

LEGISLATIVE AND OTHER MANDATES

The OHSC is established under the National Health Act (NHA), to promote and protect the health and safety of the users of health services. The OHSC is listed as a Schedule 3A public entity in terms of the PFMA. As a public entity monitoring quality in the health sector, the role of the OHSC is influenced by the following governing legislation, regulations and national policies:

CONSTITUTION OF THE REPUBLIC OF SOUTH AFRICA, 1996

The Bill of Rights underpin the entire health system, specifically Section 27 of the Constitution, which 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 regulation of the quality of health services requires all HEs 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 NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)

The NHA, reaffirms 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 NHA further obliges Members of the Executive Councils (MECs) to establish procedures for dealing with complaints within their areas of jurisdiction. Complaints provide useful feedback on the areas within HEs that do not comply with prescribed standards or pose a threat to the health and safety of users and healthcare staff alike.

The NHA provides the overarching legislative framework for a structured and uniform national healthcare system. The Act 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.

Chapter 10 of the NHA, as it relates to the OHSC, was repealed in its entirety (and other minor changes were

enacted) through the promulgation of the National Health Amendment Act, 2013 (Act No. 12 of 2013). This replaced the previous provisions that had never been brought into effect with a new independent entity, the Office of Health Standards Compliance.

The purpose of the Office is reflected in the NHA as that of protecting and promoting the health and safety of users of health services by:

- Monitoring and enforcing compliance by HEs with norms and standards prescribed by the Minister in relation to the national health system; and
- Ensuring that complaints about non-compliance with prescribed norms and standards are considered, investigated and disposed of in a procedurally fair, economical and expeditious manner.

In terms of the NHA, the OHSC must:

- **Advise the Minister** on matters relating to norms and standards for the national health system and the review of such norms and standards, or any other matter referred to it by the Minister;
- **Inspect and certify** compliance by HEs with prescribed norms and standards, or where appropriate and necessary, withdraw such certification;
- **Investigate complaints** about the national health system;
- **Monitor indicators of risk** as an early-warning system about 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 municipal health department, where 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; and
- **Keep records** of all OHSC activities.

In addition, the OHSC may:

- **Issue guidelines** for the benefit of HEs to implement prescribed norms and standards;
- **Publish any information relating to prescribed norms and standards** through the media and, where appropriate, within specific communities;

- **Collect or request any information relating to prescribed norms and standards** from HEs and users;
- **Liaise with any other regulatory authority** and, without limiting the generality of this power, request information from, exchange information with and receive information from any such authority about matters of common interest or a specific complaint or investigation; and
- **Negotiate cooperative agreements with any regulatory authority** to coordinate and harmonise the exercise of jurisdiction over health norms and standards and ensure the consistent application of the principles of this Act.

THE PROTECTION OF PERSONAL INFORMATION ACT, 2013 (ACT NO.4 OF 2013) (“POPI”)

The purpose of the PoPI is to ensure that all South African institutions, including the OHSC, conduct themselves in a responsible manner when collecting, processing, storing and sharing personal information by holding them accountable should they abuse or compromise such information in any way. The PoPI Act regards personal information as "precious goods" and gives owners of personal information certain rights of protection and the ability to exercise control over:

- when and how the information is shared (requires individual consent);
- the type and extent of information that is shared (must be collected for valid reasons);
- the transparent and accountable use of the data (limited to the purpose) and notification if/when the data are compromised;
- who accesses personal information and the right to have personal data removed and/or destroyed;
- adequate measures and controls to access personal information and tracking access to prevent unauthorised access;
- the storage of personal information (requires adequate measures and controls to safeguard personal information and protect it from theft or being compromised); and
- the integrity and continued accuracy of personal information (must be captured correctly and maintained by the institution that/person who accessed it).

PROMOTION OF ACCESS TO INFORMATION ACT, 2000 (ACT NO. 2 OF 2000) (“PAIA”)

Section 32 (1) (a) of the Constitution states that everyone has a right to access any information held by the state or another

person to protect any rights. The PAIA gives all South Africans the right to access records held by the state, government institutions and private bodies.

The objectives of the PAIA are to:

- ensure that the State promotes a human rights culture and social justice;
- encourage openness and establish voluntary and mandatory mechanisms;
- establish procedures for the right to access information quickly, effortlessly, cost-effectively and as reasonably as possible;
- promote transparency, accountability and effective governance of all public and private bodies by empowering and educating everyone to understand their rights in terms of the PAIA and in relation to public and private bodies;
- create an understanding of the functions and operation of public bodies; and
- encourage the scrutiny of and participation in decision-making by public bodies that affect individual/public rights.

PROMOTION OF ADMINISTRATIVE JUSTICE ACT, 2000 (ACT NO. 3 OF 2000) (“PAJA”)

Section 33 (1) and (2) of the Constitution guarantees that administrative action will be reasonable, lawful and procedurally fair, and it makes sure that people have the right to ask for written reasons when administrative action has a negative impact on them. PAJA aims to make the administration effective and accountable to people for its actions. The objectives of the PAJA are to:

- promote an efficient administration and good governance; and
- create a culture of accountability, openness and transparency in the public administration.

NATIONAL POLICY ON QUALITY IN HEALTHCARE, 2007 (“NPQ”)

A focus on quality assurance and improvement is not a new concept. The 2001 NPQ was revised in 2007. The policy identifies mechanisms to improve the quality of healthcare in the public and private sectors and highlights the need to involve health professionals, communities, patients and the broader healthcare delivery system (Department of Health) in capacity-building efforts and quality initiatives.

The objectives of the NPQ are 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 the evidence of effectiveness;
- ensure appropriate use of services; and
- reduce errors in healthcare.

NATIONAL CORE STANDARDS (NCS) FOR HEALTH ESTABLISHMENTS IN SOUTH AFRICA

The NCS is based on input from numerous stakeholders and extensive field experience and forms the basis for the promulgated norms and standards that the Minister prescribed into law. The norms and standards are aligned with South Africa's existing policy on healthcare.

The purpose of the NCS is to:

- Develop a common quality care definition for all HEs in South Africa to guide the public, managers and staff at all levels;
- Establish a benchmark to assess HEs, identify gaps and appraise strengths; and
- Certify HEs that comply with regulated standards.

The public health system prioritises the following six priority areas which are of major concern to patients:

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

The Minister of Health published the proposed norms and standards regulations for comment in January 2017 under Sections 90 (b) and 90 (c) of the NHA, as amended. Constructive comments were incorporated in the draft regulations and submitted to the Minister for final promulgation in the Government Gazette. The prescribed norms and standards will apply to the following categories of HEs:

- Public sector hospitals, as set out in Government Gazette, No 35101;
- Public sector clinics;
- Public sector community health centres;
- Private sector hospitals; and
- Private sector primary healthcare clinics.

The Norms and Standards Regulations will also apply to other HE categories in the NHA when the Minister, advised by the OHSC, has issued the related norms and standards. The proposed norms and standards are informed mainly by the NCS, published in 2011, with approval from the National Health Council (NHC). The OHSC has consulted extensively since 2013 to correct errors, clarify ambiguities, ensure measurability and align the framework of domains and sub-domains as areas of risk.

PROCEDURAL REGULATIONS PERTAINING TO THE FUNCTIONING OF THE OFFICE OF HEALTH STANDARDS COMPLIANCE AND HANDLING OF COMPLAINTS BY THE OMBUD

These regulations will guide the exercise of powers conferred on the OHSC and its Board, the Chief Executive Officer, the Ombud, Inspectors and Investigators.

The regulations cover the following areas:

- Collection of information from HEs and designation and duties of the person in charge;
- Appointment of Inspectors, training and expertise;
- The inspection process and timelines;
- Additional inspections;
- Entry and search of premises including prior-consent procedures or the application for a warrant if required;
- Processes of certification, renewal and suspension;
- Compliance notice and enforcement process, including formal hearing, revocation of certificate, fines or referral to prosecuting authority, appeals and reporting;
- Complaints handling, investigation and resolution procedures, lodging of complaints, screening, investigation and reporting and turnaround times; and
- General provisions about using prescribed forms (listed in Schedule 1).

NATIONAL HEALTH INSURANCE (NHI)

The NHI is based on the principles of universal health coverage, equity, right of access to basic healthcare and social solidarity, irrespective of a person's socio-economic status. An effective and well-functioning health quality system with set standards and norms that are implemented effectively is essential for the successful execution of the NHI. The OHSC's certification of HEs will in future be a prerequisite for accessing NHI funding.

BATHO PELE AND THE PATIENT'S RIGHTS CHARTER

Alongside health-specific policies and legislation, the *Batho Pele* principles govern all public services, including healthcare delivery. The *Batho Pele* ("People First") initiative encourages service-orientation, excellence and improved delivery among public servants. The eight (8) *Batho Pele* principles aimed at enhancing public service delivery (Republic of South Africa, 2007) are:

- 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.

In response, the health sector promulgated the "Patient's Rights Charter", which specifies – as reiterated in the NCS – that the rights of patients must be respected and upheld, including the right to access to basic care and receive respectful, informed and dignified attention in an

acceptable and hygienic environment. Patients should be empowered to make informed decisions about their health and complain if they do not receive decent care.

NATIONAL DEVELOPMENT PLAN (NDP)

The NDP Vision 2030 states that a health system with positive health outcomes for the country is possible and will:

- Raise the life expectancy of South Africans to at least 70 years;
- Ensure that the under-20s generation is largely free of HIV;
- Significantly reduce the burden of disease; and
- Achieve an infant mortality rate of fewer than 20 deaths per thousand live births and under-5 mortality rate of fewer than 30 per thousand.

Priority 2 in the NDP focuses on strengthening the healthcare system and includes the role of the OHSC as the independent entity mandated to promote quality by measuring, benchmarking and accrediting actual performance against quality standards. A specific OHSC focus is on achieving common basic standards in the public and private sectors.