board and expert panel remuneration	1,056,108	1,312,082	1,377,686
Catering: Departmental activities	29,484	31,047	32,599
Communication	444,366	467,917	491,313
Computer services	167,586	176,468	185,291
Consultants and professional service: Business and advisory service	293,012	308,542	323,969
Inventory: Other consumables	212,486	223,748	234,936
Travel and subsistence	637,094	670,860	704,403
Venues and Facilities	140,112	140,575	313,685
Total current payments	**11,048,093**	**11,146,196**	**13,041,414**
Total payments for capital assets	**-**	**-**	**-**
TOTAL PAYMENTS	**11,048,093**	**11,146,196**	**13,041,414**

9.4 Risk management

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

Risk No.	Risk Context	Risk name	Risk Description	Root Cause	Potential Consequence	Mitigation Plan
2.	Leadership	Interim CEO	Currently the CEO is an interim appointment for 1 year	Minister and the Board have opted to ensure continuity in transition phase	Lack of stability and long term perspective once transition over	Board with in consultation with the Minister of Health to start the process of CEO appointment
4	Reputational	Independence	Perception of not being independent Unrealistic expectations re scope, powers and 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 rec-ommendations
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
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 formalised	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

10. Programme 2: Corporate services

10.1 Programme purpose

To provide the financial, human resources, IT and administrative support necessary for the OHSC to deliver on its mandate and comply with all relevant legislative requirements.

10.2 Strategic Objectives

Strategic Objective 4.1	A fully functional Office is set-up and suitably staffed in accordance with the mandate and goals of the OHSC
Objective statement	A functional OHSC is established with a budget and personnel in place to effectively implement the mandate of the Office
Indicator	% funded staff appointed
Baseline (2014-15)	New indicator
Target 2015-20	90%

Strategic Objective 4.3	Financial management and PFMA requirements are complied with
Objective statement	The PFMA Procedures for management controls and accountability as per the PFMA are in place
Indicator	Unqualified audit report without findings
Baseline (2014-15)	New Indicator
Target (2015-20)	Annual report

Strategic Objective 4.4	The IT system leverages technology to meet the needs of the OHSC
Objective statement	Specialised IT system for the OHSC is implemented
Indicator	IT system in place and functional
Baseline (2014-15)	New Indicator
Target (2015-20)	System in place and fully functional

10.3 Resource considerations

10.3.1 Trends in the numbers of key staff:

- The CFO and all business units (Finance, IT and HR) will have initial staffing during 2015/16;
- IT staff will be essential to permit management of the design and implementation of IT systems essential for the work of the office and to enhance efficiencies, and to manage outsourced development of the system;
- As the budget and the total staff complement grows the number of posts will increase to be able to service this growth, with a focus on efficiency and effectiveness; and
- Performance management and staff development will be a focus from the start.

	(Existing)	2015/16	2016/17	2017/18
• Management (L11 – L16)	(1)	6	6	8
• Employees (L10 and below)	(1)	10	12	16
• Interns		1	2	2
• Temps/Volunteers				

10.3.2 Trends in the supply of key inputs:

- Key policies for the organisation to be operational are approved to be implemented after the transition from NDoH;
- Additional funding will enable the OHSC to put in place a proper IT system and infrastructure; and
- Financial systems and structures in place to render the OHSC compliant with PFMA and Treasury regulations.

10.3.3 Expenditure trends

- The software and other intangible budget increases to R4.2 million in 2015/16 due to the development of a customised IT system for the OHSC;
- Lease for premises budget increases from R2 million in 2015/16 to R3.8 million 2017/18 to accommodate the growing organisation within the MTEF period; and
- Communication budget increases from R1.6 million in 2015/16 to R2 million in 2017/18, the budget is to cater for recruitment costs for a growing organisation.

Programme 2: Corporate Services Budget

	Medium term estimates		
CURRENT PAYMENTS	**2015/16**	**2016/17**	**2017/18**
Compensation of employees	**8,051,490**	**10,155,842**	**13,125,066**
Salaries and wages	8,051,490	10,155,842	13,125,066
Goods and services	**13,195,876**	**16,836,755**	**18,087,032**
Advertising	66,096	92,232	266,700
Assets < than the threshold (currently R5 000)	118,385	124,660	130,893
Audit cost: External	3,000,000	3,159,000	3,316,950
Agency and support / outsourced services	303,148	319,215	335,176
Catering: Departmental activities	30,039	31,631	33,213
Communication	1,556,308	1,975,201	2,000,461
Computer services	1,941,171	3,592,345	4,084,045
Consultants and professional service: Business and advisory service	414,508	436,477	458,300
Consultants and professional service: Legal cost	750,000	789,750	829,238
Households	750,000	789,750	829,238
Inventory: Other consumables	147,420	155,233	162,995
Inventory: Stationery and printing	632,400	665,917	699,213
Operating leases (Lease of premises)	2,000,000	3,635,963	3,817,761
Operating Payments (Lease of equipment)	309,876	326,299	342,614
Office Refurbishment	897,200	448,600	471,030
Training and development	175,917	185,592	194,872
Travel and subsistence	39,760	41,867	43,960
Venues and Facilities	63,649	67,023	70,374
Total current payments	**21,634,376**	**26,992,597**	**31,212,098**
			-
PAYMENTS FOR CAPITAL ASSETS			**-**
Buildings and other fixed structures	48,000	50,544	53,071
Buildings	-	-	-
Other fixed structures	48,000	50,544	53,071
Machinery and equipment	**107,000**	**105,000**	**110,250**
Transport equipment			-
Other machinery and equipment	107,000	105,000	110,250
Software and other intangible assets	**4,208,823**	**2,594,089**	**3,167,824**
			-
Total payments for capital assets	**4,363,823**	**2,749,633**	**3,331,145**
			-
TOTAL PAYMENTS	**25,611,190**	**29,742,230**	**34,543,243**

10.4 Risk Management

Risk No.	Risk Context	Risk name	Risk Description	Root Cause	Potential Consequence	Mitigation Plan
1	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 Reduce waste and improve efficiencies
2	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
3	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

11. Programme 3: Compliance inspectorate

11.1 Programme Purpose

To manage the inspections of health establishments in order to assess and encourage compliance with national health system norms and standards as prescribed by the Minister and take measures to ensure such compliance.

11.2 Strategic Objective

Strategic Objective 1.3	Compliance with quality standards in regulated health establishments is monitored and inspected at least every 4 years
Objective statement	To ensure acceptable standards of quality and safe health care delivery through compliance Inspections in public health establishments and HEs inspected at least every 4 years and relevant action is taken
Indicator	% of public sector clinics, CHCs and hospitals inspected annually by the OHSC
Baseline (2014-15)	10%
Target (2015-20)	20%
Indicator	% of private sector clinics, CHCs and hospitals inspected annually by the OHSC
Baseline (2014-15)	New indicator
Target (2015-20)	20%

Strategic Objective 1.4	Non-compliant HE are subjected to re-inspection or review within 6 months
Objective statement	Non-compliant HE are subjected to re-inspection or review within 6 months
Indicator	% of provisionally non-compliant health establishments subjected to re-inspection or review within 6 months
Baseline (2014-15)	New indicator
Target (2015-20)	60%

Strategic Objective 4.2	Inspectors accredited 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 an staff development function
Indicator	Requirements and procedures for accreditation of inspectors approved by the Board
Baseline (2014-15)	New indicator
Target (2015-20)	Requirements approved
Indicator	No of compliance inspectors accredited as competent
Baseline (2014-15)	New Indicator
Target (2015-20)	60

11.3 Resource considerations

11.3.1 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; and
- Inspection coverage should be 25% per year in terms of the legislated mandate but the capacity will have to be built up over time. It is envisaged to that by the end of the MTEF period the Inspectorate should reach 65 staff and be able to achieve 15% coverage and still sustain follow-up activities.

	(Existing)	2015/16	2016/17	2017/18
• Management (L11 – L16)	7	12	17	19
• Employees (L10 and Below)	36	38	39	46
• Interns				
• Temps/Volunteers				

11.3.2 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, as well as IT costs and training for accreditation (funded through other budget programmes).

11.3.3 Expenditure trends

- Travel and subsistence costs represent nearly 80% of the goods and services budget, with outsourced training and development the next most important although only at 5%.

Programme 3: Compliance Inspectorate Budget

	Medium term estimates		
CURRENT PAYMENTS	**2015/16**	**2016/17**	**2017/18**
Economic classification			
Compensation of employees	**24,562,643**	**27,921,785**	**36,163,584**
Salaries and wages	24,562,643	27,921,785	36,163,584
Goods and services	**9,938,724**	**10,784,920**	**11,453,691**
Assets < than the threshold (currently R5 000)	277,572	214,329	225,045
Catering: Departmental activities	57,770	73,305	76,971
Inventory: Other consumables	49,006	51,603	54,183
Training and development	533,145	591,567	621,146
Travel and subsistence	8,849,687	9,657,513	10,269,914
Venues and Facilities	171,544	196,602	206,432
Total current payments	**34,501,367**	**38,706,705**	**47,617,275**
Total payments for capital assets	-	-	-
TOTAL PAYMENTS	**34,501,367**	**38,706,705**	**47,617,275**

11.4 Risk Management

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
		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

12. Programme 4: Complaints Management (and Ombud)*

12.1 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].

12.2 Strategic Objectives

Strategic Objective 2.1	An accessible mechanism by which Complaints can be lodged with the OHSC is in place
Objective statement	An accessible mechanism by which Complaints can be lodged with the OHSC is in place
Indicator	Call centre in place and functional
Baseline (2014-15)	New Indicator
Target (2015-20)	Call centre meeting requirements in place and functional

Strategic Objective 2.2	Complaints or concerns regarding non-compliance with norms and standards are effectively managed and disposed of
Objective statement	Complaints regarding non-compliance with norms and standards are effectively managed and disposed of
Indicator	System for receiving and managing complaints set up and functional
Baseline (2014-15)	New indicator
Target (2015-20)	System in place
Indicator	(%) of Complaints lodged by the OHSC managed and resolved within 6 months
Baseline (2014-15)	New indicator
Target (2015-20)	80%

Strategic Objective 2.3	Findings and recommendations relating to complaints of non-compliance with prescribed norms and standards are issued within 6 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	% Investigations closed within 6 months
Baseline (2014-15)	New Indicator
Target (2015-20)	80%

12.3 Resource considerations

12.3.1 Trends in the numbers of key staff:

- This is a new unit in terms of its formal functioning to support the Ombud office with the Ombud and a personal assistant funded directly through a dedicated budget;
- The Complaints management unit will have basic staffing of 13 during the 2015/16 financial year to set up the call centre and manage early review of complaints, growing to 24 staff as the systems are set up and information starts going out to the public (This capacity could be significantly increased in the following years to put in place additional Complaints capacity at district level);
- The Ombud will then need to put in place the needed skills and systems for investigation with the progressive appointment of highly specialised staff supported by an expert panel; and
- Over time it is envisaged that the emphasis on enhancing access to the Ombud for the most disadvantaged will become increasingly apparent, with models for technological enhancements as well as district-level agents being tested.

	(Existing)	2015/16	2016/17	2017/18
• Management (L11 – L16)	(1)	6	7	12
• Employees (L10 and Below)	(2)	7	8	12
• Interns				
• Temps/Volunteers				

12.3.2 Trends in the supply of key inputs:

- The 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 second staff to assist and support. The layout of the budget therefore reflects this provision;
- A call centre to be established and staffed to manage incoming complaints;
- OHSC will put in place mechanisms for the proper channels for the complaints system, including assessment and referral and communication with the Ombud regarding monitoring of the implementation of recommendations; and
- Over time, ways of extending access to the Ombud through partnerships, through technology and through district-level agents will be developed and tested.

12.3.3 Expenditure trends

- The major expenditure item for the Ombud office and the complaints management unit is salaries and wages budget which increases from R8.4 million in 2015/16 to R17 in 2017/18;
- The travel and subsistence budget needs to enable investigation of selected cases on the ground where required;
- Other major expenditures such as media / advertising, legal advice, the IT systems and training support are funded through the budgets of other units.

Programme 4: Complaints Management (and Ombud) Budget

a) Complaints Management Budget

	Medium term estimates		
CURRENT PAYMENTS	**2015/16**	**2016/17**	**2017/18**
Economic classification			
			-
Compensation of employees	**6,042,683**	**7,399,558**	**14,046,138**
Salaries and wages	6,042,683	7,399,558	14,046,138
Goods and services	**987,536**	**988,681**	**1,038,115**
Advertising	283,728	298,766	313,704
Assets < than the threshold (currently R5 000)	98,000	52,000	54,600
Catering: Departmental activities	77,996	82,130	86,236
Consultants and professional service: Business and advisory service	105,400	110,986	116,536
Inventory: Other consumables	34,892	36,741	38,578
Training and development	104,182	109,704	115,189
Travel and subsistence	266,811	280,952	294,999
Venues and Facilities	16,527	17,403	18,273
Total current payments	**7,030,219**	**8,388,239**	**15,084,253**
Total payments for capital assets	-	-	-
TOTAL PAYMENTS	**7,030,219**	**8,388,239**	**15,084,253**

b) Ombud Budget

	Medium term estimates		
CURRENT PAYMENTS	**2015/16**	**2016/17**	**2017/18**
Economic classification			
Compensation of employees	**2,418,307**	**2,553,732**	**2,694,188**
Salaries and wages	2,418,307	2,553,732	2,694,188
Goods and services	**119,792**	**126,141**	**132,448**
Assets < than the threshold (currently R5 000)	7,378	7,769	8,157
Catering: Departmental activities	12,636	13,306	13,971
Training and development	15,810	16,648	17,480
Travel and subsistence	83,968	88,418	92,839
Total current payments	**2,538,099**	**2,679,873**	**2,826,636**
Total payments for capital assets	-	-	-
TOTAL PAYMENTS	**2,538,099**	**2,679,873**	**2,826,636**

12.4 Risk Management

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 ad 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
		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

13. Programme 5: Health Standards design Analysis and support

13.1 Programme Purpose

To provide high-level technical, analytical and educational support to the work of the Office in relation to the development and analysis of norms and standards and support for their dissemination.

13.2 Strategic Objectives

Strategic Objective 1.1	All HEs obligated or regulated by prescribed norms and standards are registered annually for purposes of monitoring and inspections
Objective statement	All HEs obligated by prescribed norms and standards / regulated submit required data for registration annually
Indicator	System for annual registration of regulated health establishments set up and functional
Baseline (2014-15)	New indicator
Target (2015-20)	System set up and functional
Indicator	# regulated health establishments registered with the OHSC annually
Baseline (2014-15)	New indicator
Target (2015-20)	80%

Strategic Objective 3.2	Norms and standards for different types of HEs are consulted, developed and/or revised for submission to the Minister for promulgation
Objective statement	Norms and standards for different types of HEs are consulted, developed and/or revised for submission to the Minister for promulgation
Indicators	System and procedures for selection, development or periodic review of norms and standards for different types of health establishments set up and functional
Baseline (2014-15)	New indicator
Target (2015-20)	System set up and functional
Indicators	Norms and standards developed or reviewed annually
Baseline (2014-15)	New indicator
Target (2015-20)	3

Strategic Objective 1.2	Guidance is provided on compliance with norms and standards for regulated Health Establishments
Objective statement	National, Provincial, district and municipal authorities and hospital groups that have completed the OHSC training of trainers programme
Indicators	% of relevant authorities responsible for support to public health establishments that have received guidance on compliance with norms and standards
Baseline (2014-15)	New indicator
Target (2015-20)	90%

Strategic Objective 1.7	Early warning reports of potential situations of risk from HEs or users are monitored to prioritise inspections
Objective statement	Health establishments identified as high risk by early warning reports for which appropriate action (reporting, inspection, investigation) was taken within 2 months
Indicator	Surveillance system set up for reporting on indicators of risks to compliance
Baseline (2014-15)	New indicator
Target (2015-20)	System set up and functional
Indicator	% of high risk health establishments with action taken within 2 months
Baseline (2014-15)	New
Target (2015-20)	70%

13.3 Resource considerations

13.3.1 Trends in the numbers of key staff:

- This critical division is being set up from scratch and all business units will have initial staff in place to lead and develop the work from 2015 onwards. 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; and
- 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.

	(Existing)	2015/16	2016/17	2017/18
• Management (L11 – L16)	0	7	8	9
• Employees (L10 and below)	0	2	3	5
• Interns				

13.3.2 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; the OHSC may be required to look for strategic partnerships to be able to ensure this, as well as investing in staff development.

13.3.3 Expenditure trends

- Fees for consultants are relatively high for this programme at 50% of the goods and services budget reflecting the need to source additional expertise from consultancy, partnerships and expert advisors;
- The training budget will require review based on the identified gaps in the skill set of individual appointed staff; and
- The other key input is the IT system which is funded elsewhere.

Programme 5: Health Standards Analysis and Support Budget

	Medium term estimates		
CURRENT PAYMENTS	**2015/16**	**2016/17**	**2017/18**
Economic classification			-
Compensation of employees	**5,954,578**	**7,600,262**	**10,119,903**
Salaries and wages	5,954,578	7,600,262	10,119,903
Goods and services	**2,222,630**	**2,271,136**	**2,478,276**
Assets < than the threshold (currently R5 000)	96,462	101,575	106,653
Board and panels experts	-	-	-
Catering: Departmental activities	23,188	24,417	25,638
Consultants and professional service: Business and advisory service	1,106,700	1,165,355	1,223,623
Training and development	264,000	277,992	291,892
Travel and subsistence	302,400	318,427	334,349
Venues and Facilities	429,880	383,371	496,122
Total current payments	**8,177,208**	**9,871,398**	**12,598,179**
Total payments for capital assets	**-**	**-**	**-**
TOTAL PAYMENTS	**8,177,208**	**9,871,398**	**12,598,179**

13.4 Risk management

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
2	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
3		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 ad 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

14. Links to other plans

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

PART D
ANNEXURES

15. Annexure 1: Budget programme summary

This section covers and discusses the strategic objectives identified to achieve the set goals for the OHSC within the context of the approved budget programme structure.

OHSC Budget Programme Summary: Detailed Costing For ENE 2015

	Actual Budget			
	2014/15	**2015/16**	**2016/17**	**2017/18**
Office of the CEO	7,201,633	11,048,093	11,146,196	13,041,414
Corporate Services	29,825,558	25,611,190	29,742,230	34,543,243
Compliance Inspection	28,785,656	34,501,367	38,706,705	47,617,275
Complaints Management	3,888,450	7,030,219	8,388,239	15,084,253
Health Standards Design, Analysis and Support	6,260,660	8,177,033	9,871,757	12,598,179
Ombud	991,043	2,538,099	2,679,873	2,826,636
Total	**76,953,000**	**88,906,000**	**100,535,000**	**125,711,000**

16. Annexure 2: Technical indicator description sheet

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	New Indicator	Desired Performance	Responsibility
System for certification of compliant establishments set up and functional	System for issuing certificate of compliance within stipulated time frame, based on criteria, procedures, security provisions and quality control	System must be efficient, fair, credible and transparent and meet regulatory provisions	OHSC documents of system and procedures	N/A	Requires regulations to be promulgated	Activity	N/A	Annual	yes	System functional	Director Certification and enforcement (once appointed)
System and procedures for timely enforcement action set up	Enforcement action as defined in the legislation implemented through set criteria and procedures	Regulatory enforcement action requires standardised, fair and transparent procedures	Documented systems including criteria and procedures	N/A	Requires regulations to be promulgated	Activity	N/A	Annual	yes	System functional	Director Certification and enforcement (once appointed)
System and procedures for communication of Ombud recommendations and action to ensure implementation set up and functional	Legislated obligation on Ombud to communicate report and recommendations and on CEO to monitor their implementation and take regulatory action of necessary must be set out in system and procedures	Fair and reliable system to assure complainants and respondents that Ombud recommendations will be monitored and regulatory action taken if non-compliance	Documented systems for referral of recommendations and appropriate monitoring of affected establishments with action taken	N/A	Requires regulations to be promulgated	Activity	N/A	Annual	yes	System functional	Ombud (once appointed) EM Compliance inspectorate (once appointed)

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	New Indicator	Desired Performance	Responsibility
Number of media and communication events and campaigns to increase awareness of OHSC among public, providers or stakeholders carried out annually	Seminars, workshops, conferences and use of radio, publications or television designed to increase awareness of work of OHSC among providers and users of health services or stakeholders concerned with this.	As a new regulator with a mandate to promote the health and safety of users the OHSC must ensure all relevant parties are aware of its work and assist in enhancing its effectiveness	OHSC record of events, copies of publications distributed, media awareness programme reports	Total number of events and campaigns	Nil	Activity	Number	Annual	Yes	Performance above the target might be desirable once full capacity exists	Director Communications (once appointed)
Number of signed MOAs with regulators to protect and promote quality and safety of care in place each year	MOAs setting out respective actions of the signatories towards enhancing quality and safety are signed and current in that year.	The OHSC has a legislated and operational need to formalise its working relationships with regulators who can contribute to its mandate	Signed MOUs	Total number of signed MOUs	Will require evidence of annual review and agreement	Output	Number	Annual	Yes	Performance above the target might be desirable once full capacity exists	Director Communications
No. of reports on inspections conducted, recommendations issued, and compliance status of health establishments	No. of reports produced on either inspections conducted, recommendations issued or compliance status of health establishments as assessed	The OHSC as a regulator must ensure that stakeholders, users and providers are aware of its work and of its findings	Reports covering either inspections conducted, recommendations issued or compliance status	Total number of reports issued on inspections conducted, recommendations issued or compliance status	N/A	Activity	Number	Annual	Yes	Performance above the target might be desirable once full capacity exists	Director Communications Director Guidance and support
% of funded staff appointed	Staff for which funding exits in the annual budget who are appointed by the end of that year	Where funding is available the OHSC must ensure it is fully utilised	Register of appointed staff Annual staffing plan	Numerator: # of appointed staff in March of each year Denominator: Total # of funded posts for that year	Picture in a single month may not reflect the situation during the remainder of the year	Output	%	Annual	New	Performance above target desirable if suitable candidates found	Director HR

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	New Indicator	Desired Performance	Responsibility
Unqualified audit report without findings	Annual audit by Auditor General is unqualified without findings	As a regulator, it is critical that the OHSC should set an example	Auditor general report	N/A	N/A	Output	N/A	Annual	New	N/A	CFO
IT system in place and functional	OHSC IT system for core business functions must be in place and functional in accordance with annual project plan for roll-out	IT system is a critical enabler for OHSC to functions effectively and must be delivered according to plan	OHSC documentation on IT system implementation. Project plan for roll-out.	N/A	N/A	Activity	N/A	Annual	New	N/A	Director IT
# and % of public sector clinics, CHCs and hospitals inspected annually by the OHSC	# and % of public sector clinics, CHCs and hospitals for which an OHSC inspection team has carried out an assessment and issued a report to the HE in each year	The coverage of inspections is fundamental to the regulatory mandate of the OHSC	Inspection register Register of reports issued	Numerator: # of each type of public HE for which assessment report issued following inspection visit Denominator: total # of public sector clinics, CHCs and hospitals	Incomplete-ness or variations in the denominator numbers as supplied by the NDOH	Output	%	Quarterly	No	Performance above the target might be desirable once full capacity exists	EM Compliance inspections
% of provisionally non-compliant health establishments subjected to re-inspection or review within 6 months	Inspected health establishments not meeting current provisional threshold of 70% on inspection who are either re-inspected fully or partially, or required to submit a signed QI plan for verification, within 6 months of the initial inspection visit	Only through follow up of non-compliant establishments will changes be made towards improvement	Inspection register including re-inspections Register of submitted and signed QI plans Register of random verification visits.	Numerator: # of provisionally non-compliant health establishments re-inspected or reviewed within 6 months Denominator: total # of provisionally non-compliant HEs	Seriously non-compliant establishment may be counted twice in a 6-month period	Output	%	Annual	New	Performance above the target might be desirable once full capacity exists	EM Compliance inspections

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	New Indicator	Desired Performance	Responsibility
Requirements and procedures for accreditation of inspectors approved by the Board	Requirements as set out in a curriculum and training course and procedures relating to evaluation for accreditation of inspectors set up, functional and approved by the Board	The credibility and competence of inspectors is a legislated and operational pre-requisite.	Approved requirements and procedures for accreditation of inspectors	N/A	Progress will depend on promulgation of regulations	Activity	N/A	Annual	New		Director Guidance and support Director HR
Call centre in place and functional	Call centre for public to lodge complaints relating to non-compliance with prescribed norms and standards set up with toll free line and trained complaints officers	Access for the public to the complaints unit and Ombud is a fundamental responsibility of the OHSC	OHSC documents on toll free line and training of call-takers	N/A	N/A	Activity	N/A	Annual	New		Director Complaints management
System for receiving and managing complaints set up and functional	Receiving, logging and managing of complaints is carried out using a set of standard procedures and criteria and captured in an electronic register	The public needs to know that their complaints will be effectively , efficiently and compassionately heard and addressed	OHSC call management system records	N/A	Requires regulations to be promulgated	Activity	N/A	Annual	Yes	System functional	Director Complaints management
(%) of Complaints logged by the OHSC managed and resolved within 6 months.	Complaints that the OHSC receives through its call centre or registry and logs on its system that it assesses or investigates with production of a final report within 6 months	The efficiency with which the OHSC assesses and investigates complaints and can produce a report is important for users	OHSC complaints register showing calls logged, progress and final report with dates	Numerator: # of calls logged by OHSC that are resolved and reported within 6 months of being logged Denominator: # of calls logged by OHSC within the 6 month period	The time period covered by the numerator and denominator may differ	Output	%	Quarterly	Yes	Performance above the target might be desirable once full capacity exists	Director Complaints management

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	New Indicator	Desired Performance	Responsibility
System and procedures for investigation of complaints set up	Investigation of selected complaints based on procedures and criteria for selection, investigation and reporting	The Ombuds office will need to focus investigative resources in areas of most importance in a fair and transparent manner as guided by regulation	OHSC / Ombuds office records	N/A	Requires regulations to be promulgated	Activity	N/A	Annual	Yes	System functional	Ombud
System for annual registration of regulated health establishments set up	Procedures and register set up for all establishments covered by the promulgated norms and standards to report standardised information according to regulations	Without a listing of which establishments are subject to regulation the Office cannot plan or discharge its regulatory function	OHSC records	N/A	Requires regulations to be promulgated	Activity	N/A	Annual	Yes	System functional	Director Health standards analysis
Procedures for selection, development or periodic review of norms and standards for different types of health establishments set up	Procedures and criteria for selection, development or periodic review of norms and standards for different types of health establishments set up	Development or review of norms and standards will follow stipulated criteria in order to address priorities and ensure relevance	OHSC records	N/A	Requires regulations to be promulgated	Activity	N/A	Annual	Yes	System functional	EM Health Standards design

Indicator Name	Short Definition	Purpose / Importance	Source	Calculation Method	Data Limitations	Type of Indicator	Calculation Type	Reporting Cycle	New Indicator	Desired Performance	Responsibility
% of relevant authorities responsible for support to public health establishments that have received guidance on compliance with norms and standards	Percentage of those authorities defined in the NHAA (national, provincial, municipal) for whom documentation and a guidance workshop on the norms and standards, the assessment methods, and the obligations of health establishments have been provided in the financial year	In order for norms and standards to be implemented and regulatory action to be taken, regulated entities must be aware of the obligations placed on them, as conveyed through their relevant authorities	Register of guidance events including agenda Register of materials distributed	Numerator: # of relevant authorities provided with guidance workshop and materials in that financial year Denominator: # of relevant authorities	N/A	Activity	%	Annual	New	Performance above the target might be desirable once full capacity exists	Director Guidance and support
Surveillance system set up for reporting on indicators of risks to compliance	A surveillance system to receive standardised or ad-hoc reports indicating potential situations of risk from health establishments or communities is set up with needed procedures and forms	The legislation and regulations make provision for and early warning system to enable the OHSC top prioritise its inspections by focusing on highest risk	OHSC records	N/A	Requires regulations to be promulgated	Activity	N/A	Annual	Yes	System functional	Director Health standards analysis

Notes

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