OHSC

Office of Health Standards Compliance

Ensuring quality and safety in health care

TERMS OF REFERENCE FOR THE TECHNICAL WORKING GROUP TO REVIEW THE NORMS AND STANDARDS REGULATIONS (2018)

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DEFINITIONS

CEC:	Refers to the Certification and Enforcement Committee, which is the OHSC Board Committee responsible for the oversight of core OHSC implementation activities.
CEO:	Refers to the Chief Executive Officer of the Office of Health Standards Compliance
HASA:	Refers to the Hospital Association South Africa, which represents the owners and managers of the majority of private sector hospital beds in the country.
HSDAS:	Refers to the Health Standards Design Analysis and Support, a department in the Office of Health Standards Compliance.
NDoH:	Refers to the National Department of Health.
OHSC:	Refers to the Office of Health Standards Compliance.
Public health establishment:	Refers to the public health establishment as described in Regulation 185 (Regulations Relating to Categories of Hospitals).
Private health establishment:	Refers to a health establishment that is not owned or controlled by an organ of state as described in Regulation 185 (Regulations Relating to Categories of hospitals).
Provincial Department:	Refers to a provincial department responsible for the provision of health services.
SEIAS:	Refers to Socio-Economic Impact Assessment System which is a methodology and tool in helping better formulation of policies, legislation and regulations, in particular to better understand benefits, risks and unintended consequences, as well as measures to mitigate risks and possible costs.

Technical Working Group:	Referring to an ad-hoc forum established to review norms and standards regulations of 2018 to develop comprehensive regulations which will include health outcome measurements
Terms of Reference:	Refers to the purpose, courses of action or guiding principles intended to influence the function or determine decisions or actions of the technical working group..
UFFP:	Refers to the Unity Forum of Family Practitioners, which comprises representative bodies of Family Practitioners. Collectively, represent more than 90% of Family Practitioners (GPs) in South Africa.

1. BACKGROUND

The Office of Health Standards Compliance (OHSC) is an independent health regulator established in terms of the National Health Act, No. 61 of 2003 (as amended). The mandate of the OHSC is to protect and promote the health and safety of users of health establishments across the country. The OHSC fulfils its mandate by monitoring and enforcing compliance by health establishments with the norms and standards prescribed by the Minister of Health, and ensuring consideration, investigation, and disposal of complaints relating to non-compliance with prescribed norms and standards for health establishments in a procedurally fair, economical, and expeditious manner.

The Norms and Standards Regulations Applicable to Different Categories of Health Establishments (hereafter referred to as the "Norms and Standards Regulations") were promulgated by the Minister of Health in February 2018 and came into effect in February 2019. An incremental approach in the development of the different categories of inspection tools was taken by the OHSC, with a primary focus on primary health care. Inspections first commenced in public primary health care clinics during the FY 2019/20 and 2020/21, thereafter other levels of care were inspected as the relevant tools were developed. Inspections of acute private hospitals commenced during the financial year 2023/2024.

During the development of inspection tools and implementation of the regulations, limitations were observed on what was covered in the regulations in relation to quality and safety of health services. This observation was expected as the initial norms and standards regulations were not meant to cover all aspects of quality and safety in the provision of health services.

The process of reviewing current norms and standards regulations is undertaken to identify and address limitations of the current regulations and to progress towards the inclusion of clinical health outcome measurements, with the main goal of improving quality. In addition, the OHSC wants to ensure that the regulations are adequately comprehensive and flexible to further enable different inspection tools to be drawn from them as per the prioritisation of the National Department of Health.

During FY 2022, the OHSC undertook a desktop review of the current norms and standards applicable to different categories of health establishments. The report was submitted to the Minister of Health in 2022 as per the OHSC mandate and recommended for the review of the norms and standards regulations of 2018. In August 2024, following the global practice of quality standards for healthcare services, the OHSC also tabled a proposal for the review of the existing norms and standards regulations to the Senior Management Team meeting of the NDOH for review. There was consensus at the meeting that the review would be

undertaken by a technical working group. It is against this backdrop that the current regulations are reviewed by the Technical Working Group (TWG) comprised of the critical stakeholders within the health sector.

2. PURPOSE

The purpose of the TWG is to enable an inclusive and collaborative approach in the review of norms and standards regulations for health. The experience and expertise in the TWG will contribute towards establishing the best approach to review the norms and standards regulations to achieve more comprehensive norms and standards regulations for the health sector. The reviewed regulations are expected to be in line with international best practices, while considering the local context to enhance patient safety, improve quality of care and contribute to the improvement of clinical health outcomes.

3. COMPOSITION OF TECHNICAL WORKING GROUP

The accounting officers nominated individuals who will represent their entity/stakeholder in the TWG based on technical expertise required and sector representation. The TWG consist of the representative (s) from the following stakeholders/entities:

- National Department of Health (NDOH).
- Provincial Departments of Health.
- Hospital Association South Africa – Private Hospital Groups.
- The Unity Forum for Family Practitioners (UFFP).
- Office of Health Standards Compliance (OHSC).

4. TERM OF OFFICE

The duration of the TWG is until the reviewed norms and standards have been submitted by the OHSC Board to the Minister of Health for consideration at the National Health Council and published for public comments.

5. SCHEDULING OF MEETINGS

- The Terms of reference will be discussed and agreed upon by the TWG and meetings convened at the request of the Chair of the group.

- The meetings shall be scheduled and communicated to the TWG by the Secretariat.

6. QUORUM FOR TECHNICAL WORKING GROUP MEETINGS

- A Quorum for the TWG meetings shall be the majority of members (50%+1) present at the meeting.
- Decisions on matters before TWG shall be made by consensus. If there is no consensus, members may vote on the matter, which requires a decision to be made.

7. RESPONSIBILITIES OF TECHNICAL WORKING GROUP CHAIRPERSON

- The Executive Manager of Health Standards Development, Analysis and Support will be the chairperson of TWG.
- The chairperson will convene all the TWG meetings.
- Preside in all TWG meetings; in the absence of a chairperson, a representative from OHSC shall assume the chairperson's role.
- Conduct the scheduled meetings following the agreed agenda.
- Guide the secretariat in preparing the agenda before meetings and reviewing minutes after meetings.

8. RESPONSIBILITIES OF SECRETARIAT

- Ensure that the TWG members receive appropriate and sufficient administrative support,
- Make all the necessary logistical arrangements for the meetings.
- Facilitate the proper functioning of the TWG, liaise with TWG members as and when required.
- Oversee compilation of minutes of the meeting, develop and finalise documents in consultation with the chairperson.
- Distribute minutes and the agenda at least one week before the meeting.

9. RESPONSIBILITIES OF TECHNICAL WORKING GROUP MEMBERS

The TWG will be required to:

- Develop Social Economic Impact Assessment Study (SEIAS) to accompany the regulations and submit to the Department of Planning, Monitoring and Evaluation (DPME) for review and approval.

- Develop a comprehensive framework for the review of the norms and standards regulations.
- The review of the norms and standards regulations will be guided by documents relevant to the mandate of the OHSC, inspection reports, early warning system reports, and complaints reports produced over time. Other international quality and safety standards, developed by the World Health Organisation or other similar entities, may be used and such will be brought to the attention of the TWG.
- TWG members to review the documents mentioned below and other relevant OHSC reports to determine standards to be included as part of the review process.
- Draft Framework for the review of norms and standards regulations developed using the current norms and standards regulations, which are attached for ease of reference.
- Comparative analysis of the Norms and Standards Regulations January 2017/February 2018.
- List of norms and standards to be developed for regulations.
- Recommendations report on the review of norms and standards regulations (2018).
- National Health Insurance Act (20) 2023
- Any other relevant document.

10. SEQUENCE OF ACTIVITIES TO BE UNDERTAKEN IN THE REVIEW OF NORMS AND STANDARDS REGULATIONS

- Review the current statement of the regulations to ensure that they are appropriate and broad enough to address the quality and promote the safety of the users.
- Review the report from the benchmarking exercise to determine the standards that are missing in the current regulations to align with global practice and to measure health outcomes. (This activity will require relevant expert inputs.)
- Compilation of the revised regulations within the agreed timeframe to circulate to the determined external stakeholders for inputs.
- Conduct a workshop for external stakeholders to orient them on the developed regulations before circulating the draft revised regulations to solicit their input. This is to ascertain they understand the purpose of the review of the norms and standards regulations and the format of the document for their inputs.
- Incorporate inputs and feedback from the external stakeholders to produce draft 2 of the revised norms and standards regulations.

- Finalise and agree on the standards to be included in the revision of the 2018 regulations.
- Ensure that the revised standards represent the latest evidence-based healthcare advice and are as comprehensive as possible to be able to draw different inspection tools from them.
- Conduct a workshop for the Standards Development Review Committee to take them through the revised norms and standards regulations before circulating the revised regulations for their inputs.
- Circulate the revised regulations to the Standards Development Review Committee for their input.
- Review and incorporate inputs received from the Standards Development Committee.
- Conduct a workshop for the Standards Development Review Committee to discuss inputs received, what has been incorporated and what has not been accepted and the reason and motivation for inclusion and exclusion.
- Prepare the finalised document with proposed norms and standard regulations in preparation for submission and discussion to the Certification and Enforcement (CEC) of the OHSC Board
- Submission of the revised regulations to the CEC for review and consideration for the OHSC Board approval.
- Submission of the revised norms and regulations standards for health to the Board for approval
- Submission of the revised norms and standards regulations to the Minister of Health for consideration and approval, which will be followed by discussions at the National Health Council and released for public comments.

11. OUTPUTS

1. Comprehensive workplan
2. SEIAS document
3. Final draft of the revised regulations
4. Final report outlining the process followed to review the regulations.

12. APPROVAL AND REVIEW OF TERMS OF REFERENCE

- The CEO shall approve the Terms of Reference.
- The Terms of Reference will be reviewed as and when circumstances change to ensure their continued applicability and relevance.
- A review of the Terms of Reference may be discussed by TWG members and approved by the CEO.

13. AUTHORITY AND SIGN OFF

The CEO authorises the Technical Working Group, within the scope of its responsibilities:

- To perform activities within these terms of reference
- To engage with other advisers as deemed necessary by TWG to carry out its duties

DR SIPHIWE MNDAWENI

CHIEF EXECUTIVE OFFICER

OFFICE OF HEALTH STANDARDS COMPLIANCE

DATE: 10/09/2025