

The Review Of Norms And Standards Regulations For Different Categories Of Health Establishments

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1 DEFINITIONS

"Chief Executive Officer" refers to the person appointed as Chief Executive Officer of the Office in terms of Section 79H (1) of the Act.

"Constitution" refers to the Constitution of the Republic of South Africa, Act 108 of 1996.

"Early Warning System" is the surveillance systems that collect information of serious breaches of norms and standards that prompt interventions by the health establishment, the Office or relevant authority.

"Health Establishment" means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services.

"Inspector" is s a person appointed as an inspector in terms of Section 80(2) of the Act.

"Measure" questions asked in functional areas which are linked to standards.

"Minister" means the Minister of Health.

"NDOH" means the National Department of Health

"National Core Standards" is the policy document as published by the NDOH in 2011 containing standards and criteria.

"Norms and Standards" refer to the norms and standards prescribed by the Minister in terms of the NHA.

"OHSC" means the Office of Health Standards Compliance established by Section 77(1) of the Act.

"Regulations" means the Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud.

"the Act" means the National Health Act, 2003 (Act No. 61 of 2003).

"User" means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is—

(a) below the age contemplated in section 129 of the Children's Act 38 of 2005, **"user"** includes the person's parent or guardian, or another person authorised by law to act on the first mentioned person's behalf; or

(b) incapable of taking decisions, "user" includes the person's spouse or partner or, in the absence of such spouse or partner, the person's parent, grandparent, adult child or brother or sister, or another person authorised by law to act on the first mentioned person's behalf.

"Standard" a statement that defines the performance expectations, structures, or processes that must be in place for an organization to provide safe and high-quality care, treatment, and service.



APPLICABLE LEGISLATION AND POLICIES

- National Core Standards (National Department of Health), 2011.
- The Constitution of the Republic of South Africa, Act 108 of 1996.
- The National Health Act, 2003 (Act No. 61 of 2003), as amended.
- Norms and Standards Regulations Applicable to Different Categories of Health Establishments, 2018.
- Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud, 2016.
- National Health Quality Improvement Plan (NDOH) 2019.
- National Health Insurance Bill, 2019.

3 BACKGROUND

The Office of Health Standards Compliance was established by section 77(1) of the National Health Act, 2003 (Act No. 61 of 2003), which recognised the need to foster good quality healthcare services as a key component of health system's transformation. The functions of the Office of Health Standards Compliance (OHSC) include the inspection and monitoring of health establishments' compliance with the prescribed norms and standards regulations, submission of recommendations regarding quality assurance and management systems for the national health system, and implementing enforcement actions where there is persistent non-compliance with norms and standards regulations. The norms and standards applicable to different categories of health establishments were promulgated by the Minister of Health in February 2018 and came into effect in February 2019.

4 PURPOSE OF THE REPORT

In terms of section 79.1(a) of the National Health Act, 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. The OHSC commenced with implementation of the promulgated regulations during the financial year 2019/20. The purpose of the report is to make recommendations regarding the content of the existing regulations and provide advice for the Minister's consideration on matters relating to the norms and standards regulations and the review thereof.

5 DEVELOPMENT OF INSPECTION TOOLS TO DETERMINE COMPLIANCE WITH NORMS AND STANDARDS REGULATIONS

The norms and standards regulations which were promulgated following a consultative process and approval by the National Health Council were reduced in scope as compared to the original set of standards which were submitted by the OHSC Board in 2015. The rationale for the reduction of the scope of norms and standards, as explained by the National Department of Health (NDOH), was the intention of the NDOH to adopt a phased, incremental and progressive approach towards implementation of the norms and standards in the health care sector. This was meant to allow the health establishments to be familiarized and orientated with the concept of regulations used to determine the quality of services provided within health establishments. The NDOH, further indicated that once an acceptable level of compliance to norms and standards is achieved, both in the public and private sector, the regulations would accordingly be adjusted.

It is important to highlight that, in addition to providing a detailed framework for evaluation of compliance with the regulations, inspection tools developed by the OHSC are structured in such a way as to provide guidance to health establishments on how to achieve compliance with the regulations. The process of providing guidance to health establishments is achieved by detailing the steps undertaken in compiling the prescribed norms and standards as well as the tools used to assess the system which will ensure provision of the services as defined in the regulations. As such, the inspection tools aim to provide a blueprint for how services should be organised and delivered and more importantly how they will be assessed. The regulatory functions of the OHSC are bound by what is prescribed in the promulgated norms and standards regulations, therefore the guidance provided to health establishments is limited to the regulations and therefore cannot go beyond aspects of quality of care which are not included in the regulations.

During the development of inspection tools aligned to the promulgated regulations, the OHSC identified that regulations critical to addressing important user care and safety aspects were not adequately covered while some are missing altogether. Some of these important issues relate to patients' rights, respect and dignity and consequently these aspects cannot be measured as part of the certification process because they are not adequately addressed by the regulations. The list below outlines in some detail some of these unaddressed components:

- **Dignity and privacy of users**: There are no requirements to assess the **dignity and privacy of users** in the norms and standards regulations. The principles of dignity and privacy afforded to the users of the health system are aligned to the Batho Pele principles of the public sector in South Africa, and directly relate to the attitude of staff towards healthcare users. These issues are of particular importance and supported by the awareness that many complaints received by the Office of Health Standards Compliance are around negative staff attitudes. There has been a number of reports and published literature over recent decades indicating persistent and pervasive challenges with staff attitude towards healthcare users [1-6]. The OHSC would like to bring to the attention of the Minister this omission in the current regulations which do not permit the measurement of this vital aspect of acceptability of health services. Acceptability of services is one of the five A's defining access to care (accessibility, affordability, availability, acceptability,

and accommodation). Failure to access care due to previous negative interactions with staff may have serious consequences for the individual user, their dependents, and may lead to poor health outcomes. In addition, the current regulations do not permit for the assessment of privacy provided to healthcare users during the delivery of care. The two issues of dignity and privacy contribute directly and substantively to the constitutional right of every South African to be treated with dignity.

- **Patient experience of care:** The requirements that relate to **patient experience of care** and **complaints management** do not adequately address systems and processes that must be in place for these components to be achieved. The patient experience of care assessments allows health establishments to gather information from users on things that matter most to them when accessing healthcare services. The current regulations therefore miss an opportunity to strengthen the systems that must be in place for sustainable achievement of these crucial components of quality of care. The systems referred to include patient experience of care surveys and complaints management systems. Results of patient experience of care surveys and complaints management can result in service delivery improvement initiatives in quality of care priority areas such as access to services, patient safety, values and attitudes, patient waiting times, availability and use of medicines, as well as cleanliness and infection prevention and control.
- **Food Services:** There are no requirements with respect to **food services** in the norms and standards regulations. All users admitted to a health establishment must be provided with food at least three times a day, and this requirement is both a human rights and health issue. The consequences of a lack of assessment/evaluation in this area is evident in at least two serious cases: i) In 2018 at Cala Hospital in the Eastern Cape the Chief Executive Officer was suspended for allegedly feeding patients food that did not meet the department's standards; ii) The latest report published by the Health Ombud regarding Tembisa Provincial Tertiary hospital in January 2021, the Health Ombud found evidence that a user was not provided with food for over 48 hours.
- **Waiting Times:** The Norms and Standards Regulations make reference to monitoring of **waiting times** against National Core Standards (NCS). However, the NCS policy of 2011 did not determine specific targets for waiting times for the health sector. The regulations and related requirements do not provide adequate guidance to health establishments in how to monitor and reduce waiting times and also references an obsolete policy.
- **Diagnostic services:** The requirements relating to **diagnostic services** are only limited to assessing whether the service is accredited by a relevant regulatory body. Requirements on access to diagnostic services, protection of users and health care personnel from exposure to hazardous materials when using diagnostic services are missing. The requirements for measuring and evaluating the performance of diagnostic services are not part of the regulations but have been shown to be beneficial in ensuring safe and quality care for users. Furthermore, failure for these systems to function effectively is repeatedly linked to delays in care which may lead to avoidable harm to patients, including death.
- **Rehabilitation services:** The requirements that relate to access and management of **rehabilitation services** are not covered in the regulations despite many instances of patient harm resulting from delays in access to these services. To sight examples, permanent loss of function due to delayed physiotherapy and/or occupational therapy, prolonged waiting times for the provision of aids such as wheelchairs, lack of relevant

functional equipment available to therapists all resulting in suboptimal treatment of patients.

- **Outreach services** are not addressed in the current regulations. The provision of clinical outreach services is critical in improving access to care in underserved areas. Outreach services are a means to ensure the provision of primary healthcare and limited specialised and specialist services in underserved areas. These services in turn serve as a gateway into the overall health system, as well as in-service education of community healthcare workers, health promotion and preventative services. The added benefit of outreach services is the provision of cost-effective services to the population.
- **Maintenance of medical equipment:** The maintenance of medical equipment as a support service has been a challenge historically within health establishments, and this critical requirement is not specifically mentioned or covered in the regulations, but rather require only that medical equipment is available and functional. The availability and functionality of medical equipment is dependent on adequate and effective procurement processes and maintenance services; however, maintenance requirements are not explicitly included in the current regulations. This limitation prevents explicit evaluation of these systems and processes as part of the certification process even though they are critical to patient safety and acceptable quality care.

  Due to the critical nature of medical equipment maintenance, an attempt was made by the OHSC to cover this under Regulation 7(2)(b), which requires effective clinical risk management processes in the health establishment. However, this is not ideal and may potentially be successfully challenged in a court of law on the basis that it is not part of the regulations. A similar approach has been adopted for several issues fundamental to patient safety, which are not specifically mentioned in the regulations but come under the umbrella of clinical risk. Such areas include cleanliness of the health establishment, sterilisation processes in the Central Sterile Supplies Department (CSSD), administration of medication, and information management, amongst others. Each of these systems and processes should be explicitly addressed, both individually, and comprehensively within the regulations. Regulation 7(2) b should be solely limited to the clinical risk management and monitoring systems.
- **Mortuary services:** The mortuary services are offered in most health establishments, and if not managed according to applicable legislation can result in public health and infection prevention and control concerns within the health establishments. The Covid-19 pandemic and the resultant high mortality rates are a reminder that mortuary services are important in health establishments. This requirement is also not sufficiently covered in the current regulations.

Other identified areas of concern with the implemented regulations

- The regulations are silent on **ethical issues**, although these issues frequently cause great distress to patients and health care providers alike, with a likelihood of significant mental health distress. In addition, ethical conduct and issues within health establishments are highly likely to result in litigation, particularly in instances where families of users become involved in relation to perceived unethical conduct by healthcare providers. Given the significance of ethical matters, the regulations and inspection tools should provide

guidance on how these issues should be approached and addressed to minimise risk to patients and staff.

- Although the regulations make reference to the availability of **clinical guidelines**, no requirement is included for adherence to these guidelines by treating practitioners. This effectively means, the inspection tools cannot request evidence to be provided to confirm that health care providers adhere to these guidelines as failure to comply with such a requirement cannot be deemed to represent non-compliance or be defended successfully in court if challenged.
- The regulations contain no reference to **general or financial management of health establishments.** Neither do they contain any requirements relating to strengthening of accountability structures within health establishments. The three aspects of health service management are repeatedly referenced in reports on the South African health system as hindrances to adequate service delivery. The inclusion of guidance on the establishment and continuation of such systems will assist in the resolution of these deficits.
- **Regulation 17 addresses security services** and state that security staff must be capacitated to deal with security incidents, threats and risks. This requirement is non-specific, and the meaning could therefore be contested in court. It would therefore be useful to have sub-regulations that clearly outlines the security requirements at health establishment level. These requirements would also assist health establishments to compile SLAs and contracts with security service providers where these services are outsourced. The explicit security requirements could assist in avoiding security related incidents in future, such as those reported in the media in recent years and documented by the OHSC's Early Warning System.
- The current regulations are silent on the **management of linen services**, other than to require that sufficient linen is available in-patient care areas. However, the regulations do not make provision for the assessment of laundry services, such as the availability and functionality of washing machines, guided laundry processes for various types of soiled linen, the establishment of an effective linen management system, occupational health requirements for laundry staff, to mention a few. As such the inspection tools cannot provide guidance to health establishments on how to establish appropriate laundry management systems, which leaves facilities vulnerable to linen theft as well as inadequately laundered and maintained linen. These omissions may in turn results in patients being shown to hospital beds without linen or with torn or stained linen, which infringes on patients' rights and dignity as well as exposing them at risk of health care associated infections.
- **Staff wellness** is not addressed in the promulgated norms and standards. Health care workers are exposed to many occupational hazards and risks under normal circumstances. These occupational risks have been brought into particular focus during the Covid-19 pandemic in terms of risks associated with acquiring infections in the absence of appropriate PPEs as well as in relation to staff burnout and psychological wellness. It is strongly recommended that minimum requirements in relation to staff wellness are included in the regulations so that such programmes become mandatory in all health establishments. Effective staff wellness programmes contribute to a physically and mentally healthy workforce to improve morale and performance and assist with the attraction and retention of staff.
- The requirements for **signage** are not addressed in the regulations. This requirement relates to access to care and is important to guide users to different services within the

health establishment. The absence or inadequacy of signage, particularly in large health establishments providing services from several separate services areas, in conjunction with the elimination of the requirements for the health establishment to make individuals available to assist users and visitors, may result in the patient's journey through the health establishment becoming more confusing, frustrating and in the worst cases may result in missed appointments, repeat visits and delayed access to care.



6 EARLY WARNING SYSTEM

The Office is required to monitor indicators of risk as an early warning system (EWS) related to serious breaches of norms and standards and report any breaches to the Minister without delay in terms of Section 79 (1)(d) of the National Health Amendment Act, 2013 (Act No 12 of 2013)[1]. The purpose of an EWS is to monitor incidents and situations that could indicate non-adherence to the norms and standards regulations with serious consequences (actual or potential) in the quality and safety of care provided to users. The OHSC commenced implementation of the early warning system in March 2019, using an incremental approach to enable continuous monitoring of risk at the health establishments. The system requires health establishments to submit data on 11 indicators on a monthly basis, including zero reporting where no incidents have been observed. In addition, media reports and complaints are monitored and included in the monitoring system. Analysis of these indicators and reports demonstrates that many of the system failures leading to the adverse event are not addressed in the current regulations as the OHSC is required to indicate which standard was breached.

Some of the incidents reported that are not covered by the current standards, include hospital acquired neonatal infections such as Klebsiella cases which resulted in neonatal death, deaths of two toddlers from serious adverse events following antibiotic treatment, missing corpse and poor identification of corpse and unavailability of medicines.



7 COMPLAINTS MANAGEMENT AND MAPPING

The Complaints Management Program receives complaints related to service delivery challenges through the call centre. Any complaints that are deemed high-risk which cannot be resolved at provincial level are referred to the Health Ombud for further investigation. All

registered complaints are as far as possible mapped with the related norms and standards which have been breached. The complaints management unit has identified several categories of frequently reported complaints which lack a corresponding regulatory requirement:

- negative staff attitude
- poor supervision of junior clinical staff
- violation of patients' rights and privacy
- complaints on food services in the health establishment
- poor management and control of mortuary services



RECOMMENDATIONS

- The provision of quality health care services is a constantly developing field in multiple dimensions, including but not limited to clinical care, patient satisfaction, infrastructural requirements and ethics. To ensure that the norms and standards remain current and match the international best practice in relation to regulating quality of care, the OHSC recommends periodic review of such standards every four years following implementation.
- The limitations of scope of the existing regulations demonstrated by complaints data and early warning system indicators and other reports highlight that the existing regulations do not address certain areas of risks within health establishments.
- The reduction in scope of the promulgated regulations of 2018 as compared to the draft regulations of 2015 and 2017 will inevitably impact the quality of care in certified health establishments. The magnitude of this impact should be considered considering the imperative to improve clinical and health outcomes under NHI.

The OHSC, therefore makes the following recommendations:

1) The regulations which were published without sub regulations, for example, regulation:7(2)(b) which states "The health establishment must establish and maintain systems, structures and programmes to manage clinical risk." should have the sub regulations added to ensure that they can be measured accordingly, and to make them as specific and comprehensive as possible to enable development of indicators within the inspection tools.
2) Additional regulations are required to include aspects of quality not adequately addressed in the current published regulations. These aspects relate to neonatal units' infection prevention and control requirements, explicit patient centredness requirements, medicine availability requirements for different levels of care, mortuary services requirements, as well as more explicit requirements for patient safety incidents reporting.

9 CONCLUSION

The limitation of these standards regulations raises a cause for concern in the quality and safety of the health care users and in realising the implementation of NHI as stipulated in the National Health Insurance Bill (2019) that adequate quality of services will be a prerequisite for accessing the NHI fund. This also raises a concern that certified health establishments might not be providing services of acceptable or adequate quality to ensure patient satisfaction, patient safety or security of patients and staff within health establishments.

The promulgated norms and standards should define the national understanding of acceptable quality of care in the South African context, by documentation of the minimum standards for service delivery. The standards should encompass the full scope of responsibility of frontline workers providing direct care to patients, as well as the full range of management and support services essential to the effective and holistic provision of care within health establishments.

The South African health system is introducing universal health coverage for the benefit of all users of health care services. To achieve the desired impact of improved national health outcomes, the health care provided as part of universal health coverage must be safe and of adequate quality.

It is therefore imperative that the quality standards set for health establishments support the improvement and eventual attainment of service delivery that is safe and of adequate quality. To achieve this imperative, it is recommended that the existing norms and standards regulations are revised to accommodate an adequate comprehensive scope of requirements to ascertain that health establishments certified by the OHSC are providing both direct patient care and supporting services of adequate quality to optimise the efficiency and effectiveness of service delivery.

10 REFERENCES

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